Submitter : **Mr. Travis Francis** **Date: 08/31/2007**

Organization : **Via Christi Rehabilitation Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Travis Francis, and I am a Certified Athletic Trainer at Via Christi Rehabilitation Center in Wichita, Kansas. I manage a sports medicine department of approximately 20 Certified Athletic Trainers who work in a varied of settings including a physician's office as a physician extender. My staff of Certified Athletic Trainers all have a Kansas State License to practice as well as a National certification through the National Athletic Trainers Associations, Board of Certification. In the physician's office, my staff work under the supervision of a Board Certified physician in which they perform casting, bracing, taping, and home exercise programs for our patients. In our outreach setting, we provide these same services to area high school students, collegiate and professional athletes.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Travis Francis, MS LAT ATC

Submitter : Ms. Henry Casale **Date:** 08/31/2007

Organization : Horty, Springer

Category : Attorney/Law Firm

Issue Areas/Comments

Physician Self-Referral Provisions

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See Attachments

CMS-1385-P-15092-Attach-1.DOC

CMS-1385-P-15092-Attach-2.PDF

15092

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CONFIDENTIAL

VIA E-MAIL

August 31, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
Mail Stop C-4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1385-P
Comments on Proposed Changes to
Reassignment and Physician Self-Referral
Laws to the Centers for Medicare & Medicaid Services

To the Centers for Medicare & Medicaid Services:

The law firm of Horty, Springer & Mattern, P.C. devotes its practice exclusively to hospital and health law. We work with health care providers throughout the country, consulting with hospital boards, hospital attorneys, and medical staff leaders. In submitting these comments to CMS, File Code-1385-P (the "Proposed Regulations"), we are not acting on behalf of any client.

PHYSICIAN SELF-REFERRAL PROVISIONS

1. ANTI-MARKUP PROVISIONS

We find the Anti-Markup Provisions that have been included in the Proposed Regulations (i.e., 42 C.F.R. '414.50 and 42 C.F.R. '424.80) to be less confusing than the rules that had been proposed in the August 22, 2006 Federal Register. We also welcome CMS's request for comments on how to be sure that the Anti-Markup Provisions are consistent with the rules that

have been promulgated under Section 1877 governing In-Office Ancillary Services (42 C.F.R. '411.355(b)) (the "In-Office Ancillary Services Rules").

In our opinion, the changes to the Anti-Markup Provisions that have been included in the Proposed Regulations address the arrangements that were described in the Preamble in the August 22, 2006 Federal Register (See 71 Fed. Reg. 48982, 49054-49058) (August 22, 2006). We agree with CMS that addressing these arrangements in the broader context of changes to the Anti-Markup Provisions will create clarity, permit legitimate arrangements that further patient care, while at the same time prevent gaming the current Medicare reimbursement system through so-called "pod lab arrangements" and other arrangements that have been marketed to physicians since the In-Office Ancillary Services Rules were published on March 26, 2004.

However, the Anti-Markup Provisions should be amended so that they are consistent with the terminology used in the regulations to Section 1877. We also urge CMS to consider the comments that we have proposed to be made to the In-Office Ancillary Services Rules in order to further protect the Medicare program from abuse.

As proposed, 42 C.F.R. '414.50(a)(3)(ii) provides that "an outside supplier is someone other than a full-time employee of the billing physician or medical group." (Emphasis added.) We find the reference to a "full-time employee" to be confusing and inconsistent with the defined terms that are set forth in the Section 1877 regulations at 42 C.F.R. '411.351.

42 C.F.R. '411.351 defines a "Member of the group or member of a group practice" as "a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section) or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes 'patient care services' to the group as defined in this section. An independent contractor or a leased employee is not a member of the group (unless the leased employee meets the definition of an 'employee' under this '411.351)." (Emphasis added.)

On the other hand, a "Physician in the Group Practice" is a separate definition under 42 C.F.R. '411.351. The definition of a "Physician in the group practice" as revised by CMS-1810-F, is as follows: "a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section)

for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under '411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in '411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in '424.80(b)(2) of this chapter (see also section 30.2.11 of the CMS Internet-only Manual, publication 100-04, Claims Processing Manual, Chapter 1 (general billing requirements), as amended or replaced from time to time)."

We would recommend clarifying the term "full-time employee of the billing physician or medical group" by replacing this term with the defined term "Member of the group or member of a group practice." Using the defined term "Member of the group or member of a group practice" will avoid the confusion created by the use of "full-time" versus "part-time" which can vary significantly depending on the nature of the employment relationship. The use of the term "member of the group or member of a group practice" will allow for flexibility while at the same time make it clear that independent contractor relationships are not permitted.

In our experience, it is independent contractor relationships that have been involved in most of the arrangements that the Anti-Markup Provisions are intended to address. We appreciate that the changes to the definition of a "Physician in the Group Practice" that have been included as CMS-1810-F are intended to address such arrangements. However, it is not unusual for physicians to work on a part-time basis for any number of entities. Since the requirements of 42 C.F.R. '414.50(c)(a)(3)(ii) will apply to all types of physician practices, these rules need to reflect the economic realities facing any Group Practice as that term is defined in 42 C.F.R. '411.352. Using the defined term "Member of the group or member of a group practice" has a sufficient nexus to the group that should address CMS's concern with prohibiting disguised "purchased service" arrangements while providing group practices with the flexibility to organize themselves in a manner that is efficient and cost-effective.

Similarly, in the Proposed Changes to 42 C.F.R. '424.80(d)(3), the special rules that are described therein apply "following a reassignment from a physician or other supplier who performed the technical or professional component and who was not a full-time employee of the billing physician or medical group at the time the service was performed." (Emphasis added.) Again, for the reasons described above, the term "full-time employee" should be replaced with the defined term "Member of the group or member of a group practice."

2. IN-OFFICE ANCILLARY SERVICES RULES

We agree with CMS that one of the most important exceptions to the physician self-referral prohibition are the In-Office Ancillary Services Rules. Unfortunately, these In-Office Ancillary Services Rules have also allowed some physician practices to unfairly compete with hospitals.

CMS accurately states that at the time of enactment of Section 1877, In-Office Ancillary Services were limited and presented little, if any, risk of abuse. However, change in technology and the failure of the In-Office Ancillary Services Rules to be updated to take into account those changes have permitted a number of services to be provided under the In-Office Ancillary Services Rules that should be provided in a hospital. Those rules have also permitted some physician practices to use, or to attempt to use, the In-Office Ancillary Services Rules to establish arrangements that are more for the physician's benefit than for the benefit of Medicare beneficiaries.

For example, the Office of Inspector General for the Department of Health and Human Services ("OIG") has found certain "turnkey" in-office service arrangements that purportedly satisfied the In-Office Ancillary Services exception to Section 1877 to violate the anti-kickback statute. (See, OIG Advisory Opinion 404-8 June 23, 2004 described below.)

It is also reassuring to see that CMS has recognized the fact that the In-Office Ancillary Services Rules that are currently in effect are so lax that private insurers such as Highmark Blue Cross have chosen to adopt Provider Credentialing Guidelines such as those that have been attached to this letter (See, https://www.highmarkblueshield.com/pdf guidelines.pdf#search=%highmark%20 privileging%guidelines%20radiology%22) in order to halt the proliferation of In-Office Ancillary Service arrangements that are currently permitted by the in-office ancillary exception.

In the Proposed Rules, CMS has declined to publish a specific proposal for amending the In-Office Ancillary Services Rules. Rather, CMS is soliciting comments as to whether changes are necessary and, if so, what changes should be made. The changes that have been included in CMS-1810-F do not prohibit part-time block leasing arrangements in the same building to the same extent as such arrangements are prohibited in a "centralized building," and, for the reasons described below, we urge CMS to do so. We also urge CMS to adopt credentialing criteria as part of the In-Office Ancillary Services Rules that will prohibit a physician from billing for an In-Office Ancillary Service unless a "member of the group or a member of a group practice" has

been granted the clinical privileges from a local hospital that are necessary to interpret that service.

Our rationale for these recommendations is as follows:

(a) Location of Centralized Building

CMS should be aware of the fact that CMS's definition of the term "Centralized Building" does not require that the Centralized Building be within a certain distance of the ordering physician's practice. As a result, a physician practice may locate a Centralized Building at a significant distance from the location where the patient has received professional services. We are aware that some physicians have gone so far as to place a Centralized Building in a different state from the state in which the professional services were provided in order to avoid state Certificate of Need rules. In doing so, the use of a Centralized Building can actually inconvenience beneficiaries. This stretches the intended purpose of a Centralized Building beyond the breaking point.

Therefore, CMS should revise the definition of a "Centralized Building" in 42 C.F.R. '411.351 to require that the Centralized Building be located within a certain defined distance of the location where the physician provided the professional services that gave rise to the ancillary services. One benchmark that may be used is the 250 yards used in the Medicare provider-based rules to define a provider's "campus." (42 C.F.R. '413.65(a).) At a minimum, CMS should require the Centralized Building to be in the same state as the ordering physician's practice.

CMS's failure to require that the Centralized Building be in close proximity to the physician's office location permits arrangements intended to circumvent state law, allows for numerous types of abusive relationships and, most importantly, inconveniences Medicare beneficiaries.

(b) Credentials of Physicians Who Interpret In-Office Ancillary Services

The In-Office Ancillary Services Rules require the In-Office Ancillary Service to be furnished personally by the referring physician, by a physician who is a "member of the same group practice" as the referring physician, or by an individual who is supervised by the referring physician or by another "physician in the group practice" (see 42 C.F.R. '411.355(b)(1)). The In-Office Ancillary Service must then be billed by the physician performing the supervision or the group practice when the supervising physician is a "member of the group" or a "physician in the group practice." (See 42 C.F.R. '411.355(b)(3).) While we recognize that the changes to

the definition of "Physician in the Group Practice" that were included in CMS-1810-F will help to address some of our concerns, for the reasons stated above, and in order to be consistent with the Proposed Changes to the Anti-Markup Provisions, we urge CMS to delete "a physician in the group practice" wherever this definition appears in the In-Office Ancillary Services Rules and limit the applicability of this exception to services ordered and interpreted by a "Member in the group or a member of a group practice."

Even then, CMS does not describe the qualifications of the physician who will interpret the In-Office Ancillary Service. This lack of specificity has led to situations where physicians are eligible to submit a claim for services to CMS that are performed in their office under the current In-Office Ancillary Service that the physician would not be permitted to perform if that service were provided in a hospital.

Therefore, we urge CMS to consider including credentialing requirements in the In-Office Ancillary Services Rules that are similar to those described in the attached Highmark Privileging Guidelines. At a minimum, CMS should adopt regulations that state that CMS will not pay a physician for a DHS that is performed as an In-Office Ancillary Service if the physician who interprets the service is not a member in the group or a member of a group practice and does not possess the clinical privileges needed to interpret that service if it were performed at a hospital where the physician maintains clinical privileges and would be subject to peer review.

(c) On-Site Versus Off-Site

A part-time leasing arrangement will not comply with the definition of a "Centralized Building" (42 C.F.R. '411.351) and, as such, is prohibited. Notwithstanding this clear prohibition of a part-time leasing arrangement in an off-site Centralized Building, the In-Office Ancillary Services Rules permit a provider of the ancillary services to lease space and equipment on a part-time basis to a physician or physician group practice that practices in the same building. This fact has not been affected by the publication of CMS-1810-F. CMS should consider revising the location-specific nature of part-time lease arrangements by prohibiting all part-time leasing arrangements, regardless of whether they are provided in a "Centralized Building" or the "same building" as the ordering physician.

When discussing the scope of the In-Office Ancillary Services Rules, the Preamble to the Phase I Regulations to the Section 1877 prohibition on referrals pursuant to a part-time lease in a building that is not located in the same building in which the Physician Group practices, the Preamble to those regulations states "what will not be protected by Phase I of this rule-making

are a number of part time, intermittent arrangements that functionally are nothing more than shared off-site facilities." (Emphasis added.) 66 Fed. Reg. 856, 881 (Jan. 4, 2001).

The Preamble to the Phase II Regulations to Section 1877 made it clear that the Phase II Regulations to Section 1877 specifically adopted this portion of the Phase I rule by stating "we are also retaining without substantive change the Phase I centralized building test for group practices under the In-Office Ancillary Services exception. To prevent abuse of off-site DHS arrangements such as part-time MRI or CAT scan rentals, Phase I provided that the group practice must have full-time, exclusive ownership or occupancy of the centralized space. While many commenters objected to this requirement, we are not changing the rule." 69 Fed. Reg. 16054, 16072. (Emphasis added.)

Therefore, both the Phase I and the Phase II Regulations to Section 1877 clearly state that DHS that are provided in an off-site "centralized building" pursuant to a part-time lease arrangement will not qualify as an In-Office Ancillary Service. The Phase II Regulations to Section 1877 further describe the manner in which a "centralized building" has been defined in 42 C.F.R. '411.351 and the rules governing the use of a "centralized building" in the In-Office Ancillary Services exception. (42 C.F.R. '411.355(b)(2)(ii) and (iii).) We urge CMS not to alter this prohibition.

In the Preamble to the Phase II Regulations to Section 1877, CMS distinguished a part-time lease arrangement in an off-site Centralized Building from a part-time leasing arrangement that is located in the same building as the referring physician by stating that "Under the regulations, a solo practitioner may provide DHS through a shared facility as long as the supervision, location and billing requirements of the In-Office Ancillary Services exception are satisfied." 69 Fed. Reg. at 16071. Unfortunately, CMS failed to define what is meant by a "shared facility" and did not include any type of discussion that would provide any meaningful guidance as to what CMS meant by a "shared facility."

CMS's reference to a "shared facility" in the Preamble to the Phase II Regulations to Section 1877 and CMS's response to certain comments in the November 14, 2004 changes to the Medicare Reassignment Rules have resulted in a proliferation of various types of part-time lease arrangements in the same building as the Physician Group's practice even if the group maintains a primary practice in close proximity elsewhere and the referring physician or one or more members of the referring physician's group practice regularly practice medicine in that building a mere six hours per week pursuant to 42 C.F.R. '411.355(b)(2)(C)(3).

CMS should consider that in the Preamble to the Phase II Regulations to Section 1877, when discussing the fact that the same building requirement excludes mobile vans or other facilities not permanently affixed to the building, CMS observed "as we stated in the Phase I Preamble (66 F.R. 891) part-time rentals of DHS equipment are precisely the arrangements that Section 1877 of the Act was designed to restrict." 69 Fed. Reg. at 16074. If one reviews the section of the Phase I Preamble that is cited in this quote, one will find that among CMS's concerns with a mobile van were arrangements that "would seem to be calculated to enhance physician revenue, rather than patient convenience, since patients would be encouraged, if not required, to schedule appointments on the day that the physician stands to profit from the services." 66 Fed. Reg. at 89.

The fact that (1) CMS references this section of the Phase I Preamble when discussing part-time leasing arrangements in the same building as the Physician Group, (2) the Medicare Purchased Service Rules will apply regardless of whether the test is performed at the physician's office or at another facility (Ch. 13 ' 20.2.4.1 of the Medicare Claims Processing Manual), and (3) in many instances, the effect of a part-time lease, whether in the "same building" or in a "Centralized Building," will be that beneficiaries "will be encouraged, if not required, to schedule appointments on the day that the physician stands to profit from the services," 66 Fed. Reg. at 891, should cause CMS to prohibit <u>any</u> part-time lease from qualifying for the In-Office Ancillary Services exception, regardless of whether it is in a "Centralized Building" or in the "same building" as the physician practice. Regardless of the location, the effect of and the intent in structuring such a part-time lease arrangement are to "enhance physician revenue, rather than patient convenience." 66 Fed. Reg. at 891.

While the proposed changes to the Anti-Markup Provisions and the change to the definition of a "Physician in the Group Practice" that has been included in CMS-1810-F are an excellent start, without further changes to the In-Office Ancillary Services Rules under Section 1877, the potential for abusive arrangements continues to exist and we urge CMS to halt these abusive arrangements.

(d) Consistency with the Anti-Kickback Statute

Compliance with the Stark Regulations "sets a minimum standard for acceptable financial relationships" and the mere fact that an arrangement is permitted by the Regulations to Section 1877 does not mean that it will comply with the Medicare Anti-Kickback Statute. 66 Fed. Reg. at 863 and, more recently, 70 Fed. Reg. 4858, 4863 (January 31, 2005).

We recognize that CMS lacks the regulatory authority to comment on the Anti-Kickback Statute. However, CMS must take notice of the fact that many "same building," part-time leasing arrangements that are permitted by CMS's arbitrary distinction between a "Centralized Building" and a "Same Building," besides being inconvenient for patients and difficult to manage, have been found by the OIG to potentially generate prohibited remuneration under the anti-kickback statute. See OIG Advisory Opinion 04-8 (June 23, 2004) and OIG Advisory Opinion 4-17 (December 17, 2004).

The location of the service was not a significant factor in the OIG's analysis of the compensation arrangement that was at issue in these Advisory Opinions. Rather, the OIG recognized that the actual financial and business risk for the group would be minimal or nonexistent because the physician group would have complete control over the amount of business the group would send to the lab and would, in fact, make substantial referrals to the lab. The OIG then ruled that the proposed in-office lab could potentially generate prohibited remuneration and that the OIG could potentially impose administrative sanctions under Section 1128(b)(7) or 1128(a)(7) of the Social Security Act. (See also the Discussion in the OIG's Supplemental Compliance Program Guidance for Hospitals at 70 F.R. 4866.)

(e) Non-governmental Payor Policies May Affect Use

While CMS is not required to consider the payment policies of private payors, ambiguous rules regarding the payment for In-Office Ancillary Services have caused a proliferation of In-Office Ancillary Services. This in turn has caused many private health plans to adopt, or to be in the process of adopting, payment policies that will prohibit a group practice from being paid by that plan for certain types of In-Office Ancillary Services for which CMS's current rules will permit payment, even after the publication of CMS-1810-F. As such, the latitude permitted by the In-Office Ancillary Services Rules under Section 1877 requires CMS to make additional regulatory revisions to those rules.

For example, one of the "additional provisions" in the attached Highmark Blue Cross/Blue Shield "Professional Provider Privileging Guidelines" states that the plan will "only reimburse providers for diagnostic imaging services if the services are provided on imaging equipment (i) owned by the provider or (ii) leased by the provider on a full-time basis. Owned or leased on a full-time basis is defined as (a) the provider has possession of the equipment on the provider's property and the equipment is under the provider's direct control and (b) the provider has exclusive use of the equipment, such that the provider and only the provider uses the equipment."

These rules apply regardless of whether the ancillary service is provided in a Centralized Building or in the same building in which the referring physician practices.

We, therefore, urge CMS to adopt additional rules that will clearly and unambiguously describe the circumstances under which a physician or group practice will be reimbursed for In-Office Ancillary Services that are provided to a Medicare beneficiary under Section 1877.

3. OBSTETRICAL MALPRACTICE INSURANCE SUBSIDIES

CMS correctly recognized that the current exception for obstetrical malpractice insurance subsidy is unnecessarily restrictive, does not allow for certain malpractice insurance subsidy arrangements that may be provided without a risk of program or patient abuse and does not permit hospitals to respond in a reasonable and appropriate manner when physicians who are appointed to the medical staff are confronted with precipitous increases in their malpractice insurance premium. However, the fact that CMS continues to limit this exception geographically and to obstetrical malpractice insurance is of little benefit to Medicare beneficiaries (few of whom need obstetrical services) and ignores the fact that malpractice insurance subsidies may be needed in a variety of geographic settings, by any medical specialty, and that a properly structured subsidy may be provided in any such circumstances without the threat of program abuse.

Therefore, CMS should adopt a malpractice insurance subsidy exception that will permit <u>any</u> hospital to provide malpractice subsidies to <u>any</u> physician who is appointed to the hospital's medical staff. As such, we recommend that CMS completely revise 42 C.F.R. '411.357(r).

Section 1877 of the Social Security Act applies to any hospital, regardless of its location, that provides inpatient or outpatient services if those hospital inpatient or outpatient services are paid for in whole or in part by the Medicare program. Whether a particular financial arrangement violates the law depends on whether the parties are capable of satisfying the exception to Section 1877 of the Social Security Act.

We fail to find any basis in Section 1877 or in the legislative history to Section 1877 that justifies limiting an exception for a compensation arrangement to a specific medical specialty or to a specific location. If Congress had intended certain compensation arrangements to be limited to certain medical specialties, to rural areas, to an HPSA or to any other limited geographic area, then Congress would have created such a limited exception similar to the exception that pertains to a physician's ownership or investment interests in rural providers of DHS. (See 42 USCA

' 1395nn(d)(2).) Having failed to do so provides compelling evidence that Congress intended all of the exceptions that relate to compensation arrangements to apply to any limited geographic area.

However, we are cognizant of the position on this issue that CMS provided in the Preamble to CMS-1810-F. Therefore, while CMS may possess the regulatory authority to limit a compensation arrangement to a few hospitals based on the location of a hospital, we question the policy rationale for doing so in this instance, which when examined is inconsistent with the intent of Section 1877.

As currently drafted, and even if revised in the manner described in the Proposed Regulations, 42 C.F.R. ' 411.357(r) does not permit a hospital that is not located in the limited geographic areas described in the Proposed Regulations to enter into the type of arrangements that may be necessary to further the charitable mission of the hospital and to provide services to the Medicare beneficiaries who reside within the geographic area served by the hospital.

Therefore, the proposed revisions to 42 C.F.R. ' 411.357(r) are unduly restricted geographically and, given the paucity of fertile octogenarians, of absolutely no benefit whatsoever to Medicare beneficiaries. The proposed exception for obstetrical malpractice subsidies simply will not provide an exception under Section 1877 for a number of legitimate transactions which the OIG has found to benefit Medicare beneficiaries, without the threat of program abuse.

As such, while the proposed amendments to 42 C.F.R. ' 411.357(r) constitute a significant improvement over the final rule, those changes still limit application of that exception to a few hospitals and to the sole medical specialty of obstetrics. Based on the findings of the Office of Inspector General, the need for a realistic exception in this area is significant and is not adequately addressed by the limited amendments that have been proposed to ' 411.357(r). See, OIG Letter on Hospital Corporation's Medical Malpractice Insurance Assistance Program, available at http://oig.hhs.gov/fraud/fraudalerts.html, Draft Supplemental Compliance Program Guidance for Hospitals (69 FR. 32012), the OIG's Final Supplemental Compliance Guidance for Hospitals (70 FR. 4869) and OIG Advisory Opinion (04-19) (Dec. 30, 2004 which permitted a hospital that was not located in a rural area to assist two neurosurgeons with the increase in the cost of their malpractice liability insurance premium and with the cost of tail insurance.

CMS has repeatedly recognized that a hospital may be interested in providing malpractice assistance to physicians who are appointed to its medical staff (see 63 Fed. Reg. 1659, 1702 and 1703 (Jan. 9, 1998); 66 Fed. Reg. 855, 907 and 920 (Jan. 4. 2001); 69 Fed. Reg. 16054, 16093,

16094, 16115 and 16121 (March 26, 2004)) and again in 72 Fed. Reg. 38182, but has consistently failed to provide a reasonable, practical exception that is available to all hospitals, regardless of their location, to provide the type of malpractice insurance assistance that the OIG's hospital's compliance guidance has stated is consistent with the Medicare Anti-Kickback Statute to any physician regardless of specialty.

Simply put, if '411.357(r) is not substantially revised, then it will be impossible for all but a handful of hospitals to provide malpractice assistance to an obstetrician, even if such assistance is required in order to meet the health care needs of their community, meet the health care needs of the Medicare population served by the hospital, further a tax-exempt hospital's charitable mission, and not violate the Medicare Anti-Kickback Statute.

Page 303 of CMS-1810-F states: "We see no reason why the fair market value compensation exception in '411.357(e) cannot be used to offer medical staff assistance with malpractice insurance, provided that the value of the assistance is fair market value for services actually provided by the staff and the other requirements of the exception are met."

However, this statement ignores the fact that the amount of a malpractice insurance subsidy is determined by the amount of the increase in a particular physician's premium. It may also include the cost of tail coverage. Where the physician is required to provide certain services, generally those services have greater value to the community served by the hospital, rather than directly to the hospital.

Also, two similarly situated physicians who will perform the same service may receive a different amount of subsidy since again the value of the subsidy is based on the physician's premium cost, not the value of the service to the hospital. Given the statement on page 303 of CMS-1810-F, please confirm that CMS is now revising its position with regard to the scope of the fair market value exception (411.357(e)).

We also disagree with the statement on page 304 of CMS-1810-F where CMS states that "OIG has not issued any guidance of general application that is broader than this exception and safe harbor." The OIG's general advice in the OIG Letter on Hospital Corporation's Medical Malpractice Insurance Program, the advice in the Draft and Final Supplemental Compliance Guidance for Hospitals and the specific guidance in OIG Advisory Opinion 04-19 are much broader and provide a reasonable manner in which a hospital can provide such malpractice assistance without the need to seek an advisory opinion from either OIG or CMS.

We request that CMS specifically comment on how a hospital such as the one described in OIG Advisory Opinion 04-19 is to fit such an arrangement under a current exception to Section 1877. Since the physicians involved were neurosurgeons, '42 C.F.R. 411.357(r) would not apply even though it is much more likely that a Medicare beneficiary would require the services of a neurosurgeon than an obstetrician. Due to the type and nature of the subsidy and the fact that the amount of the subsidy is not based on the value of the services provided to the hospital, this arrangement does not satisfy 42 C.F.R. '411.357(d) ("Personal Services Arrangements") or '411.357(l) ("Fair Market Value Compensation"). The physician was not relocating to the geographic area served by the hospital and did not receive an offer from another hospital to move from an HPSA or an area determined by the Secretary to have a demonstrated need. Therefore, neither 42 C.F.R. '411.357(e) nor '42 C.F.R. '411.357(t) applies, even after the revisions to these two exceptions by CMS-1810-F.

If faced with the same facts as OIG Advisory Opinion 04-19, CMS would be hard pressed to reach a conclusion that differs from the OIG. However, despite the statements on pages 303 and 304 of the Preamble to CMS-1810-F, the current regulations and Section 1877 do not provide an exception that is available to all hospitals to provide such needed financial assistance. We urge CMS to promulgate a new rule to replace 42 C.F.R. '411.357(r) that will create an exception to Section 1877 of the Social Security Act that is consistent with the OIG's compliance guidance cited above. Such an exception could be narrowly drawn and consistent with OIG pronouncements in this area by using the following factors that were described in Advisory Opinion 04-19:

> (r) malpractice insurance subsides B remuneration provided by a hospital to a physician or group of physicians regardless of whether the group meets the definition of a group practice as set forth in '411.352 if:
>
> (1) the arrangement as set forth in writing is not in effect for longer than a two-year contract period in which the physicians agree to continue practicing and the hospital agrees to subsidize some (but not all) of the increase in their insurance costs;
>
> (2) during the first year of the agreement, the hospital would pay 75% of the difference between the cost of the policy from the original carrier and the cost

of the policy from a new carrier to cover the physicians' continued practice;

(3) the hospital may subsidize premium increases charged by the new carrier in the second year of the agreement only to the extent the community need persisted;

(4) the hospital may purchase tail coverage for the physicians' continued practice, if necessary, regardless of the date on which this obligation becomes due, with the cost of the tail coverage to be determined by a number of factors, such as the length of time the physicians continued to practice;

(5) the subsidy may be paid directly to the physicians, upon receipt of documentation showing their expenditures, or it may be paid directly to the insurance company;

(6) the amount of the subsidy would not take into account the volume or value of referrals or business otherwise generated by the physicians for the hospital;

(7) the physicians were not required to refer patients to, or otherwise generate business for, the hospital;

(8) the insurance would apply to services furnished by the physicians at any location, not just at the hospital; and

(9) in return for this financial assistance, the hospital shall require any physician who received such assistance to provide the following services throughout the period that the assistance remains in effect:

(i) maintain a full-time practice of the physician's specialty in the geographic area served by the hospital;

(ii) take emergency department call for the hospital's emergency department;

(iii) participate in assigned hospital committees;

(iv) continue to provide care to beneficiaries of the Medicare program;

(v) provide at least as much Medicaid and/or indigent care as they were providing when they entered into the agreement with the hospital; and

(vi) cooperate with any hospital's efforts to recruit additional physicians practicing that specialty to the geographic area served by the hospital regardless of whether any such recruit joined the physician or physician's group.

(10) The arrangement does not violate the anti-kickback statute ('1128B(b) of the Act) or any federal or state law or regulations governing billing or claims submission.

4. UNIT OF SERVICE (PER CLICK) PAYMENTS IN SPACE AND EQUIPMENT LEASES

CMS has often noted the distinction between therapeutic modalities and diagnostic modalities and that abuse of arrangements involving therapeutic modalities is unlikely to occur. For example, in CMS's proposed changes to the definition of "radiology and certain other imaging services" that were set forth in CMS - 1392-P at page 620, CMS specifically states "in the

definition of 'radiology and certain other imaging services' at 411.351, we exclude x-ray, fluoroscopy or ultrasound procedures that require the insertion of a needle, catheter, tube or probe, through the skin or into a body cavity because we do not believe that a physician would inappropriately subject a Medicare patient to such a procedure."

In addition, at 72 Fed. Reg. 38179, the Preamble to these Proposed Regulations, CMS specifically states "we stated that, although we welcome comments in all aspects of our proposal, we are particularly interested in receiving comments on whether diagnostic imaging tests should be accepted from any of our proposed provisions...." (Emphasis added.) CMS makes a similar distinction between therapeutic and diagnostic services in CMS-1810-F at 41. If CMS were to review the Highmark Provider Privileging Guidelines described above, CMS will note that those services are limited to diagnostic services and do not apply to therapeutic procedures.

Therapeutic equipment such as a cyber-knife, which has limited and specific therapeutic uses, or a therapeutic service such as hyperbaric oxygen therapy for the treatment of diabetic wounds of the lower extremities, with very specific conditions of coverage (see Transmittal AB-02-183), should be exempt from the rules prohibiting per click payments as diagnostic equipment where the conditions of treatment are less defined and are more easily subject to abuse.

Therefore, we urge CMS to continue to study this issue. To the extent that CMS determines that CMS must exercise its regulatory authority to prohibit a practice that it has specifically found to be consistent with Congressional intent, CMS should exercise the discretion as narrowly as possible. We also urge CMS to consider the distinction between per click arrangements involving diagnostic services and therapeutic modalities which should be excluded from any such prohibition.

Finally, given the fact that per click or per use payments are specifically permitted by the statute, there are a significant number of these arrangements currently in effect. Therefore, the proposed amendments affecting unit of service payment in space and equipment leases will constitute a major change to the regulations, will result in a significant restructuring of a number of current arrangements and, as such, will have a significant regulatory impact on both DHS providers and physicians.

5. "STAND IN THE SHOES"

After reading the discussion in the Preamble to CMS-1810-F of the effect of the "Stand in the Shoes" standard on the indirect compensation rules currently set forth in the Regulations to Section 1877 (See, 42 C.F.R. '411.354(b)(5); '411.354(c)(2) and '411.357(p)), we have a much greater appreciation of the application of this standard than we did prior to the public availability of CMS-1810-F.

We do, however, request clarification as to the manner in which the "Stand in the Shoes" standard will be applied in the following situation. The example that CMS uses in 72 Fed. Reg. 38184 states "a hospital would stand in the shoes of a Medical Foundation that it owns or controls (such as where the hospital is the sole corporate member of a non-profit corporation)." Please clarify that the fact that such a hospital would "Stand in the Shoes" of the Medical Foundation for purposes of application of the referral prohibitions that are set forth in the regulations to Section 1877 would not make the hospital the "alter ego" of the Medical Foundation, nor does CMS intend for the "Stand in the Shoes" standard to preclude the hospital-related Medical Foundation from satisfying the definition of a "group practice," as that term is defined in 42 C.F.R. '352.412.

In addition, please clarify if the "Stand in the Shoes" rules would apply to an entity which is related to a DHS entity through common ownership or control, rather than as a direct subsidiary.

Specifically, 42 C.F.R. '411.352(a) states that the group practice must consist of "a single, legal entity operating primarily for the purpose of being a physician group practice and any organizational form recognized by the state in which the group practice achieves legal status." However, the Preamble to the Phase II regulations to Section 1877 (69 Fed. Reg. at 16077 March 26, 2004) specifically states:

> As we explained in the Phase I Preamble (66 F.R. 898-899), treating a 'group' of hospital employed physicians as a 'group practice' for purposes of Section 1877(h)(4) of the Act would stretch the meaning of a 'group practice' too far. It would enable hospitals that employed two or more physicians to use the In-Office Ancillary Services exception inappropriately to protect virtually all inpatient and outpatient services. We do not believe that Congress intended the In-Office Ancillary Services exception,

> which focuses on services provided by physician practices, to be used to exempt hospital services from the scope of Section 1877 of the Act. Under the 'group practice' definition, a hospital may legally organize, own, or operate a group practice that is a separate legal entity; however, the hospital itself (or other facility or entity, the primary purpose of which is something other than the operation of a physician group practice) cannot be a group practice for purposes of Section 1877(h)(4) of the Act. Hospitals that employ physicians can appropriately structure their arrangements with physicians that fit in the employment exception. (Emphasis added.)

Please clarify the manner in which the "Stand in the Shoes" standard would be used, provide further discussion as to the relationship between the "Stand in the Shoes" standard to the indirect compensation rules and the fact that CMS does not intend for the "Stand in the Shoes" provision to disqualify any hospital-owned or hospital-affiliated "group practice" from continuing to qualify as a "physician group" under 42 C.F.R. ' 411.352. Given the statement in CMS-1810-F at p. 61 that "a separate corporation formed by a hospital to employ physicians can constitute a single legal entity...," it is clear that CMS does not intend for the "Stand in the Shoes" standard to be so construed.

Please be aware that the manner in which the "Stand in the Shoes" standard has been articulated in the Proposed Rules could lead to such an erroneous conclusion. Also, the fact that the current definition of "locum tenens physician" is "a physician who 'stands in the shoes' in exigent circumstances for a physician..." (emphasis added) at 42 C.F.R. ' 411.351 seems to imply such a finding. As such, we specifically recommend CMS describe the "Stand in the Shoes" standard with as much specificity as possible and clarify the fact that, in the above-described example, the fact that the hospital may "Stand in the Shoes" of the legal foundation for the purpose of the application of Section 1877 does not disqualify the medical foundation from being a "physician group."

6. SERVICES FURNISHED "UNDER ARRANGEMENTS"

According to Section 2118 of the Medicare Provider Reimbursement Manual, the term "under arrangement" refers to a manner of furnishing services by a provider with payment to the provider for the services, with respect to which the individual being entitled to have payment made by the program discharges the individual's liability to pay for the services. The providers

may furnish services under arrangement with outside suppliers, including other providers. The amount charged by the supplying organization and paid by the provider for the services rendered then becomes a cost to the provider. The services are treated as though they were furnished directly by the provider and thus meet all of the Medicare provider-based rules. This is clear from the definition of "Inpatient Hospital Services" (42 C.F.R. '411.351) where the definition states that "Inpatient Hospital Services" include services that are "furnished either by the hospital directly or under arrangements made by the hospital with others." (Emphasis added.)

According to the Supplemental Compliance Guidance for Hospitals, issued by the Office of Inspector General of HHS on January 31, 2005, OIG stated that even though the arrangement provides for payment on a "per use" basis, and thus based on the volume of procedures referred by the physician owners of the joint venture, the arrangement should not automatically pose a problem as long as the amount paid to the entity in which the physicians have an ownership interest is not inflated.

CMS has proposed a subtle yet significant change to the definition of an "entity" that is set forth in 42 C.F.R. '411.351. Rather than the current focus on whether the entity presented the claim for the DHS, CMS has proposed changing the definition of an "entity" to a person or entity that has performed the services or a person or entity that "presented a claim, or caused a claim to be presented for Medicare benefits for the DHS."

By adding any entity that causes a claim to be presented, CMS states that it intends to prohibit physician investment in an entity that provides services "under arrangement" to a DHS provider if the physician has an investment interest in the under arrangement entity that provides the services to the DHS provider. Currently, physician investment in such an entity would not be precluded.

MedPAC recognized that certain "under arrangement" joint ventures may be problematic. However, given the amount of study that MedPAC has given to this issue prior to issuing its March 2005 Report to Congress, we urge CMS to adopt MedPAC's recommendation that prohibited interests should be limited "to physician interest in an entity that derives a substantial portion of its revenue from a provider or designated health service." CMS cites this report in CMS-1910-F at p. 18 and, despite the time and study devoted to developing the Phase III Rules, CMS stated that it was making "no substantive changes to the definition of entity in this Phase III final rule." Id.

By failing to adopt MedPAC's recommendation, especially after citing the MedPac Report in CMS-1810-F, CMS has created a significant amount of uncertainty as to what constitutes an entity that "causes claims to be submitted to Medicare for the DHS." The MedPAC definition permits legitimate businesses to provide services to a referral source, which is only prohibited if that entity derives a substantial portion of its revenue from the DHS provider. CMS's proposal would prohibit any level of business at all with a DHS provider without any investigation into the circumstances that cause certain "under arrangement" joint ventures to be abusive and which under arrangement ventures that MedPAC found should be permitted to continue to provide services under arrangement to a DHS entity.

Therefore, CMS should not undertake any change in the definition of an "entity" at this point in time. Rather, CMS should consider MedPAC's recommendations, should devote further study to the effects of "under arrangement" joint ventures on the Medicare program, and should undertake a separate and thorough rule-making specifically on the issue of whether, and under what circumstances, physicians should be permitted to have an investment interest in an entity that provides a service to a DHS provider under arrangement.

At the very least, CMS should consider only applying these proposed rules relating to ownership of under arrangements entities to entities that provide services under arrangement on a per unit of service basis, but not to those which provide services under arrangement for a fixed fee that does not vary based on the volume or value of services provided.

Again, the proposed change to the definition of the term "entity" will affect a number of arrangements that are currently in effect. Therefore, the proposed amendment to this definition will constitute a major change to the regulations, will result in a significant restructuring of a number of current arrangements and, as such, will have a significant regulatory impact on both DHS providers and physicians.

7. SET IN ADVANCE AND PERCENTAGE-BASED COMPENSATION ARRANGEMENT

We found the discussion of the "set in advance" and "percentage-based compensation arrangements" that was included in the Proposed Regulations to be somewhat confusing. Furthermore, the definition of percentage-based compensation arrangements fails to consider the manner in which a physician group may compensate a physician for services provided under the direction or medical supervision of a non-physician practitioner. Finally, we need the ability to

Highmark
Professional Provider Privileging Guidelines

Purpose

The following guidelines are intended to promote reasonable and consistent quality and safety standards for the provision of imaging services. Highmark will not reimburse providers for imaging services performed if they do not satisfy the following guidelines. These guidelines affect all Highmark members except those covered under traditional indemnity plans.

General Requirements for Imaging Providers

- All imaging providers must provide a written report within 10 business days from date of service to the ordering provider. (Mammography reports must be completed within 30 days, per Mammography Quality Standards Act (MQSA) guidelines.)
- All imaging facilities must have a documented Quality Control Program inclusive of both imaging equipment and film processors.
- All imaging facilities must have a documented Radiation Safety Program and As Low As Reasonably Achievable (ALARA) Program.
- All imaging facilities utilizing equipment producing ionizing radiation must have a current (within 3 years) letter of state inspection, or calibration report, or physicist's report.
- Highmark Medical Policy will apply to the delivery of services detailed in the guidelines.
- All imaging providers must be Highmark credentialed (hereinafter referred to as "credentialed").

Guidelines Specific to Plain Films

- Providers must have a state certified or American Registry of Radiologic Technologists (ARRT) certified technologist on-site taking all films, or must arrange for a credentialed radiologist to over-read all films within 5 business days from date of service.
- At minimum, an automatic processor must be used to develop all analog plain films.

Guidelines Specific to Bone Densitometry

- Bone Densitometry must be performed by hospitals, or by credentialed radiologists, endocrinologists, rheumatologists, obstetricians/gynecologists, orthopedists, internists, and family physicians.
- Must be performed on an axial Dual Energy X-ray Absorption (DEXA) system or a Quantitative CT.
- At least one physician from each practice location must be a credentialed radiologist or achieve certification by the ISCD (International Society for Clinical Densitometry), and one technologist from each practice location must be ARRT certified or achieve certification by the ISCD (International Society for Clinical Densitometry) within one year of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Nuclear Cardiology

- Nuclear cardiology practices must employ at least one physician who is credentialed in diagnostic radiology, nuclear medicine or has received certification by the Certification Board of Nuclear Cardiology (CBNC).
- Nuclear cardiology practices that do not meet the above criteria will be considered for participation upon submitting evidence that at least one physician has satisfied the Level II training in Nuclear Cardiology as recommended in the American College of Cardiology/American Society of Nuclear Cardiology, Core Cardiology Training Symposium (COCATS) Training Guidelines.
- Nuclear cardiology imaging systems must have the capability of assessing both myocardial perfusion and contractile function (ejection fraction and regional wall motion).
- Cardiac stress tests must be performed under the direct supervision of a credentialed physician who has a current Advanced Cardiac Life Support (ACLS) certification.
- Nuclear cardiology practices must provide a copy of a Radioactive Materials License that indicates the practice address and the name of the nuclear cardiology physician(s) performing and/or

Submitter : **Miss. Amanda Flores** **Date: 08/31/2007**

Organization : **Carthage College**

Category : **Other Practitioner**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Amanda Flores, and I am certified and licensed as an Athletic Trainer in the state of Wisconsin. I am currently working on my Masters of Education with an emphasis in counseling, at Carthage College, where I also work as a graduate assistant in the athletic training room. I am currently working with women s soccer, men s/women s cross country, women s golf and women s tennis, but have experience with all sports offered here at Carthage College. After I finish here at Carthage, at the end of May, I will be looking out looking for a job which may bring me to the clinic setting.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Amanda Flores LAT ATC

Submitter : Earl Beam III **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15094-Attach-1.DOC

15094

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

ADVANCED PAIN MANAGEMENT

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Earl Beam III, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Dr. Erin Guinan **Date:** 08/31/2007

Organization : DeRosa Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please consider adding a provision that prohibits prescribing individuals from self-referring their patients to physical therapy clinics that they themselves own. Thank you- Erin Guinan, PT

Submitter : Aric Blom **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15096-Attach-1.DOC

15096

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

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There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	**Anesthesiologists -05 (Non-Facility)**	**Interventional Pain Management Physicians - 09 (Non-Facility)**
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The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

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The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Aric Blom, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Dr. Diane Hartley **Date:** 08/31/2007

Organization : Hartley Health Care Services, Inc

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I have been a physical therapist for 33 years and have owned Hartley Health Care Services, Inc., a Medicare Certified Rehabilitation Agency, for 25 years. I have earned both a bachelor of science and a doctorate degree in physical therapy as well as taken over 6,000 hours in continuing education. I strongly believe it is most advantageous to both the patient and CMS to only pay for physical therapy services that are delivered by licensed physical therapist in a non-physician owned setting.

Physical therapy delivered as "in-office ancillary service" has a high potential for fraud and abuse. There is a potential for conflict of interest when the services prescribed can give finacial gain to the referrer. For example, the physician may refer the patient for physical therapy services that are not needed or unnecessarily legnthen the period of treatment.

We have seen physical therapy given as an "in-office ancillary service" in physician's offices being administered by non physical therapists either massage therapists or athletic trainers as well as by peoplc with no related education. Physical therapy is a very skilled profession requiring graduating from an accreditaed physical therapy program with either a masters or doctorate degree and being licensed to practice physical therapy.

We have seen over utilization of physical therapy services when provided in the physician's office. There have been serveral published studies that document the over utilization of physical therapy when provided in the physician owned facilllity. The first study that I read was conducted in 1991 by The Florida Health Care Cost Containment Board. This study showed that physician owned physical therapy practices had a significant over utilization pattern as well as higher profits, and may provide less complex treatment regimes and a lower quality of care. The most recent study was released May 1, 2006 by the Office of Inspector General showed that 91% of physical therapy billed by physicians in the first 6 months of 2002 did not meet the programs requirements.

We have seen a drop of over 35% of patients due to the growing numbers of physician owned physical therapy practices. Patients have told us that their doctor said that they had to go to "thcir physical therapy facilitiy so that they can keep tract of their care". Physicians have refused to give them a referral or prescription to any other facility. We have seen an increase in the number of complex patients who have had previous "physical therapy" in their physicians office that did not receive the proper physical therapy and now are suffering with more pain or complications.

Disallowing physical therapy provided in physician's offices as "in-office ancillary services" would save CMS money and put limits on potential fraud and abuse. It would ensure that only licensed physical therapists or physical therapist assistants deliver physical therapy treatments which would consistently give a higher quality of care. I urge CMS to remove physical therapy from the "in-office ancillary services" exception to the federal physician referral laws in the 2008 proposed Medicare fee schedule rule.

Thank you for you time and consideration. Please feel free to contact me if I can be of any help.

Submitter : Ms. Jo Ann Platko **Date:** 08/31/2007

Organization : American Association of Nurse Anesthetists

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15098-Attach-1.DOC

CMS-1385-P-15098-Attach-2.DOC

15098

August 21, 2007
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244–8018
RE: CMS–1385–P (BACKGROUND, IMPACT) ANESTHESIA SERVICES

Dear Administrator:

As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS' proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS' proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services. This increase in Medicare payment is important for several reasons. First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.

Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers' services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule. Third, CMS' proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments. Additionally, if CMS' proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation). America's 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency's acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,

Jo Ann Platko, CRNA, MSN
Name & Credential
49 Patrick Henry Drive
Address
Hanover Township, PA 18706
City, State ZIP

Submitter : Mr. Michael Gurtowsky **Date:** 08/31/2007

Organization : UMHS MedSport

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Michael Gurtowsky, I am certified athletic trainer working the clinic/high school outreach setting.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Michael Gurtowsky, ATC

Submitter : **Mr. Greg Obray** **Date: 08/31/2007**

Organization : **Idaho State University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Greg Obray, I am an Assistant Athletic Trainer at Idaho State University and Licensed by the Idaho State Board of Medicine. I am currently working on a thesis to complete my Masters Degree and hold a Bachelors Degree in Athletic Training. I am certified through the National Athletic Trainers' Association. My current job requires me to provide health care to the Idaho State University Women's Volleyball and Softball teams. In the past I have also worked for Pocatello Physical Therapy Clinic, the San Francisco 49ers, Boise State University, and the University of Washington.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

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Sincerely,

Greg Obray, ATC/L, CSCS

Submitter : Gregory Cavanaugh **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15101-Attach-1.DOC

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August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

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Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

ADVANCED PAIN MANAGEMENT

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Gregory Cavanaugh, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Dr. Kathryn Kozak **Date:** 08/31/2007

Organization : west Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15102-Attach-1.PDF

15102

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Kathryn Marie Kozak, M.D.

Submitter : **Ms. Ann Berkey** **Date: 08/31/2007**

Organization : **McKesson Corporation**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

Attached are McKesson Corporation's comments on the Proposed Elimination of Exemption for Computer-Generated Facsimiles

CMS-1385-P-15103-Attach-1.DOC

15103

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Senior Vice President
Public Affairs

[redacted]

McKESSON
Empowering Healthcare

August 31, 2007

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
Attn: CMS-1385-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

Dear Mr. Secretary:

On behalf of McKesson Corporation (hereinafter "McKesson"), I am submitting comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions as proposed in the above-captioned rulemaking.

For over 170 years, McKesson has led the industry in the delivery of medicines and healthcare products to drug stores. Today, a Fortune 18 corporation, we deliver vital medicines, medical supplies, care management services, automation, and health information technology solutions that touch the lives of over 100 million patients in healthcare settings that include more than 25,000 retail pharmacies, 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, the Department of Veterans Affairs, the Department of Defense and other government facilities.

As the largest health information technology company in the world, McKesson is actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce the cost and variability of care and improve healthcare efficiency. McKesson processes approximately 70% of all electronic pharmacy transactions through our connection to more than 90% of U.S. pharmacies. We also serve as the CMS contractor of TrOOP administration for the Medicare Part D prescription drug benefit.

Our perspective on the proposed rule is based on our extensive experience with health information technology in hospitals, health systems and pharmacies.

PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

McKesson applauds CMS for promoting efforts to further encourage physicians and pharmacy professionals to adopt and use electronic prescribing (eRx) technology. Increased use of eRx technology is essential to eliminate medication errors, promote greater efficiencies and reduce overall healthcare costs. We are concerned, however, that the proposed rule to eliminate the exemption for computer-generated facsimile (fax) transmissions from the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for transmitting prescription and certain prescription-related information for Part D eligible individuals could actually have the unintended consequence of further delaying adoption of eRx technology.

Potential Impact on Providers and Pharmacies & Timeline for Elimination of Exemption
CMS requests comments on the impact of the proposed elimination of this exemption on providers and pharmacies, including the total number of practices and pharmacies that will be affected and the time required for them to implement SCRIPT-enabled software. Today, it is our understanding that only about 10% of physician offices use eRx technology. Additionally, CMS has reported that 20% of independent pharmacies have eRx capability; however, that means that approximately 80% of independent pharmacies, or 30% of all pharmacies, many in rural and under-served communities, lack the ability to use eRx technology today. Additionally, our estimates show that approximately 40% of independent pharmacies currently utilize legacy platforms that cannot support eRx technology. Both physician practices and pharmacies will require significant investment to upgrade to new systems that employ the required technology. The proposed rule lacks any incentives to aide physicians and pharmacies in making these investments.

Given the technological and financial investment required to enable eRx, McKesson believes that the effective date for eliminating the exemption for computer-generated fax transmissions is too aggressive to transition to a completely electronic environment for processing prescriptions without jeopardizing patient safety. McKesson proposes that CMS delay the implementation of the exemption's elimination to allow providers and pharmacies adequate time to acquire the needed new systems.

Computer-generated faxes serve as an important incremental step while eRx technology is adopted. Without the ability to fax a computer-generated prescription to a pharmacy, physicians may resort to faxing *handwritten* paper prescriptions to pharmacies. Physicians could also misinterpret the intent of the proposed fax elimination and cease faxing any prescriptions for Part D eligible individuals, thus prompting greater use of telephone, paper and pen to process prescriptions. This unnecessary interruption in a physician's and pharmacist's workflow could delay availability of medicines for Medicare beneficiaries.

The timeline provided for compliance is also inconsistent with other requirements of the Medicare Modernization Act of 2003, which mandates the implementation of standards for eRx by April 2009. At a minimum, we suggest that this rule to eliminate the fax exemption be delayed for one year after the required standards implementation date of April 1, 2009 to enable adequate implementation time for physician practices and pharmacies that require system upgrades.

Potential to Revert to Paper Prescribing

CMS also requests comments regarding the extent to which elimination of the exemption would increase use of paper prescribing. Providers who do not currently have eRx technology can transmit prescriptions via computer-generated fax, telephone, or handwritten prescription. While computer-generated faxing may retain some of the disadvantages of paper prescriptions, translation error most frequently results from handwritten information which is eliminated by a computer-generated fax. If the computer-fax exemption is eliminated, physicians will have no alternative but to rely on paper prescriptions or the telephone until they are able to acquire new technology.

Other Factors

McKesson believes that CMS should consider several other factors before eliminating the computer-generated fax exemption. First, uniform standards that allow for the full security, adoption and use of eRx have not yet been formalized, and variations in state laws and regulations governing use of electronic signatures can create confusion and impede the adoption of eRx.

Additionally, the Drug Enforcement Agency (DEA) has not provided any guidance on the use of eRx for controlled substances. Controlled substance prescriptions represent over 10% of all prescriptions written; therefore, an exemption for faxes of controlled substance prescriptions will be needed until the DEA promulgates rules for electronic transmission. If the exemption is eliminated, the fulfillment of controlled substance prescriptions would require a reversion back to manual delivery methods.

Finally, computer-generated fax transmissions of prescriptions serve as the backup for transmitting prescription information in the event of network outages or failures. Any modification of the computer-fax exemption should, at a minimum, allow for transmission of prescriptions via computer-fax in the event of an emergency. Without this alternative transmission method, clinicians will be left with pen, paper and the telephone.

CONCLUSION

McKesson strongly advocates and endorses swift adoption and use of eRx, and we applaud CMS for promoting this goal. However, we must allow providers and vendors sufficient time to transition to new technology so that patient safety is not compromised. Harmonization of federal and state laws governing eRx, combined with financial incentives for physicians and pharmacists to implement eRx technology, will be necessary to rapidly foster the adoption of eRx. In this interim period, the current exemption for use of computer-generated faxes of prescriptions acts as a bridge between paper-based scripts and full eRx adoption. We believe it is too early to eliminate this bridge and recommend that CMS not limit the ability for physicians to use computer-generated faxes to transmit Part D prescriptions.

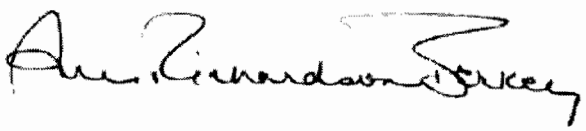
In summary, we recommend that the final rule include the following modifications:

- Extend the exemption of computer to fax transmissions for eRx to at least April 1, 2010 to allow clinicians adequate time to adopt eRx technology and assure consistency with standards for eRx transmissions that will be implemented in April 2009;
- Provide a specific exemption of the computer-fax transmission for controlled substances until the DEA promulgates rules for eRx;

- Encourage the DEA and state agencies to collaborate with CMS to assure that federal and state laws governing eRx do not pose conflict for its adoption; and
- Exempt the use of computer-fax transmission in the event of a network outage or failure or other emergency.

We appreciate the opportunity to provide our comments on the proposed elimination of the exemption of computer-fax transmissions for eRx and look forward to working with you as you finalize and implement this rule. Should you have questions or need further information, please contact me at (415) 983-8494 or ann.berkey@mckesson.com.

Sincerely,



Ann Richardson Berkey

Submitter : **Mr. Lanny Bradford** **Date: 08/31/2007**

Organization : **University of California, Berkeley**

Category : **Academic**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Lanny Bradford, and I am an associate athletic trainer working at the University of California, Berkeley. My educational and athletic training backgrounds are ones of great diversity and strength. I have developed a passionate interest for athletic training while gaining my undergraduate degree at Iowa State University, my masters degree at Purdue University, professional experience at The University of Arizona, and now at the University of California, Berkeley. I hold national certification in athletic training from the Board of Certification, Inc., and licensure in the state of Arizona to practice athletic training.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Lanny Bradford, MS, ATC
Associate Athletic Trainer
University of California, Berkeley
203 Memorial Stadium
Berkeley, CA 94619-4426

Submitter : William Civiletta-Kalich **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15105-Attach-1.DOC

1505

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

William Civiletta-Kalich, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Dr. Robert Colandreo **Date:** 08/31/2007

Organization : Dr. Robert Colandreo

Category : Academic

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Dear Sir or Madam:

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities in 1385-P.

I am currently an assistant professor and clinical edueation coordinator for the athletic training education program at Bridgewater State College. In addition to being a certified athletic trainer I am also a licensed physical therapist. I am personally well aware that the rehabilitation training provided to athletie training student is at a level that exceeds that of a physical therapy aide or physical therapy assistant.

While I am concerned that these proposed changes to the Hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality healthcare for patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that patients I work with receive quality healthcare. State law and hospital medical professionals have deemed athletic trainers qualified to perform these services and these proposed regulations attempt to circumvent those standards. The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive their services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Robert M. Colandreo, DPT, PT, ATC, LAT

Submitter : Megan Hackel **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15107-Attach-1.DOC

1507

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

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RESOURCE-BASED PE RVUs

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4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Megan Hackel, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Ms. Donna Fiorentino** **Date: 08/31/2007**

Organization : **International Society for Clinical Densitometry**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See 5 attachments which include ISCD comments on Total Work RVU 77080 (Dual Energy X-Ray Absorbtiometry)
Work RVU 77080 (Dual Energy X-ray Absorptiometry)
Direct Practice Expense RVU 77080 (Dual Energy X-Ray Absorptiometry)
Indirect Practice Expense RVU 77080 (Dual Energy X-Ray Absorptiometry)
Refinement Panel as it relates to RVU 77080
Definition of Imaging Services under DRA
and 4 attachements including Appendices A-H

CMS-1385-P-15108-Attach-1.DOC

CMS-1385-P-15108-Attach-2.DOC

CMS-1385-P-15108-Attach-3.DOC

CMS-1385-P-15108-Attach-4.DOC

CMS-1385-P-15108-Attach-5.DOC

1510e

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August 31, 2007

Kerry Weems
Administrator Designate
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1385-P: Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Comments:

Total Work RVU 77080 (Dual Energy X-Ray Absorbtiometry)
Work RVU 77080 (Dual Energy X-ray Absorptiometry)
Direct Practice Expense RVU 77080 (Dual Energy X-Ray Absorptiometry)
Indirect Practice Expense RVU 77080 (Dual Energy X-Ray Absorptiometry)
Refinement Panel as it relates to RVU 77080
Definition of Imaging Services under DRA

Dear Mr. Weems:

SUMMARY

Osteoporosis is a major chronic disease that affects up to 50% of Medicare beneficiaries. DXA is the gold standard for diagnosing this disease and monitoring response to medical therapy. Once identified, medical therapies are available which reduce fracture risk and save lives. Significant health care savings could be realized if preventive efforts could be expanded. CMS has recently championed the importance of preventive health and DXA testing as part of the "Welcome to Medicare Exam". Despite this, screening rates for osteoporosis using DXA remain extremely low at slightly less than 10% annually. Unfortunately, the recent Medicare 5 year review has assigned a new RVU to central DXA that so profoundly undervalues this service that virtually all physicians in the non-facility setting will abandon DXA testing by 2010, thereby crippling CMS efforts to increase screening rates and recognition of this serious but preventable disease. Based on a series of surveys we have participated in with other clinical societies, we enumerate errors in data input used to calculate the new DXA RVUs that, if corrected, would more appropriately value DXA reimbursement. A recent analysis by the Lewin Group also points to a DXA cost that approximates reimbursement previously provided at the 2006 RVU level. Appropriately valued, DXA will be the centerpiece tool in the CMS effort to prevent osteoporosis among Medicare beneficiaries.

INTRODUCTION

The International Society for Clinical Densitometry (ISCD) welcomes the opportunity to comment on the CMS proposed rule 1385-P: Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B payment Policies for CY 2008. Specifically, we would like to address CPT code 77080 (axial DXA) and inputs used to determine the assigned RVU.

The ISCD is a multidisciplinary nonprofit professional society whose mission is to enhance knowledge and quality of bone densitometry among health care professionals. It seeks to educate clinicians and technologists, increase patient awareness and access to bone densitometry, and to support clinical and scientific advances in the field. Presently, there are over 6,000 members in 56 countries, 93% of whom currently practice in the United States. 60% of ISCD members are physicians and 40% are technologists. Membership spans more than 20 health care disciplines, including Internal Medicine, Family Practice, Pediatrics, Gerontology, Gynecology, Rheumatology, Endocrinology, Orthopedics, Radiology and Nephrology.

Osteoporosis causes fractures in approximately half of women and one quarter of men. Over 20% of adults who sustain a hip fracture die within the following year and many more never regain independence. Annual direct health care costs for fracture care in the United States currently approximate $16.9 billion and are projected to exceed $25 billion by 2025. Despite the epidemic proportions of osteoporosis, the test used to diagnosis this preventable disease, and hailed by the Surgeon General in 2004, as "one of the most significant advances in the last quarter century," is in danger of being eliminated from the women's health care arsenal by Medicare payment policies. The test, DXA (Dual Energy X-Ray Absorptiometry) (CPT code 77080), and a companion procedure, VFA (Vertebral Fracture Assessment) (CPT code 77082), are critical for osteoporosis diagnosis and for monitoring response to treatment. The 40% reduction in the Medicare Physician Fee Schedule reimbursement for DXA in the non-facility setting (implemented in 2007 with the Deficit Reduction Act) has already caused some physicians to lay off staff, to delay or cancel the purchase of new bone density measurement equipment, or to discontinue offering this vital service. By 2010, DXA reimbursement will have dropped approximately 75%. With reimbursement far below operating costs, over 90% of physicians have indicated that they will stop performing DXA studies by 2010, and this essential preventive service will largely disappear from the non-facility environment (see Appendix A).

We will provide information regarding methodology and results from 3 surveys that were conducted within the last 16 months that identify flaws in data input, data omission, and erroneous assumptions that have contributed to the incorrect calculation of reimbursement for DXA. These surveys include the following:

- a clinical society survey in 2006 of physician work and direct practice expense;
- a clinical society survey in 2007 of physician responses to the scheduled; DXA reimbursement cuts to be phased in over the next 4 years; and
- a DXA cost analysis performed by the Lewin Group.

We urge CMS to carefully consider the valid survey data presented in these comments as required by Pub. L.106-113; 113 Stat.1536, which states in relevant part:

"The Secretary of Health and Human Services shall establish by regulation (after notice and opportunity for public comment) a process (including data collection standards) under which the Secretary **will accept for use and will use,** to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations (other than the Department of Health and Human Services) to supplement the data normally collected by that Department in determining the practice expense component under section 1848 (c)(2)(C)(ii) of the Social Security Act (42 U.S.C. 1395w-4(c)(2)(C) (ii) for purposes of determining relative values for payment for physicians' services under the fee schedule under section 1848 of such Act."

Utilizing the results of the first two surveys outlined above to assign more accurate values for physician work and direct and indirect practice expenses, the reimbursement for DXA more closely approximates the 2006 Medicare reimbursement rate of $139. That these inputs mirror real world expenses are confirmed by the Lewin Group report. The Lewin group was commissioned by the International Society for Clinical Densitometry (ISCD) the American Association of Clinical Endocrinologists (AACE), The American College of Rheumatology (ACRh) and The Endocrine Society (TES) to conduct a survey of physicians performing DXA in the non-facility setting. One of the purposes of this study was to determine the true operating costs for DXA. The Lewin Group concluded that the median DXA operating cost in the non-facility setting was $134; far exceeding not only CMS recommendations for reimbursement in 2010 but also current (2007) reimbursement rates.

While CMS has an obligation to review all comments received during the rule making process, we call on Medicare to carefully consider the requests contained in this document as this particular payment policy will undermine the agency's preventive health care agenda as it relates to osteoporosis care. Moreover, if CMS does not fairly value DXA and grossly underestimates operating costs, then the agency is not serving the people's mandate as articulated by the Medicare Payment Advisory Committee (MedPAC) in their March 2007 report to Congress:

"The Commission is concerned that differences in the profitability across physician services create financial incentives for physicians to favor furnishing some procedures and services over other, less profitable ones. In this environment, beneficiary access to relatively undervalued services-and to the providers that perform them—may be threatened...Misvalued services should be identified and payments corrected...Also, revisiting the RBRVS may be needed to explore the possibility of including other factors—in addition to input costs—in the pricing of individual services."

Undervalued services will always see a fall in volume and thus will undermine CMS' very own efforts to improve recognition of osteoporosis through increased DXA testing. In the case of central DXA, the current RVUs from this most recent 5 year review are so far below operating costs for the procedure, that virtually all physicians in the non-facility setting will stop performing DXAs. The result will be the virtual dismantling of the infrastructure for delivering osteoporosis care in this country.

ISCD requests that CMS reevaluate the following:

1. The total RVU for central DXA should be fairly valued to encourage appropriate DXA testing among Medicare beneficiaries and to help promote CMS policies of improved osteoporosis prevention.

2. The Physician Work RVU for 77080 (DXA) should be increased from 0.2 to 0.5, consistent with the most comprehensive survey data available (Clinical Society Survey of 2006).

3. The Direct Practice Expense RVU for 77080 (DXA) should reflect the following adjustments:

A. The equipment type for DXA should be changed from pencil beam to fan beam, with a corresponding increase in equipment cost from $41,000 to $85,000 (Clinical Society Survey 2006; Lewin Group survey 2007).

B. The utilization rate for preventive health services involving equipment designed to diagnose and treat a single disease should be calculated in a different manner than other utilization rates so as to reflect the actual utilization of that service. In the case of DXA and VFA, the 50% utilization rate should be changed to reflect the actual utilization rate for DXA of 13%; (Lewin Group Survey)

C. The technician time to perform a DXA study should be increased from 31 minutes to 43 minutes as approved by the RUC in April of 2007. Current CMS documents fail to reflect this change.

D. Maintenance Contracts for DXA should approximate 8%, not the 5% as listed, reflecting current costs (Clinical Society Survey 2006).

E. Total time per year should be based on the time that a non-facility clinic is in operation. The Lewin Group survey of physicians performing DXA in the non-facility setting calculated this at 131,340 minutes.

4. The inputs used to derive Indirect Practice Expense for DXA and VFA should be transparent and easily accessible by those interested in determining the applicability of the data. For DXA, where the specialty mix has changed significantly over the last 8 years in the non-facility setting, this may alter calculations of the Practice Cost Index, indirect and direct percentages.

5. The DXA CPT Code (77080) should not be considered an imaging service within the meaning of the section 5012 (b) of the Deficit Reduction Act of 2005.

1. ISCD REQUESTS CMS FAIRLY VALUE DXA REIMBURSEMENT TO HELP ADVANCE APPROPRIATE PREVENTION INITIATIVES.

The total RVU for central DXA should be fairly valued to facilitate appropriate DXA testing among Medicare beneficiaries. Similar to a recent increase in RVU's for cognitive services, CMS has the ability to drive physician behavior. Given the low

percentage of individuals currently being tested neither a lower RVU in the non-facility setting or centralized testing are likely to reverse the annual incremental declining rates. The results of a Lewin Group survey will be presented documenting the approximate total cost to perform a DXA study in the non-facility setting. Using more appropriate inputs with existing RVU methodology leads to a very similar value. Such appropriate reimbursement would enhance the likelihood of CMS achieving its goals of prevention in osteoporosis.

Background:

As shown in Table 1 below, the number of claims submitted to CMS for DXA studies in the office and hospital setting has increased markedly from 1994 to 2006. Specifically, from 1998 to 2006, there has been a 2.5 fold increase. On closer inspection however, one sees that the annual incremental increase peaked in 1999 and that the rate of increase has slowed significantly in the last 3 years. This decline in rate of claims submission is striking considering the multiple Federal initiatives over the last decade to increase DXA testing including the US Preventive Services Task Force recommendations in 2002, the Surgeon General's Report on Osteoporosis in 2004, the incorporation of DXA testing in the "Welcome to Medicare Exam" in 2005 and the increasing number of Medicare beneficiaries.

Table 1: CMS Claims for 77080 (77065): Non-Facility and Hospital

Year	Axial DXAs	Incremental Test (Annual)
1994	77,122	
1998	1,013,362	234,060
1999	1, 332,393	319,031
2000	1,582,552	250,159
2004	2,426,361	210,952
2006	2,583,981	78,810

Despite osteoporosis screening being a service emphasized by CMS in their recent preventive services campaign, in 2006 only 9.34% of qualified women enrolled in Medicare had a DXA test. As DXA reimbursement in the office setting is currently far below operating costs and is slated for much greater reduction by 2010, it is not surprising that a recent survey found that virtually all physicians will stop DXA testing of Medicare patients. As 2/3^{rds} of DXA studies are currently done in the office setting, migration of these patients to the hospital setting is problematic. Although some might argue that centralizing DXA testing in the hospital setting would be more efficient, placing additional barriers to performance of an essential, and currently underutilized, procedure is unlikely to increase screening rates among Medicare patients.

Moreover, moving DXA testing to the hospital setting would increase complexity of care as the patient must now go to another location for DXA testing with another provider and a different DXA machine. Additionally, the patient must then make another visit

with their primary doctor to review study results. It is well documented that reduced access to care acutely affects vulnerable populations such as rural, ethnic, low-income and elderly particularly. Moreover additional costs are incurred in transporting patients and forwarding records. Finally, there is discontinuity of care and an inability to assess a patient's response to medical therapy over time when one switches bone density measuring machines.

Screening rates which are sub-optimal now, would decline further with the increased barriers to care. Instead of saving money, a decline in reimbursement rates for DXA would lead to increased costs as fracture rates increase. The Lewin Group conducted a Congressional Budget Office (CBO)-style scoring analysis of 5 year costs to Medicare if the DRA and Medicare Physician Fee Schedule reimbursement cuts were reversed, thus restoring the DXA reimbursement rate to the 2006 level of $139. The Lewin analysis found that program costs over a five-year period resulting from the increase in direct DXA payment would equal $648 million (see Appendix B). However, after accounting for savings associated with avoided fractures and the cost of treating at-risk individuals, restoring DXA payments will actually save the Medicare program $1.14 billion over the same five year period (see Appendix B).

What is an appropriate value for central DXA? The Physician Fee Schedule assigns a value to a summation of physician work, practice expense and malpractice costs. If the value relative to other services is fair, then submitted claim volumes should be appropriate. To determine what is an appropriate value to assign to central DXA, the ISCD along with AACE, TES and ACRheum commissioned the Lewin Group to perform a cost analysis of central DXA in the non-facility setting. Rather than segregating this into physician work, malpractice and practice expenses, total operational costs, including fixed and variable costs, were calculated and linked to total volume of procedures for each clinic surveyed. The full results of the survey, including a detailed accounting of the methodology used is provided in Appendix C.

Conducted in July of 2007, 163 complete surveys were received representing 8 specialties. Primary care comprised 39% of respondents, while rheumatology accounted for 37%, endocrinology 13% and radiology 3%. The median cost for a DXA study was $134.13, with the 25th % of 95.07 and 75th % of $195.02. The median number of studies per machine per year was 768 or about 64 studies per machine per month. There is a steady decrease in the average cost per procedure, until a practice reaches 1,500 procedures per year. Procedures in excess of 1,500 often have a higher per-procedure cost. The higher overhead associated with larger centers may play a role here and argues against incremental increasing efficiencies with higher volume centers.

Other important findings from this analysis included the following: a utilization rate of 13% and Number of operational minutes per year of 131,340.

Conclusions: An analysis performed by the Lewin Group of operational costs per DXA study in the non-facility setting demonstrated a median cost of $134. This closely approximates the 2006 CMS reimbursement for DXA of $139. As the new methodology used to determine RVUs for other procedures has not been called in to doubt, the specific inputs used to determine DXA values may be incorrect.

2. ISCD REQUESTS CMS RE-EVALUATE THE PHYSICIAN WORK RVU FOR DXA (77080).

Background of the reduction in physician work RVU:

RUC decreased work RVU for DXA: In August 2005, The American College of Radiology (ACR) conducted a survey of the physician work component of DXA (77080). Fifty one radiologists provided complete responses. The survey concluded that the physician work RVU for DXA should remain at 0.3. Subsequently, a working group comprised of six RUC members recommended that the value be reduced from 0.3 to 0.2 (the 25th percentile of the ACR survey) stating that "...the (RUC) workgroup believed that the actual work is less intense and more mechanical than the specialty society's description of the work." This RUC subcommittee was comprised of a vascular surgeon, anesthesiologist, general surgeon, pulmonologist, psychiatrist, and a family practitioner. Only one of these physicians, the family practitioner, could be expected to be knowledgeable about DXA interpretation. Reflecting their lack of knowledge that quality DXA interpretation requires specialized knowledge and expertise, the subcommittee inappropriately substituted their personal opinion for empirical survey data.

In August and October of 2006, CMS proposed rules (CMS-1512 and 1321) adopting the RUC recommendation to reduce the physician work RVU for DXA. The ISCD, along with numerous other clinical societies, patient advocacy groups and other interested stakeholders, urged CMS to reconsider the reduction in the work RVU.

Supporting this recommendation, the ISCD reported results of a clinical society survey conducted in August 2006, in cooperation with ASBMR, AACE, TES ACR – Rheum and the North American Menopause Society (NAMS).The survey instrument was almost identical to the 2005 ACR RUC survey. A detailed summary of the results and a copy of the survey are included in Appendix D, and a copy of the survey is included in Appendix E.

Briefly, this survey of 453 physicians from multiple specialties who routinely perform DXA studies concluded that the Physician Work RVU should be **increased** from 0.2 to 0.5 (substantially higher than the ACR survey, which noted a median work RVU of 0.3). The responding physicians noted that DXA complexity had increased, rather than decreased. Careful review of the technical inputs, consideration of clinical risk factors, overall assessment of fracture risk, comparison to prior studies where applicable, general recommendations for treatment and timing of follow up study were felt to be essential elements of the DXA report. Physicians most closely linked the physician work component of a DXA study with cognitive codes for physician office visits (99213 and 99214).These survey results clearly refuted the perception of decreased complexity and intensity underlying the RUC workgroup recommendation.

In addition, if the current physician work value of 0.2 is retained for central DXA, it will create a rank order anomaly when compared with a far less complex test (peripheral DXA) which has a work RVU of 0.22 and radiographic absorptiometry which would have the same physician work RVU of 0.2. Peripheral DXA systems measure a single site such as the forearm, finger or heel. Analysis and reporting of results takes far less time and is significantly less complex. WHO criteria do not apply to this technology and determination of fracture risk is limited. The ability to monitor response to drug therapy

from this test has also not been demonstrated. Such a rank order anomaly is further evidence that central DXA is undervalued.

CMS convenes Refinement Panel to consider work RVU: CMS received numerous comments disagreeing with the proposed decrease in the Physician Work RVU outlined in CMS-1512 and 1321. In response to the large number of comments, CMS convened a Refinement Panel on September 26, 2006 to re-look at the Physician Work RVU for DXA. CMS asked The American College of Rheumatology to present information regarding the physician work RVU for DXA to the panel (see attached Appendix F for the complete presentation to the Refinement Panel). The American College of Rheumatology presented information from both surveys--the ACRadiology survey of 51 radiologists that supported maintaining the work RVU at 0.3 and the ISCD clinical society survey of 453 physicians that supported increasing the work RVU to 0.5. The Refinement Panel rejected all empirical survey data presented and affirmed the CMS proposal to reduce the Physician Work RVU to 0.2.

Concerns with the Refinement Panel process:

The Refinement Panel convened by CMS in September 2006 was shrouded in secrecy and lacked procedural due process protections. Indeed, CMS has never adopted regulations regarding the proper conduct of these Refinement Panel proceedings which help to determine critical public policy issues and essentially become binding on the agency and other interested stakeholders.

The selection of panel members, the information presented, and any records of the proceedings, including votes taken, was conducted without notice and outside the formal regulatory process. The American College of Rheumatology (invited panelists) were given insufficient time to make their presentation, and non-voting members of the Refinement Panel were allowed to make comments at the end of the presentation, an action not allowed under the Agency's own rules. At the conclusion of the Refinement Panel process, the panel's decision was effectively binding on the Agency and the other stakeholders, who were largely unaware that a proceeding determining their rights, had in fact even taken place. The results of the refinement panel were then incorporated into the rulemaking process.

The lack of notice, resulting in the secrecy with which this Refinement Panel was conducted, is contrary to the transparency that should accompany the rule making process and is a disservice to the public that the agency is required to serve. The resolution of this hotly contested issue is too important to be left to a process that excludes the public and lacks the procedural safeguards of formal rulemaking.

REQUEST SUMMARY:

ISCD requests CMS reconsider the Physician Work RVU for DXA by conducting an independent assessment of the survey data previously presented by the American College of Radiology and Clinical Society Survey (2006) and increase the RVU for DXA to 0.5 (see Appendix G for the effect of changing physician work on 2008 MPFS).

The ISCD understands that CMS routinely uses the Refinement Panel to help process the business of the agency. However, in this case, given the serious health care policy

ramifications and the threat to patient access by substantially undervaluing a critical preventive service, ISCD requests CMS to conduct an independent evaluation of the survey evidence that has been presented to the agency. Given the overwhelming weight of this evidence, we request CMS increase the Physician work RVU for DXA to 0.5.

3. ISCD REQUESTS CMS RE-EVALUATE THE CALCULATION OF THE PRACTICE EXPENSE RVU COMPONENT FOR DXA AS FOLLOWS:

A. Incorrect equipment type/cost input for DXA

Background for assignment of equipment type and cost:

In 2006, ISCD and numerous other clinical societies provided comments to CMS-1321-P regarding the incorrect equipment type and cost used to calculate practice expense for DXA (77080). While the cost was appropriately listed for VFA, the companion procedure performed on the same equipment, (fan beam densitometer at $85,000), axial DXA was assigned a cost of $41,000, based on pencil beam instrumentation. Of the two largest United States manufacturers of DXA instruments, one no longer produces pencil beam machines with 100% of all units shipped since 2005 being fan beam. The other manufacturer reported that such low-end pencil beam units comprised less than 20% of sales. Thus fan beam densitometers made up the vast majority of densitometers currently in use in practice. Additionally, the ISCD clinical society survey of 453 practitioners who performed DXA, conducted in the summer of 2006, reported 93% respondents used the more expensive and newer fan beam instrumentation, while only 7% used pencil beam. Presented with this overwhelming evidence**, in the final rule published in November 2006**, CMS revised the data input for equipment type and cost for axial DXA to reflect the fan beam instrumentation.

In the current proposed rule, the equipment type and cost for axial DXA has been changed back to pencil beam technology at $41,000, with no explanation given. Since the publication of the proposed rule, ISCD has learned that the incorrect equipment type code was mistakenly forwarded to the RUC by a group of clinical societies, including ISCD, that were reevaluating practice expense for DXA and VFA. Since the focus of that particular practice expense review was technician time, ISCD and other working group members did not notice the incorrect code for pencil beam technology for DXA that was included in the submission to the RUC. In addition, those clinical societies who had commented on this issue in the summer and fall of 2006, believed the equipment type and cost for DXA had been resolved and corrected by the publication in the final rule. In addition, ISCD has also learned that in April, CMS incorporated this incorrect input for equipment into the reimbursement for 77080.

REQUEST SUMMARY:

ISCD requests that CMS immediately correct this error and restore the equipment type and cost for CPT codes 77080 by reinstating the $85,000 cost for the fan beam instrument and amending the reimbursement to reflect this corrected input.

B. Utilization Rate

ISCD requests that CMS adopt a different utilization rate for preventive health services involving equipment designed to diagnose and treat a single disease. Such utilization rates should be calculated in a different manner than other utilization rates so as to reflect the actual utilization of the service. In the case of DXA, the 50% utilization rate should be changed to reflect the actual utilization rate for DXA of 13%.

Background:

Utilization rates for DXA are listed at 50%. It is important to note that the 50% utilization rate used by CMS is not based upon survey data, but was provided as an estimate by consultants to the Agency. CMS continues to apply this rate to all procedures including advanced diagnostic imaging services. In a recent MedPAC report (MedPAC, Report to the Congress: Increasing the value of Medicare, 2006), MRI machines were found to have a utilization rate of greater than 90% and CT machines a utilization rate of greater than 70%. In contrast, DXA is a lower cost single disease state procedure, with over 2/3rds of CMS claims originating in the non-facility setting. The Lewin Group survey determined that the utilization rate for DXA in the non-facility setting is 13%.

Utilization rates for preventive services: Increasing access to critical preventive services is an important part of the CMS mission. Unlike other high volume procedures where patients are referred to dedicated imaging centers, DXA is frequently performed by primary care physicians, family practitioners, gynecologists, rheumatologists and endocrinologists and offered as point-of-care service. This point of service care has been the driving force behind increasing osteoporosis screening rates over the past decade. Based on 2002 Medicare data, 70% of DXA studies are performed in the office or non-facility setting. While offering testing in the physician office has helped to increase screening rates by making testing more convenient, volume in the office setting will tend to be lower than in imaging centers. Despite the current low utilization rate of 13% for DXA in the non-facility setting, significant increases could be realized if DXA is appropriately valued and physicians and patients are educated about the importance of osteoporosis prevention.

The current DXA payment policy contradicts CMS prevention efforts and initiatives, such as the Physician Quality Reporting Program (PQRI), to enhance quality of care in the Medicare program. The PQRI, which has 4 measures related to osteoporosis, 2 of which require DXA testing should also help drive screening rates higher. Compliance with these quality measures depends heavily upon the availability of DXA scanners and the ability of the provider and patient to access this essential technology.

Utilization rates for "single disease state" imaging procedures: Equipment used to diagnose a single disease, such as DXA, will necessarily have lower utilization rates than equipment used to diagnose multiple diseases. In the situation of equipment used to diagnose a single disease, such as DXA, when reliable survey data demonstrate lower utilization, CMS should use the lower rate.

REQUEST SUMMARY:

ISCD requests that CMS adopt a 13% utilization rate for DXA, a preventive health service which utilizes equipment designed to diagnose and treat a single disease.

Consistent with the findings of the Lewin Group study, the 13% will more accurately reflect the actual utilization rate of this service.

C. Technician Time

ISCD requests that the technician time to perform a DXA study should be 43 minutes, and not the assigned 31 minutes.

The technologist time under Direct Practice Expense had been listed as 31 minutes based on a 2002 determination by PEAC/RUC from an ACRad survey. Using more current information from the Clinical Society Survey of 2006 and subsequent discussions with ACRadiology, AACE and ACRheumatology the organizations respective RUC members determined that 46 minutes was a more accurate time reflecting changes to the pre-service, intra-service and post service clinical labor time. This was presented at the February 2007 meeting of the RUC approved at 43 minutes but then deferred to the April 2007 RUC meeting because of questions about vital signs (height and weight) included as part of the pre-service period.

These issues were resolved, and 43 minutes was approved by the RUC. To date (August 30 communication with CMS), this change has not been put into effect.

REQUEST SUMMARY:

ISCD requests that CMS adopt the RUC recommendation regarding technician time.

D. Maintenance Contracts

ISCD requests that maintenance contracts for DXA should approximate 8%, and not the 5%, as over 90% of physicians have indicated that they will stop performing DXA studies by 2010 % as listed, reflecting current costs.

The Clinical Society Survey of 2006 surveyed 453 members. Median annual costs for central DXA included service contracts of $5,000 (25% 2,025; 75% 9,000) and software upgrades of $2,000 (25% 1,000; 75% 8,000). The median total of $7,000 for an $85,000 fan beam machine represents approximately 8% of the total cost.

REQUEST SUMMARY:

ISCD requests that CMS assign an appropriate figure of 8% to maintenance contracts for DXA.

E. Total Time Per Year

ISCD requests that the CMS base the total time per year that a non- facility clinic is in operation on data from the Lewin Group survey indicating a 131,340 minutes, instead of the 150,000 minutes currently used (see Appendix H for calculations regarding Practice Expense RVUs).

4. THE ISCD REQUESTS THAT INPUTS USED TO DERIVE INDIRECT PRACTICE EXPENSE RVU SHOULD BE PUBLIC KNOWLEDGE.

The methodology used to determine Indirect Practice Expense is complex. Additionally, the inputs used to derive a number of these variables include Practice Cost Index (PCI) and direct and indirect percentages and have not been provided either in the CMS Final Rule or after repeated requests to the appropriate CMS officials dating back to February of 2007. This is especially problematic for DXA, which has seen the mix of physician specialty types change significantly over the last 8 years from radiology to specialists (rheumatology, endocrinology) and now to primary care. The ISCD has justifiable concerns that variables such as PCI may be inaccurate or outdated. These concerns were echoed by MedPAC in their August 17, 2006 comments regarding CMS-1512-PN:

"CMS should strive to be as transparent as possible given the complexity of the method to calculate indirect practice expense RVUs. CMS could improve the transparency of its proposal by publishing the scaling factors and the indirect practice cost index values for each specialty."

REQUEST SUMMARY:

ISCD requests CMS publish scaling factors and the indirect practice cost index values for each specialty as well as the specialty mix for each procedure.

5. ISCD REQUESTS THAT CMS REEVALUATE AND REVERSE THE DECISION TO INCLUDE DXA CPT CODE 77080 AS AN IMAGING SERVICE UNDER THE DEFICIT REDUCTION ACT OF 2005.

The proposed rule references the definition of imaging services included in Section 5102(b) (1) of the Deficit Reduction Act (DRA). The rule sets out the criteria and analysis the Agency will use to determine which procedures to include in the definition of imaging services and which to exempt from the DRA's definition.

Under the DRA, imaging services are defined as "imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography". In the rule, CMS articulates the analysis that it will use to determine which CPT codes are to be included under the DRA definition, as well as those codes that are to be considered exempt from the law.

CMS states, "We believe that imaging services are those that provide visual information, thereby assisting in the diagnosis or treatment of illness or injury". CMS notes the following procedures as examples of exceptions to the definition of imaging services under the Act: bronchoscopy with or without fluoroscopic guidance and upper gastrointestinal endoscopy with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s). CMS articulates the rational for these exceptions: "In these cases, we are unable to clearly distinguish imaging from non-imaging services because, for example, a specific procedure may or may not utilize an imaging modality, *or the use of an imaging technology cannot be segregated from the performance of the main procedure*" (emphasis added).

Therefore, applying this CMS analysis, CPT Code 77080 (DXA) should be excluded from the definition of imaging services in the diagnosis and treatment of osteoporosis. The DXA test uses equipment that produces a numerical value of bone mass (in units of grams/cm^2), which is compared to young normal controls to derive a T-score). This number is used to estimate the patient's risk of osteoporotic fracture. Although the DXA equipment also generates an image, the image itself is not used to diagnose and therefore cannot be segregated from the main procedure which forms the basis for clinical decision making.

REQUEST SUMMARY:

ISCD requests that CMS reverse its earlier decision and exclude CPT Code 77080 (DXA) from the definition of imaging services under the DRA.

CONCLUSION:

The most recent five year review of the Medicare Physician Fee Schedule employs new methodology and inputs. Reimbursement for central DXA (77080) would fall 75% compared to 2006 reimbursement levels. Using a series of valid surveys, we have identified errors and omissions in input for physician work and direct and indirect practice expense. When corrected, these inputs would increase DXA reimbursement to $129 if the Conversion Factor is frozen at its current level. Employing a different type of analysis that looks at true operational costs, the Lewin Group has determined that the median DXA cost is $134. These numbers are quite similar and approach the 2006 MPFS reimbursement of $139. We believe these studies are complimentary and support the validity of our corrected inputs (see Appendices G and H).

CMS has identified osteoporosis as a major health care concern in the United States. The agency has designated axial DXA as the key diagnostic tool for the screening of Medicare beneficiaries and for monitoring response to treatment. Current Medicare payment policies, that profoundly undervalue this service in the non-facility setting, will severely curtail patient access to quality skeletal assessment. Furthermore these policies will undermine the agency's efforts to promote access to preventive services. Efforts to increase axial DXA screening rates above the current level of 10% annually, which have slowed in the past few years, will be crippled by the inappropriate valuation of this service.

ISCD has presented evidence from multiple surveys that DXA is now an undervalued service. With reimbursement far below operating costs, this essential preventive service will largely disappear from physician's offices, where the majority of tests are currently performed. The infrastructure of the osteoporosis delivery system, and patient access to that system, is in jeopardy as providers lay off staff, cancel the purchase of DXA equipment, or stop providing the service altogether.

ISCD urges CMS to take a fresh look at the valuation of this service by reexamining the specific inputs for both Practice Expense and Work RVU for DXA to arrive at a reimbursement that more approximates the median cost of performing the service of $134, as identified by the Lewin Group

Sincerely,

Neil Binkley, MD, CCD
Co-Chair Public Policy, ISCD

Andrew Laster, MD, FACR, CCD
Vice President, ISCD
Co-Chair Public Policy, ISCD

Appendix A

Impact of DXA Reimbursement Cuts

As you know, DXA reimbursement in the physician's office (non-facility) setting was reduced by ~40% this year. Unless Congress acts, DXA payments will incrementally drop by ~75% in 2010. VFA reimbursement will be cut by ~50% by 2010.

A group of societies with an interest in bone health is collecting information about how reimbursement cuts for DXA and VFA procedures may affect physicians and patients. This information will be used by these societies on Capitol Hill as we pursue legislative relief from the revisions to the Medicare Physician Fee Schedule and the Deficit Reduction Act. Your participation and input in this survey is important and will contribute to the success of these efforts. **Please complete this survey if you are a physician who performs DXA in the office (non-facility) setting.**

Please note: You may receive this survey from more than one organization, please only complete the survey once.

Thank you.

1 Do you perform DXA primarily in the office (non-facility) setting?

- ☐ Yes 78%
- ☐ No 22%

2 Have you discontinued performing DXA in your office as a result of the recent Medicare reimbursement cuts?

- ☐ Yes 7%
- ☐ No 93%

3 We are collecting information regarding how the cuts have already affected patient access to DXA. If you have discontinued DXA service, please provide your name, email, and the date DXA service was discontinued. This information will be used to tell the DXA story in Washington.

If you do not wish to share your name with us, simply skip this question and click submit to continue.

Name:
Email:
Date DXA was
Discontinued:

4 I am a member of the following organization(s) *(check all that apply)*:

- ☐ American Association of Clinical Endocrinologists (AACE) 39%
- ☐ American College of Rheumatology (ACRheum) 16%
- ☐ International Society for Clinical Densitometry (ISCD) 68%
- ☐ The Endocrine Society (TES) 29%
- ☐ None of the above 7%

5 Identify Your Primary Area of Practice:

6 Identify Geographic Practice Setting:

- ☐ Rural 17%
- ☐ Suburban 45%
- ☐ Urban 37%

7 Identify Primary Type of Practice:

☐ Solo Practice 23%
☐ Single Specialty Group 44%
☐ Multi-specialty Group 27%
☐ Medical School Faculty Practice Plan 6%

8 Does Your Practice Own or Lease DXA Equipment?

☐ Own 75%
☐ Lease 25%

9 You indicated that your practice owns DXA equipment. Are you still making payments or have you paid in full for the equipment?

☐ I am making payments on this equipment. 40%
☐ I have paid in full for this equipment. 60%

10 Will Medicare payment cuts affect your ability to pursue professional development activities in the field of osteporosis for physicians and/or technologists (i.e.: attending courses, obtaining certification and/or facility accreditation)...

at 2007 rates of approximately $82 ? ☐ Yes 73% ☐ No 27%
at 2008 rates of approximately $80 ? ☐ Yes 75% ☐ No 25%
at 2009 rates of approximately $57 ? ☐ Yes 67% ☐ No 4%
at 2010 rates of approximately $35 ? ☐ Yes 97% ☐ No 3%

11 Will Medicare payment cuts for DXA cause you to stop seeing Medicare patients...

at 2007 rates of approximately $82 ? ☐ Yes 73% ☐ No 76%
at 2008 rates of approximately $80 ? ☐ Yes 75% ☐ No 68%
at 2009 rates of approximately $57 ? ☐ Yes 67% ☐ No 33%
at 2010 rates of approximately $35 ? ☐ Yes 71% ☐ No 29%

12 Will Medicare payment cuts for DXA cause you to stop providing DXA procedures for your Medicare patients...

at 2007 rates of approximately $82 ? ☐ Yes 36% ☐ No 64%
at 2008 rates of approximately $80 ? ☐ Yes 45% ☐ No 55%
at 2009 rates of approximately $57 ? ☐ Yes 91% ☐ No 9%
at 2010 rates of approximately $35 ? ☐ Yes 93% ☐ No 7%

13 Will Medicare payment cuts for DXA procedures cause you to stop accepting new Medicare patients...

at 2007 rates of approximately $82 ? ☐ Yes 30% ☐ No 70%
at 2008 rates of approximately $80 ? ☐ Yes 35% ☐ No 65%
at 2009 rates of approximately $57 ? ☐ Yes 66% ☐ No 34%
at 2010 rates of approximately $35 ? ☐ Yes 69% ☐ No 31%

14 Will Medicare payment cuts for DXA cause you to cancel plans to purchase or lease new DXA equipment...

at 2007 rates of approximately $82 ? ☐ Yes 80% ☐ No 20%
at 2008 rates of approximately $80 ? ☐ Yes 84% ☐ No 16%
at 2009 rates of approximately $57 ? ☐ Yes 94% ☐ No 6%
at 2010 rates of approximately $35 ? ☐ Yes 94% ☐ No 6%

15 Will Medicare payment cuts for DXA cause you to lay off staff or delay hiring new staff...

at 2007 rates of approximately $82 ? ☐ Yes 52% ☐ No 48%
at 2008 rates of approximately $80 ? ☐ Yes 59% ☐ No 41%
at 2009 rates of approximately $57 ? ☐ Yes 84% ☐ No 16%

at 2010 rates of approximately $35 ? ☐ Yes 86% ☐ No 14%

16 If you were unable to perform DXA in your office due to the Medicare payment changes, would your patients have access to DXA within a reasonable proximity to where they live?

☐ Yes 66%
☐ No 34%

17 If you decide to discontinue providing VFA services, what level of reimbursement will affect your decision?

☐ $39 to $33 40%
☐ $32 to $27 15%
☐ $26 to $21 7%
☐ $20 to $ 0 6%
☐ Already discontinued 32%

Thank you for participating in this survey. The results of this survey will be used on Capitol Hill as we pursue a legislative remedy to the DRA and Medicare Physician Fee Schedule changes.

among individuals aged 65 and older. We then increased this number each year of the period. This calculation was based on the compound rate of growth in peer reviewed literature of 0.0459 corroborated with growth in the beneficiary population from the Medicare Trustees Report (2007) and cost of fractures inflated at CPI.[2]

We then estimated the number and cost of osteoporotic fractures avoided through "recovered" procedures under the restored payment rates. This calculation was based upon evidence contained in the peer reviewed literature[3] wherein in 2008, if approximately 361,000 individuals were scanned, approximately 18,048 fractures would be prevented through at-risk individuals initiating a medication to improve bone density. (In essence, we assume that for every 100 DXAs, 5 fractures would be prevented.)

This calculation is dependent upon the mix of osteoporotic/osteopenia individuals screened and also the compliance rate of those given a prescription. Compliance rates have been observed to be generally low for patients who are prescribed bone enhancing medications. We expect that because alendronate will be available in generic form in 2008, compliance rates will improve significantly, improving the chance of preventing osteoporotic fractures.

What follows is a detailed description of the methodology employed in the analysis and the model.

[2] Burge R, Dawson-Hughes B, Solomon D, et al. (2007) Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. Journal of Bone and Mineral Research 22(3): 465-475.

[3] King AB, Saag KG, Burge RT (2005). Fracture reduction affects Medicare economics (FRAME): impact of increased osteoporosis diagnosis and treatment. *Osteoporosis Int.* 16: 1545-1557.

Methodology

In this study, The Lewin Group used a cost accounting methodology similar to that used by the Congressional Budget Office (CBO) to determine the impact on the federal budget of a proposal to freeze DXA rates at 2006 levels. This methodology entails first estimating both the **price** and **volume** of the services that are or would be provided under the baseline scenario. In this analysis, the baseline scenario reflects the cuts made in reimbursement from both the DRA and the changes in the Medicare Physician Fee Schedule. Table A-1 contains the reimbursement rates for DXA that were used in the baseline scenario.

Table A-1: Baseline Reimbursement for DXA

Year	DXA Payment
2007	$82.33
2008	$81.66
2009	$56.82
2010 - 2012	$35.48

Using a combination of secondary data and expert judgment, we developed an algorithm to determine the budgetary impact to Medicare if DXA reimbursement was restored to $139.46. Our methodology is presented in two sections: first, we present the methods used to estimate one and five year costs of the proposal. Then we present the methods used to estimate the potential cost offsets from identifying and treating beneficiaries at risk of an osteoporotic fracture. Potential savings accrue from the avoided cost of osteoporotic fractures for a subset of the identified population, given the costs of implementing the proposed legislation and the costs of providing pharmaceutical treatment to the identified at-risk population.

Step One: Estimate Medicare Spending under DRA and other cuts for 2008-2012

- Number of procedures: uses CMS Preliminary Part B Extract and Summary System File (BESS), 2006 and Q1 2007. Approximately two thirds of procedures are performed in physician offices, and one third in hospital outpatient departments. Reduction in the number of procedures beginning in 2007 is estimated using the results of an ISCD Task Force Survey dated March, 2007. The clinical survey of multispecialty densitometry professionals reported that eight percent of respondents had already stopped providing DXA in their offices due to cuts in Medicare reimbursement. Approximately 36 percent of respondents reported that they would stop providing DXA in 2008 and 2009, and by 2010, these services would not be provided at all by respondents in their offices.

- Medicare spending: uses BESS, 2006 and Q1 2007. Reimbursement rates for 2008-2010 from Medicare Physician Fee Schedule contained in Table A-1 above multiplied by the number of estimated procedures.

Table A-2: Medicare Spending under DRA and Other Cuts 2008-2012

	2008	2009	2010	2011	2012	Total
Global DXA payments under physician fee schedule 2008-2010, flat in 2011 and 2012	$81.66	$56.82	$35.48	$35.48	$35.48	
Estimated Number of DXA's (uses CMS BESS 2006 and Q12007 data as base, then clinical survey results)	1,236,298	927,223	695,418	625,876	563,288	4,048,103
Total baseline Medicare spending for DXA under the DRA and other cuts	$74,000,808	$38,617,982	$18,085,613	$16,277,051	$14,649,346	$161,630,800

Step Two: Estimate Medicare Spending under the Proposal to Freeze DXA Rates at 2006 Levels

Table A- 3: Medicare Spending under Proposal 2008-2012

	2008	2009	2010	2011	2012	Total
Global DXA payments under proposal 2008-2012	$139.46	$139.46	$139.46	$139.46	$139.46	
Estimated Number of DXA's (uses CMS BESS 2006 and Q12007, then escalation proportionate to growth in beneficiary population)	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
Total estimated Medicare spending for DXA under proposal	$203,462,305	$206,514,240	$209,611,953	$212,823,323	$216,084,879	$1,048,496,700

- Number of procedures: uses CMS BESS, 2006 and Q1 2007 inflated at projected rates of beneficiary population growth (1.5% per year until 2011 when rate increases to 3% obtained from Medicare Trustees Report, 2007).
- Medicare spending: uses CMS BESS, 2006 and Q1 2007. Reimbursement rates for 2006 frozen through 2012 per proposal.

Step Three: Estimate net Medicare Spending under Proposal and Number of Procedures "Recovered"

- Determine cost of proposal by taking the difference in spending for DXA between the baseline scenario in Step One and the estimates in Step Two.
- Deduct Part B premium adjustment equal to 25% of new spending.
- Determine net cost to Medicare of proposal.
- Determine number of DXA procedures "recovered" by proposal.

Table A- 4: Cost of Proposal 2008-2012

	2008	2009	2010	2011	2012	Total
Baseline spending for DXA under DRA and other cuts	$74,000,808	$38,617,982	$18,085,613	$16,277,051	$14,649,346	$161,630,800
Total estimated Medicare spending for DXA under proposal	$199,114,370	$202,101,086	$205,132,602	$208,209,591	$211,332,735	$1,025,890,385
Number of DXA procedures not lost due to DRA and other cuts	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
Gross cost of proposal	$125,113,563	$163,483,104	$187,046,990	$191,932,540	$196,683,389	$864,259,585
Net cost of proposal after Part B premium of 25%	$93,835,172	$122,612,328	$140,285,242	$143,949,405	$147,512,542	$648,194,689

Step Four: Determine potential cost offsets from reduced osteoporotic fractures using peer reviewed literature

- Determine both current and 2008-2012 number and cost of osteoporotic fractures among Medicare beneficiaries. Approximately 71% of the two million annual osteoporotic fractures are among individuals aged 65 and older. These calculations were based on the compound rate of growth in peer reviewed literature of 0.0459 corroborated with growth in beneficiary population from Medicare Trustees Report (2007) and cost of fractures inflated at CPI[4]
- Estimate number and cost of osteoporotic fractures avoided through "recovered" procedures. This calculation was based upon evidence contained in the peer

[4] Burge R, Dawson-Hughes B, Solomon D, et al. (2007) Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. Journal of Bone and Mineral Research 22(3): 465-475.

reviewed literature[5] wherein in 2008, if approximately 361,000 individuals were scanned, approximately 18,048 fractures would be prevented through at-risk individuals initiating a medication to improve bone density. (In essence, we assume that for every 100 DXAs, 5 fractures will be prevented.) This calculation is dependent upon the mix of osteoporotic/osteopenia individuals screened and also the compliance rate of those given a prescription. Compliance rates have been observed to be generally low for patients who are prescribed bone enhancing medications. We expect that because alendronate will be available in generic form in 2008, compliance rates will improve significantly, improving the chance of preventing osteoporotic fractures.

- Estimate total cost savings from avoiding an increase in osteoporotic fractures. Per fracture cost calculated using peer reviewed literature (net $9,699 after beneficiary copayment and deductible of 20%).[6]

Table A- 5: Potential Cost Offsets from Avoiding Osteoporotic Fractures 2008-2012

	2008	2009	2010	2011	2012	Total
Number of osteoporotic fractures among aged 65 and older (71% of total)	1,592,181	1,665,262	1,741,698	1,821,642	1,905,255	8,726,039
Per fracture cost after beneficiary copayment and deductible of 20%	$9,699	$9,695	$9,690	$9,829	$9,970	
Number of DXA scans "recovered" under proposal	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
Number of fractures prevented by each scan: .05 (King et al, 2005)	18,048	34,699	47,505	53,451	59,123	212,826
Gross Savings to Medicare of avoiding osteoporotic fractures through DXA before cost of proposal and treatment of at-risk individuals	$175,040,214	$336,397,008	$460,350,535	$525,392,608	$589,477,113	$2,086,657,478
Net cost of proposal after Part B premium of 25%	$93,835,172	$122,612,328	$140,285,242	$143,949,405	$147,512,542	$648,194,689
Savings to Medicare after cost of implementing proposal	$81,205,042	$213,784,680	$320,065,293	$381,443,203	$441,964,571	$1,438,462,789

[5] King AB, Saag KG, Burge RT (2005). Fracture reduction affects Medicare economics (FRAME): impact of increased osteoporosis diagnosis and treatment. *Osteoporosis Int.* 16: 1545-1557.

[6] Burge ibid.

Step Five: Determine cost of treating identified at-risk individuals

- Determine gross cost of medications for beneficiaries found to be at risk of osteoporotic fractures under Medicare Part D. We used evidence from the FRAME study that showed that for one million individuals screened, 440,000 would be treated with a bone-specific medication. Annual cost of treatment assumed to be $900 per individual (assumes perfect compliance).

- Reduce gross cost of medications under Part D for enrollment (approximately 58% of beneficiaries enrolled in Part D) and for the plan cost management factor which is 27% discount on branded drugs achieved by Part D plans in 2007.[7]

- Part D premium adjustment equal to 25.5% of new spending per CBO.

- Reduce net cost of generic medications beginning in 2008 by 60% [8] when alendronate goes off patent and the generic is available

Table A- 6: Estimated Cost of Treating Identified At-Risk Individuals 2008-2012

	2008	2009	2010	2011	2012	Total
Cost of treatment if .44 individuals are given Rx and all beneficiaries are covered under Part D	$142,936,697	$274,817,843	$376,242,932	$423,330,315	$468,250,309	$1,685,578,096
Cost of medications for the 58.5% of beneficiaries covered under Part D	$83,617,968	$160,768,438	$220,102,115	$247,648,234	$273,926,431	$986,063,186
Cost of medications after Part D premium of 25.5% per CBO	$62,295,386	$119,772,486	$163,976,076	$184,497,934	$204,075,191	$734,617,074
Cost of medications once generic alendronate is available (60% discount)	$24,918,154	$47,908,995	$65,590,430	$73,799,174	$81,630,076	$293,846,830
Net savings to Medicare after cost of implementing proposal and treating at-risk individuals	$56,286,888	$165,875,686	$254,474,862	$307,644,029	$360,334,495	$1,144,615,960

[7] Congress of the United States: Congressional Budget Office. A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit. July, 2004.

[8] Statement of Lester M. Crawford, D.V.M., P h H.D. Acting Commissioner of Food and Drugs before the Committee on the Judiciary, United States Senate on "The Law of Biologic Medicine". June 23, 2004: "Generic drugs cost 50-70% less than their brand-name counterparts."

Step Six: Determine net cost (savings) from reduced osteoporotic fractures through "recovered" DXA procedures minus the cost of treatment

- Subtract cost of proposal and cost of treatment from the cost of the avoided fractures. Cost of proposal is based on the difference between the number of DXAs that we estimate would be performed under the DRA and other cuts and the number we estimate would be performed based on current utilization if reimbursement was frozen at 2006 levels. See Table A-7 on the following page.

Table A- 7: Estimated Net Savings to Medicare after Cost of Proposal and Cost of Treating Identified At-Risk Individuals 2008-2012

	2008	2009	2010	2011	2012	Total
Gross Savings to Medicare of avoiding osteoporotic fractures through DXA before cost of proposal and treatment of at-risk individuals	$175,040,214	$336,397,008	$460,350,535	$525,392,608	$589,477,113	$2,086,657,478
Net savings to Medicare after cost of proposal	$81,205,042	$213,784,680	$320,065,293	$381,443,203	$441,964,571	$1,438,462,789
Cost of medications once generic alendronate is available (60% discount)	$24,918,154	$47,908,995	$65,590,430	$73,799,174	$81,630,076	$293,846,830
Net Medicare savings from reduced fractures after treatment cost	$56,286,888	$165,875,686	$254,474,862	$307,644,029	$360,334,495	$1,144,615,960

Model

Cost Estimation of Keeping 2006 Medicare DXA Reimbursement								
	Base Year		2009		2010			2007-2012
Baseline DXA Spending under DRA and Other Cuts								
ojected number of Medicare beneficiaries with Outpatient claims	34,796,514	35,318,462						
ecline from prior year		8%						
umber of central DXA procedures performed in physician offices	1,550,389	1,648,397						
lobal DXA payments 2007-2010 per Medicare physician fee schedule		$82.33						
lowed charges from CMS correspondence	$263,843,771	$135,712,535						$220,505,866
tal Medicare Payment for DXA from CMS correspondence	$193,272,703	$99,477,288						
Estimated DXA Spending Under Proposal to Freeze Rates at 2006 Levels (with proportionate escalation in procedure volume)								
obal payment for central DXA under proposed freeze in rates to 2006 vels	$139.46	$139.46	$139.46	$139.46	$139.46	$139.46	$139.46	
mber of central DXA procedures in physician offices under freeze ding 2006 payment levels with volume increases proportionate to neficiary population growth	1,550,389							
timated Medicare spending in physician offices under freeze volumes increases proportionate with growth in beneficiary ulation	$193,272,703							
ference between estimated spending under DRA and other cuts and ending under proposal to freeze rates (cost of proposal)	$0							
Total Estimated Medicare Spending for DXA under Proposal								
tal baseline Medicare spending for DXA under DRA and other cuts	$193,272,703	$99,477,288	$74,000,808	$38,617,982	$18,085,613	$16,277,051	$14,649,346	**$161,630,800**
tal estimated Medicare spending in physician offices under eze with volume increases proportionate with growth in neficiary population	$193,272,703	$196,171,794	$199,114,370	$202,101,086	$205,132,602	$208,209,591	$211,332,735	**$1,025,890,385**
tal difference in DXA and VFA spending under DRA and other cuts d spending under freeze(Total cost of proposal)	$0	$96,694,505	$125,113,563	$163,483,104	$187,046,990	$191,932,540	$196,683,389	**$864,259,585**
t cost of proposal after beneficiary Part B premium	$0	$72,520,879	$93,835,172	$122,612,328	$140,285,242	$143,949,405	$147,512,542	**$648,194,689**

	2006 = Base Year							
Cost Savings from Reduced Fractures after Implementation of Proposal								
umber of annual osteoporotic fractures among aged 65 and older 1%) inflated by .0459 per year beginning in 2006 per Burge et al, 07	1,455,500	1,522,307	1,592,181	1,665,262	1,741,698	1,821,642	1,905,255	8,726,039
nual cost to Medicare of osteoporotic fractures with $16.9 billion in 05 dollars (87% of costs for age 65+) increased by CPI and growth in neficiary population = roughly equivalent to .0466 compound rate of owth per year per Burge et al, 2007	$17,661,000,000	$18,463,692,450	$19,302,867,272	$20,180,182,589	$21,097,371,888	$22,382,201,836	$23,745,277,928	**$106,707,901,513**
r fracture cost calculated, as. $12,134 per Burge, Dawson-Hughes, lomon et al, 2007.	$12,134	$12,129	$12,124	$12,118	$12,113	$12,287	$12,463	
t per fracture cost after beneficiary Part B copays and deductibles 0%)	$9,707	$9,703	$9,699	$9,695	$9,690	$9,829	$9,970	
umber of DXAs performed under DRA cuts - from above	1,550,389	1,648,397	1,236,298	927,223	695,418	625,876	563,288	4,048,103
umber of central DXA procedures under proposal	1,550,389	1,573,644	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
umber of central DXA procedures lost under DRA and other cuts proposal not implemented	0	-74,753	360,951	693,984	950,108	1,069,016	1,182,450	**4,256,510**
tal net cost to Medicare of increased fractures from losing DXA ocedures under DRA and other cuts - after beneficiary copay	$0	-$36,266,280	$175,040,214	$336,397,008	$460,350,535	$525,392,608	$589,477,113	**$2,086,657,478**
edicare savings from reduced fractures taking into account the cost proposal/ Cost of increased fractures minus cost of freeze- 2007 is a st to Medicare, outyears are savings	$0	-$108,787,159	$81,205,042	$213,784,680	$320,065,293	$381,443,203	$441,964,571	**$1,438,462,789**
Annual Cost of Treatment @ $900 per Beneficiary under Part D								
ost to Medicare of medications under Part D if all beneficiaries vered under Part D - for every scan (n=3,406,877), .44 prescriptions e written per King et al	$0	($29,602,066)	$142,936,697	$274,817,843	$376,242,932	$423,330,315	$468,250,309	$1,685,578,096
ost of medications with 58.5% beneficiaries in Part D - rest uninsured other plans	$0	-$17,317,208	$83,617,968	$160,768,438	$220,102,115	$247,648,234	$273,926,431	$986,063,186
								$986,063,186
								$734,617,074
								$293,846,830
edicare savings from reduced fractures taking into account the st of the treatment - these are savings	$0	-$99,369,195	$56,288,888	$165,875,686	$254,474,662	$307,644,029	$360,334,495	$1,144,615,960

Appendix C

Assessing the Costs of Performing DXA Services in the Office-Based Setting: Methodology and Findings of The Lewin Group Study

The American Association of Clinical Endocrinologists (AACE), International Society of Clinical Densitometry (ISCD), American College of Rheumatology (ACR), and The Endocrine Society (TES), commissioned The Lewin Group to survey office-based providers of dual energy x-ray absorptiometry (DXA) to develop estimates of the costs associated with providing the DXA services.

From the basis of the provider, Lewin was asked to estimate all costs associated with providing DXA, including practice expense, malpractice expense and physician work. Practice expense and malpractice expense estimates were generated by a Lewin Group survey. Physician work estimates were based on a separate clinical survey of multi-specialty densitometry professionals, which provided time required for clinical input (in minutes) for all aspects of DXA provisions. These components were summed to yield total costs. Finally, Lewin compared these costs to the global reimbursement for DXA services in the office-based setting.

I. FINDINGS

Our analysis yields a 2007 median total cost per procedure for DXA of $134.13, $5 less than the 2006 Medicare reimbursement, and about $50 more than the 2007 reimbursement. 2007 payment of $82 represents 61% of our median cost estimate. This payment level also represents 86% of the 25th percentile cost ($95.07) and 42% of the 75th percentile costs ($195.02) (Figure 1).

Figure 1: Ratio of 2007 Payment to Cost per DXA Procedure by 25th, 50th and 75th Percentile

[redacted]					
25th percentile	$95.07	$82	$13.07	360	86%
50% (Median)	$134.13	$82	$52.13	768	61%
75th percentile	$195.02	$82	$113.02	1572	42%

In 2007, only 14% of respondents are being reimbursed by Medicare at or above their costs. No provider will be adequately reimbursed at the fully implemented payment rates in 2010 of $35.

There is a wide variation in the cost of providing DXA procedures, with a minimum value of $42.57 and a maximum value of $788.09 (Figure 2).

Figure 2: 2007 Median Cost per DXA Procedure

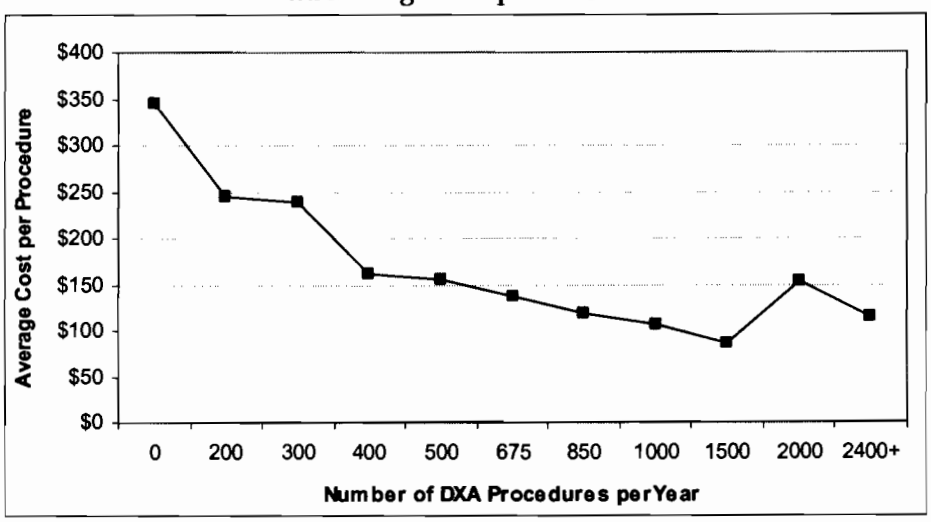
		Cost per Procedure		
DXA	768	$134.13	$42.57	$788.09

As Figure 3 demonstrates, there is an inverse relationship between average cost per procedure and the number of DXA procedures performed per year. There is a steady decrease in the average cost per procedures as practices increase the number of procedures performed per year, until they reach 1500 procedures per year. Procedures in excess of 1500 per year often have a higher per procedure cost, possibly attributed to the extra fixed costs and overhead that is associated with operating a practice that can handle the capacity. Providers with high procedure volume are typically identified as efficient and operating with fewer costs per procedures. Across all practices represented in the survey, there is an overall utilization rate for DXA machines of 13%, defined as total annual hours equipment is used for patient-care divided by total annual hours equipment is available for DXA.

Of those practices that have costs under $82, they perform, on average, 2125 procedures per year. This average number of procedures per year is influenced by a number of practices performing DXA in excess of the 90th percentile of procedures performed in a year. This procedure volume is significantly higher than the median number of procedures performed per year of 768, or approximately 3 procedures per day. There are still many providers, however, that are contained in the 86% of providers who have costs that are not covered by payments.

As a result, industry research indicated that many large providers have closed their doors and eliminated DXA as a provided service. (We noted these closures during the conduct of our survey.) After accounting for cost inflation and the continual decline of DXA payments through 2010, even fewer providers will be able to sustain providing DXA services to Medicare beneficiaries in the coming years. The active closure of larger, efficient providers validates our study in that providers typically are not adequately reimbursed for performing DXA.

Figure 3: Relationship between Number of DXA Procedures Performed and Average Cost per Procedure



a. Sensitivity Analysis

In creating the NPRM, CMS assumed indirect expenses account for 63% of the total practice expense. Indirect as direct expenses are defined as the following:

Figure 4: Components of Practice Expense, Indirect and Direct

Indirect expenses	Direct expenses
Non-clinical (administrative) labor	Direct labor for clinical personnel
Office Space	Equipment Expenses
All other expenses not related to directly performing the procedures	Medical Supplies and Equipment

Results of the Lewin survey yield a median indirect percentage of 37% of the total practice expense cost, or $34 dollars of the median cost of $134. Overall, practice expense represents 70% of the total DXA per procedures cost. As a test of sensitivity, we imputed the survey data to reflect the CMS distribution of direct and indirect costs.

Figure 5: Allocation of Practice Expense by Allocation Methodology, Lewin Survey vs. CMS NPRM Inputs

Methodology	Median Total Cost	Practice Expense			Physician Work	Malpractice
		Total	Indirect	Direct		
Lewin Survey	$134.13	$34.17	$60.12	$94.29	$38.49	$1.34
CMS NPRM	$202.33	$102.37	$60.12	$162.50	$38.49	$1.34

CMS methodology yields a total cost of $202 per procedure, with $152 allocated to practice expense (Figure 6). Furthermore, this imputation results in an indirect cost per procedures of $102.37, about $68 higher than the Lewin results demonstrates. Overall, this analysis yields a higher total cost per DXA procedure of $202.33 compared to the Lewin analysis of $134.13.

Lewin Appendix A

I. METHODS

We discuss the methodology for each component below:

b. Practice Expense and Malpractice Expense

1. Survey Administration

The Lewin Group survey was distributed electronically to 14,537 members of AACE, ISCD, ACR and TES. The survey was accessible via the internet, with the option of completing the survey on paper and faxing a copy to The Lewin Group. The survey collected information on the characteristics of the practice and physician (e.g., specialty, geographic region, hours practice is open and available to perform DXA), as well as equipment expenses and financial information (e.g., total salaries, office expenses, malpractice insurance). See Appendix B for the survey collection instrument.

One-hundred sixty three useable surveys were received representing approximately 1% of the sample. Respondents who provided incomplete survey data were contacted via telephone for clarification. Any respondent who was not able to be contacted was excluded from our analysis. As an incentive to complete the survey, The Lewin Group offered to provide the individual practice's cost of providing DXA to the physician at the completion of the survey analysis.

2. Generating Practice Expense and Malpractice Expense Cost Components

The Lewin survey collects expenses for entire individual practices[9]. The analysis consists of first estimating total aggregate DXA costs and then generating a practice expense and malpractice cost per DXA procedure for each practice. We report the median cost, 25th percentile and 75th percentile statistics. Lewin also investigated the range of expenses for different cost categories and the effect procedure volume has on per DXA procedure costs. Consistent with CMS methodology, Lewin used the median as our metric of central tendency to reduce the effect of data outliers.

Financial and utilization measures were collected for the most recent complete fiscal year. To make the costs comparable to the current 2007 payments for DXA, practice expense and malpractice expense cost categories were inflated by the CPI-U, approximately 4.1% for 2007.

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[9] For the purpose of this survey, "practice's expenses" are defined as all expenses that are captured in a Profit and Loss (Income) Statement for all services the practice provides. Respondents were not to differentiate between divisions that provide DXA and all other services provided.

Total practice expense and malpractice expense per procedure is calculated based on the sum of the three cost components, divided by the total number of DXA procedures performed annually for each practice. We describe each component below:

- Equipment Costs
- Space allocated to DXA
- An allocation of overhead expenses attributed to DXA (e.g., malpractice expense, non-clinical labor and expenses, medical supplies and materials)

Equipment costs

Equipment costs contain expenses that practices incur annually in the maintenance and upkeep of their DXA machines. These expenses for DXA machines include: 1) cost of interest on loans used to purchase the DXA machine; 2) cost of service contracts; 3) costs of software upgrades; and the 4) cost of the last PAC/DICOM upgrades. These expenses were totaled at the practice level for all machines reported.

Space allocated to DXA

Respondents indicated the total amount of square footage in their practice as well as the square footage attributed to providing DXA. Respondents were to only include areas that are solely used for DXA (i.e., area where the machines are located, and exam rooms that are reserved for DXA patients). The square feet allocated to DXA multiplied times the indicated lease per square foot is included in the cost for providing DXA to be allocated back to the procedure cost. As noted below, we also used the proportion of square feet attributed to DXA services provisions to allocate indirect expenses back to DXA procedures.

Allocation of overhead expenses attributed to DXA

Practices incur numerous indirect expenses that need to be allocated back to providing DXA. Based on the proportion of square feet attributed to DXA to the total number of square feet in the practice, overhead expenses were allocated. Costs included in this allocation include:

- professional medical liability/malpractice insurance;
- salaries for administrative and clerical staff;
- non-clinical office expenses;
- medical materials and supplies; and
- all other indirect expenses.

Survey respondents additionally provided total clinical non-physician payroll expenses (i.e., radiology technicians and registered nurses) and total provider (i.e., physician, physician assistants) payroll expenses. To eliminate the potential for "double-counting" salary expenses for personnel who provide direct labor in DXA procedures, the non-clinical non-physician payroll expense category was excluded in its entirety, due to the inability to indicate which percent of the expenses are attributed to indirect supports. Additionally, total provider payroll expenses were excluded with the assumption that time spent by the physician would be captured in "physician work" on a per-task basis.

As a result, the percent of indirect costs allocated back to DXA may be conservative, for we expect some personnel in these categories to provide DXA services that are not identified in the task breakdown. Additionally, bad debt expense was excluded from the analysis, consistent with CMS' methodology for identifying reimbursable expenses.

c. Physician Work

1. Survey Administration

Physician work was derived from a 2006 clinical survey of multi-specialty densitometry professionals. Administered by ISCD, this survey was distributed electronically to 2884 office-based providers of DXA who were members of AACE, ACR, ISCD, TES, American Society for Bone and Mineral Research (ASBMR), and North American Menopause Society (NAMS). The survey collected information on the characteristics of the practice and the average time and personnel required to perform each task associated with performing one DXA procedure. Four-hundred fifty-three useable responses were received, or 15% of the sample.

Survey data on the average time it takes to perform each task was analyzed, yielding an estimate of a median time per task (in minutes). The proportion of the total time personnel types were performing indicated tasks was calculated as well (i.e., What percent of the time are technician performing this task compared to registered nurses?). The required personnel included physician time, as well as clinical and non-clinical staff.

2. Generating Labor Costs Attributed to Providing DXA

To cost the labor associated with physician and other clinical work, The Lewin Group analyzed the raw data from the 2006 clinical survey of multi-specialty densitometry professionals. Personnel salary data were provided by the United States Department of Labor, Bureau of Labor Statistics (BLS), May 2006, "National Occupations Employment and Wage Estimates". Benefit costs were also provided by BLS in their "Employer Costs for Employee Compensation" survey, September 2006, and included in the salary estimates. A weighted average annual salary was generated based on the proportion of time each personnel category was responsible for performing an indicated task. The annual weighted salary was then calculated as a per minute cost (based on the number of hours the practice was open) and multiplied by the median number of minutes reported for each task. All tasks were totaled to generate a total "labor cost" per procedure.

This labor costing methodology generates a conservative estimate for the cost per procedures. Some practices indicated that they were open in excess of 8 hours a day. In theory, this could require two staff members, rather than just one. Dividing the annual salary per staff member by fewer hours open would result in a higher cost per minute, and ultimately a higher cost per task and procedure. Being unfamiliar with the structure of each practice and the number of staff

members providing the service, we assumed one staff member per task, regardless of the number of hours open.

d. Generating a per Procedure DXA cost

Survey respondents indicated an average number of DXA procedures performed per month per DXA machine. Lewin calculated the average number of DXA procedures per year for each practice. This calculation is used to denominate the sum of the practice expense, malpractice and physician work costs to derive cost per DXA procedure.

e. Utilization Rate

Lewin calculated an overall utilization rate for DXA machines based on the number of hours DXA equipment was used to provide patient care and number of hours equipment is available to provide DXA:

- **Total available equipment hours**: We calculated total available equipment hours for each practice by multiplying the reported hours available each week by the total indicated hours per year the practice is open for in each practice.
- **Total patient-use equipment hours**: We calculated the hours for total patient-use by multiplying the number of DXA procedures performed per year by the RUC approved time per procedure (15 minutes). Due to the inability to estimate the amount of time DXA machines are used in each practices, this estimate may be conservative.
- **Utilization Rate**: Total patient-use equipment hours divided by total available equipment hours.

II. SAMPLE CHARACTERISTICS

Both survey efforts captured data from numerous specialties that provide DXA services. Responses to The Lewin Group survey were received from 8 different specialties. Rheumatology represents 37% of the sample while Primary Care (Internal Medicine, Family Medicine and Gynecology) collectively represent 39% of the responses (Figure 6). Based on 2004 claims data for office-based services, 28% of claims are from Internal Medicine while 24% are Radiology. As a test for representativeness, we re-weighted the final results of our study based on the CMS claims data distribution by specialty and obtained comparable median costs per DXA procedure. This ensured that specialty distribution did not affect our analytic results.

Figure 6: Distribution of Specialty for Lewin and Multi-specialty Survey Compared to 2004 CMS Claims Analysis

Rheumatology	37%	37%	12%
Internal Medicine	20%	11%	28%
Endocrinology	13%	22%	5%
Family Practice	10%	7%	11%
OB/GYN	9%	9%	7%
Other	6%	6%	14%
Radiology	3%	5%	24%
Orthopedics	2%	3%	-

Responses from the 2006 clinical survey of multi-specialty densitometry professionals represented 18 specialties, which were aggregated in Figure 6. Rheumatology represents 37% of the sample (identical to the Lewin survey) whereas Endocrinology represents 22%. Primary Care (Internal Medicine, Family Medicine and Gynecology) collectively represents 27% of the total sample.

Lewin Appendix B

Office Based (Non-Facility) DXA Cost Survey Questionnaire July 9, 2007

Thank you for agreeing to participate in this important survey to help understand DXA costs.

Instructions

To accurately assess DXA costs, we need to collect information on a variety of clinic operating expenses. To ensure the most accurate information, **we suggest that you share this survey with your clinic administrator and/or business manager so they can assist you in its completion.** Please make sure you include all of your practice(s)'s expenses (unless specified), not just those attributed to DXA. The time spent completing this will be invaluable in arriving at a true cost analysis that may **result in a more accurate reimbursement.**

This survey will collect practice level information regarding procedure volume and equipment costs and professional expenses for your most recently completed fiscal year.

To submit this paper survey:

- **Print, complete and fax responses to Audrey El-Gamil at The Lewin Group at 703-269-5501, or**
- **Complete electronically and email responses to Audrey El-Gamil at The Lewin Group at audrey.el-gamil@lewin.com.**

Please make sure that you insert your log-in information at the top of the first page of the survey!

Again, we assure you that The Lewin Group is treating all information as confidential. Under no circumstances will individual practice information be reported or shared with anyone. Furthermore, The Lewin Group will provide only aggregated data across providers.

If you have questions or wish to discuss any issues related to the survey, please call Audrey El-Gamil at The Lewin Group between the hours of 9 am ET and 6 pm ET, or leave a message, at (703) 269-5771. Alternatively, you can email Audrey at audrey.el-gamil@lewin.com.

Survey Deadline: July 20, 2007

Information about You

(Please complete this survey only if you are not a hospital based practice billing under the Hospital Outpatient Prospective Payment System (OPPS))

A-1	**Your name:**
A-2	**City where practice is located:**
A-3	**State where practice is located:**
A-4	**Zip code of practice:**
A-5	**Location of practice: (check one)** **____ Urban ____ Suburban ____ Rural**
A-6	**Specialty you practice: (check one)** **____ Endocrinology** **____ Family Practice** **____ Gynecology** **____ Internal Medicine** **____ Orthopedics** **____ Rheumatology** **____ Radiology** **____ Other (specify:_____)**
A-7	**Years practicing specialty:** **_____ years**
A-8	**Are you ISCD Certified as a CCD (Certified Clinical Densitometrist)?** **____ Yes** **____ No**
A-9	**Is your practice based in a hospital?** **____ Yes** **____ No** **If yes, do you bill for DXA using the Hospital Outpatient Department (HOPD) rate also referred to as the Hospital Outpatient Prospective Payment System (OPPS)?** **____ Yes** **____ No** ***If you answered "yes" to both questions, please do not complete the rest of the survey. This survey is only for office-based/non-facility based practices whose payment is based on the Medicare Fee Schedule. Thank you for your time! Please fax your***

responses to Ted Kirby at 703-269-5501.

Information about Your Practice

B-1	How many: _____ physicians are in your practice? _____ of those physicians, how many are reading DXAs? Do you have non-physician providers (NP, PA) who read DXAs? ____ Yes ____ No If yes, how many? _____ non-physician providers
B-2	Which central sites do you routinely measure? _____ spine only _____ one hip only _____ spine and one hip _____ spine and both hips
B-3	Do you do forearm DXAs? _____ Yes _____ No* *Skip to Question B-6*
B-4	If you do forearm DXAs, do you do them: _____ in all patients having central DXA?* *Skip to Question B-6* _____ only in selected patients?
B-5	If only in selected patients, what percent of patients having central DXAs also have forearm DXAs? _____ percent having central DXA and forearm DXA _____ percent having only forearm DXAs
B- 6	How much of your DXA volume comes from your own practice and how much is referred to you from outside of your practice? (total must equal 100%) _____% from your practice _____% referred to you
B-7	When you bill for DXA, do you bill the global fee or the professional component? _____ global fee _____ professional component only (-26)

Survey Deadline: July 20, 2007

B-8	What is the average number of hours per week that your office is open for business? _____ hours per week
B-9	How many days of the week is your office open for business? _____ days of the week
B-10	How many weeks of the year is your office open for business? _____ weeks of the year
B-11	What is the average number of hours per week that DXA is available/offered in your office? _____ hours per week
B-12	How many central DXA procedures are performed in an average month per machine? _____ procedures

Information about VFA

C-1	Do you have VFA capability? ____ Yes ____ No
C-2	Do you read VFA? ____ Yes ____ No* *Skip to next section*
C-3	How many VFA procedures are performed in an average month per machine? _____ procedures
C-4	How many machines are used for VFA? _____ machines

Survey Deadline: July 20, 2007

For the next sections, we suggest that you share the questionnaire with your clinic administrator and/or business manager so they can assist you. The time spent completing this will be invaluable in arriving at a true cost analysis that may result in a more accurate reimbursement for central DXA.

Information about Your Equipment Costs

Total number of DXA machines in your practice: _____

Please fill out one row in the following table for each DXA machine in your practice.

Please specify if the manufacturer is:

- **Hologic,**
- **Norland/Cooper, or**
- **GE/Lunar**

D-1

Machine					
1					
2					
3					
4					

D-2 **Cost per year of interest on loan(s) used to purchase your DXA machine(s):**

$_____ per year

D-3 **Cost per year of any service contract(s) for your DXA machine(s):**

$_____ per year

D-4 **Cost per year of software upgrade(s) for your DXA machine(s):**

$_____ per year

D-5 **Cost of the last PAC/DICOM upgrade(s) (ability to transmit radiographic images electronically):**

$_____

Information about Your Professional Expenses (your last full fiscal year)

Please answer the remaining sections based on your last full fiscal year. Make sure to include your entire practice's expenses, rather than those just attributed to DXA. We will use this information to calculate the proportion of your clinic's overhead expenses that are attributed to DXA procedures.

For the purpose of this survey, "practice(s)'s expenses" are defined as all expenses that are captured on your Profit and Loss (Income) Statement for all services your practice provides. Do not differentiate between DXA and all other services provided. We list some examples of expenses you should and should not include in your totals:

Do include:

- *Rent and utilities for your entire practice, not just areas attributed to DXA services*
- *Salary amounts (and benefits) for visiting physicians or support staff that are paid by your practice, but also serve or support other practices*

Do not include:

- *Salaries for visiting physicians that use your clinic space but are not paid a salary from your practice*
- *Rent for neighboring practices that share space (i.e., waiting rooms)*

If you have any further questions, please call Audrey El-Gamil at The Lewin Group at (703) 269-5771

E-1	**What is the start and end date of your last full fiscal year?** **Start Date: Month_____ Year _____** **End Date: Month_____ Year _____**
E-2	**What is the total square footage for your practice?** (If practice has more than one location include total square footage of all offices) _____ **sq ft.** **What is the total square footage attributed to DXA use?** (If an exam room is set aside for DXA only, then you would provide the square footage of the exam room itself. If part of the room where DXA machine is located is used for other purposes, then you would list the square footage of that portion of the room reserved for DXA. If practice has more than one DXA machine include square footage reserved for each machine.) _____ **sq ft.** **What is the lease per square foot for your practice(s)? $_____**
E-3	What was your practice's **professional medical liability or malpractice** insurance premium for your last full fiscal year, to the nearest thousand dollars? **$_____ Premium Amount**
E-4	What were your practice's **non-clinical non-physician** payroll expenses for your last full fiscal year were solely for individuals involved with administrative, secretarial, or clerical activities (to the nearest thousand dollars)? Include all sites for which your practice bears these costs (e.g. practice managers, schedulers, billing personnel, record clerks, clerical, etc.). **$ _____**

Survey Deadline: July 20, 2007

E-5	What were your practice's total clinical **non-physician** payroll expenses for your last full fiscal year, including fringe benefits (to the nearest thousand dollars)? Include all sites for which your practice bears these costs (e.g. nurses, technicians). $_____
E-6	What were your practice's total **provider** payroll expenses for your last full fiscal year, including current or deferred compensation (to the nearest thousand dollars)? (Physicians, Nurse Practitioners, Physician Assistants). Include all sites for which your practice bears these costs (e.g. salaries, bonuses, dividends, and pension funds). $_____
E-7	What were your overall practice's expenses for **medical materials and supplies** not separately reimbursable that are used for clinical purposes for your last full fiscal year (to the nearest thousand dollars)? Include all sites for which your practice bears these costs (e.g. X-ray films, processor chemicals, laundry and disposable medical supplies). Do not include expenses for non-clinical office supplies or medicines which are separately reimbursable. $_____

Information about Your Non-Clinical Expenses (your last full fiscal year)

F-1	What were your practice's **non-clinical office** expenses for your last full fiscal year, including non-clinical office equipment and supplies, rent, mortgage interest, depreciation and maintenance costs on office and medical buildings, commercial property insurance, property taxes, utilities and telephone, supplies for billing, scheduling and business functions (to the nearest thousand dollars)? Include all sites for which your practice bears these costs. $_____
F-2	What were your practice expenses for **all other** expenses for your last full fiscal year, including marketing expenses, legal fees, accounting, office management services, contracted billing expenses, professional car upkeep and depreciation, professional association memberships, professional journals, continuing education (CME), all employee-provided insurance other than malpractice, and other expenses that have not been listed (to the nearest thousand dollars)? $_____
F-3	What were your practice's **bad debts** for services provided in your last full fiscal year (to the nearest thousand dollars)? $_____

Do you have any additional comments?

Congratulations, you have finished the survey!
Thank you for your responses.
To submit your complete survey, please fax it to
Audrey El-Gamil at the Lewin Group, 703-269-5501

Survey Deadline: July 20, 2007

The work RVU values for DXA CPT code 76075 are substantially higher than that recorded in the ACR survey, which noted a median work RVU of 0.3 and a 25th percentile of 0.2.

Thus, for both the physician time component and the physician work RVU, substantially higher values were obtained when 453 physicians from multiple disciplines were surveyed in contrast to 51 physicians from a single specialty (radiology).

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Appendix E

Physician Work and Direct Practice Expense Survey

August 2006

Thank you for participating in the ISCD's survey. This survey is important to your patients and you because these values determine the rate at which Medicare will reimburse for central DXA and VFA. To accomplish this, ISCD's Public Policy Committee needs to acquire additional data to assist in crafting ISCD's formal response to CMS. T**his online survey is critical to our response to CMS.**

There are 4 components to this survey which takes approximately 45-60 minutes to complete online:

- Demographic information
- Physician work survey for DXA
- Practice expense effort survey for DXA and VFA (most will complete only one of the two sections)
    - Site of Service – Facility
    - Site of Service – NonFacility
- Questionnaire regarding type of DXA machine and utilization rates

To assure data integrity, surveys that do not include your name, address, specialty, and other demographic information will not be considered. This survey **must be electronically completed** no later than Thursday, **August 10**. You may receive the survey from more than one society. Only complete the survey once. If you are an ISCD member, **please only complete the survey received from the ISCD.**

This survey, adapted from the survey used to generate data that CMS utilized to determine reimbursement for DXA and VFA services, is detailed and complex.

When using a paper copy for data collection (data submission MUST be done online):

1. Save the email you received from ISCD or other specialty society because it contains the link to the online survey. Only online survey results will be considered.
2. The Practice Expense Effort Survey portion is divided into sections based on your Site of Service. Most survey participants will only complete one of those two sections based on the definitions outlined in the survey.
3. When entering your information online, please note, the question numbering on the paper copy **will not exactly** match the numbering in the online survey.

The results of this survey will be shared with you. Thank you for assisting ISCD in providing CMS with this information.

Sincerely,

ISCD Public Policy Committee

Physician Work and Direct Practice Expense Survey

1 Demographic Information

Physician's LAST Name
Physician's FIRST Name
Physicians' Primary Office
(STATE)
E-mail
Address
Phone number

2 Check all specialty societies of which you are currently a member:

☐ AACE – American Association of Clinical Endocrinologists
☐ ACR – American College of Rheumatology
☐ ASBMR - American Society for Bone and Mineral Research
☐ ISCD - International Society for Clinical Densitometry
☐ NAMS – North American Menopause Society
☐ TES – The Endocrine Society

3 Specialty:

4 Additional Demographics:

Years Practicing
Specialty
Years Reading
DXA

5 Primary **Geographic** Practice Setting (choose one)

☐ Rural
☐ Urban
☐ Suburban

6 Primary **Type** of Practice (choose one)

☐ Solo Practice
☐ Single Specialty Group
☐ Multi-specialty Group
☐ Medical School Faculty Practice Plan

7 Do you have VFA capability?

☐ Yes
☐ No

8 Do you read VFA?

☐ Yes
☐ No

9 Are you ISCD Certified as a CCD (Certified Clinical Densitometrist)?

☐ Yes
☐ No

The Physician Work Survey for DXA

Introduction

"Physician work" includes the following elements:

- Physician time it takes to perform the service
- Physician mental effort and judgment
- Physician technical skill and physical effort
- Physician psychological stress that occurs when an adverse outcome has serious consequences

All of these elements will be explained in greater detail as you complete this survey.

"Physician work" does **not** include the services provided by support staff who are employed by your practice and cannot bill separately, including registered nurses, licensed practical nurses, medical secretaries, receptionists, and technologists. These services are evaluated in the practice expense relative values component of the survey which follows this section.

Background

Refer to the Reference Services list below that have been selected for use as comparison services for this survey because their relative values are sufficiently accurate and stable to compare with other services. The "work RVU" value presents current Medicare work RVUs (relative value units). In the following question, you will be asked to select one code that is most similar to the surveyed CPT code descriptor and typical patient/service described below.

This survey will evaluate the DXA code listed below with a "typical patient" to consider when completing the survey. Keep this "typical patient" in mind when answering the following questions.

***CPT Code:* 76075**

***CPT Descriptor:* Dual energy x-ray absorptiometry (DXA), bone density study, one or more sites axial skeleton (e.g., hips, pelvis, spine)**

Typical Patient: A 66 year old woman had previous bone density demonstrating severe osteoporosis. The patient has been on hormone replacement therapy for one year and a follow-up DXA scan is ordered.

Note: Vertebral fracture assessment (CPT code 76077) when ordered and performed is coded separately.

10 Which of the Reference Services (CPT codes) in the following list of CPT codes, is most similar in terms of physician work to the surveyed DXA CPT code Descriptor and Typical Patient Service described above? Choose one Reference Service code for the code being surveyed.

IMPORTANT: Make note of the CPT code you choose as you will be asked to refer to it throughout this survey. It will be referred to as "Reference CPT code" throughout the survey.

"CPT five digit-codes, two-digit number modifiers and descriptions only are copyrighted by the American Medical Association."

☐ Physician Work RVU=**0.17** CPT Code **93000**
. . . Electrocardiogram, complete

☐ Physician Work RVU=**0.17** CPT Code **99211**
. . . Office/outpatient visit, established patient

☐ Physician Work RVU=**0.17** CPT Code **76077**
. . . DXA bone density/v-fracture (VFA)

☐ Physician Work RVU=**0.20** CPT Code **76078**
. . . Radiographic absorptiometry

☐ Physician Work RVU=**0.22** CPT Code **76076**
. . . DXA bone density/peripheral

☐ Physician Work RVU=**0.22** CPT Code **71020**
. . . Chest xray, two views, frontal and lateral projections

☐ Physician Work RVU=**0.22** CPT Code **72070**
. . . Xray exam of thoracic spine (2 views)

☐ Physician Work RVU=**0.25** CPT Code **76070**
. . . CT bone density, axial

☐ Physician Work RVU=**0.31** CPT Code **71022**
. . . Chest xray, two views, frontal and lateral with oblique projections

☐ Physician Work RVU=**0.32** CPT Code **74022**
. . . Xray exam series, abdomen, includes supine, erect, and/or decubitus views, single view of chest

☐ Physician Work RVU=**0.32** CPT Code **92370**
. . . Repair & adjust spectacles

☐ Physician Work RVU=**0.36** CPT Code **72114**
. . . Xray exam of lower spine (complete with bending views)

☐ Physician Work RVU=**0.45** CPT Code **99212**
. . . Office/outpatient visit, established patient

☐ Physician Work RVU=**0.61** CPT Code **69210**
. . . Remove impacted ear wax

☐ Physician Work RVU=**0.67** CPT Code **99213**
. . . Office/outpatient visit, established patient

☐ Physician Work RVU=**0.67** CPT Code **76942**
. . . Ultrasound guidance for biopsy (thyroid FNA biopsy)

☐ Physician Work RVU=**0.79** CPT Code **20610**
. . . Drain/inject, major joint/bursa

☐ Physician Work RVU=**1.10** CPT Code **99214**
. . . Office/outpatient visit, established patient

For the following question, physician work is described as follows:

Description of Physician Work

Pre-Service Period:
The pre-service period includes work before the procedure begins and may include preparing to see the patient, reviewing records and prior imaging studies, and communicating with the technologist and other professionals.

Intra-Service Period:
The intra-service period includes the services provided while you are with the patient and/or family, plus supervision of the procedure and image interpretation. The intra-service period ends at completion of report dictation.

Post-Service Period:
The post-service period includes report review and signature, plus communications with the patient, family and other professionals after report dictation.

NOTE: Only the physician's time can be considered and only activities that are performed for the typical patient can be considered. Time spent by technologists and other clinical staff is not included in valuing physician work.

11 How much of your own time (day of procedure) is required per patient treated for each of the following steps in patient care related to this procedure? Indicate your time (in minutes) for DXA CPT code 76075. (Refer to definitions above. Record time in minutes below.)

Pre-Service Time
Intra-Service Time
Post-Service Time

Questions 12 & 13 Directions: For both the surveyed DXA CPT code 76075 and the Reference CPT code you chose from the reference list in Question 10, based on the typical patient described below rate the AVERAGE pre-, intra-, and post-service *complexity/intensity* on a scale of 1 to 5 (1 = low 3 = medium 5 = high).

In 12, rate the complexity/intensity for the surveyed DXA CPT code 76075.

In 13, rate the complexity/intensity for the Reference CPT code you chose from the reference list in Question 10. (*The Reference CPT code is the one you were asked to make note of earlier in the survey. If needed, you can use the "Back" button in your browser to review that page again to make note of the code now.*)

Typical Patient: A 66 year old woman had previous bone density demonstrating severe osteoporosis. The patient has been on hormone replacement therapy for one year and a follow-up DXA scan is ordered.

12 Based on the typical patient described previously, rate the AVERAGE pre-, intra-, and post-service complexity/intensity for the surveyed DXA CPT code 76075.

1	2	3	4	5
Low		Medium		High

Pre-Service Complexity Rating for 76075 DXA

1	2	3	4	5

Intra-Service Complexity Rating for 76075 DXA

1	2	3	4	5

Post-Service Complexity Rating for 76075 DXA

1	2	3	4	5

13 Based on the typical patient described previously, rate the AVERAGE pre-, intra-, and post-service complexity/intensity for the Reference CPT code you chose from the reference list in Question 10.

1	2	3	4	5
Low		Medium		High

Pre-Service Complexity level for Reference CPT Code

1	2	3	4	5

Intra-Service Complexity level for Reference CPT Code

1	2	3	4	5

Post-Service Complexity level for Reference CPT Code

1	2	3	4	5

Background for Question 14

In evaluating the work of a service, it is helpful to identify and think about each of the components of a particular service. Focus only on the work that you perform during each of the identified components. The descriptions below are general in nature. Within the broad outlines presented, think about the specific services that you provide.

Physician work includes the following:

- **Time** it takes to perform the service
- **Mental Effort and Judgment** necessary with respect to the amount of clinical data that needs to be considered, the fund of knowledge required, the range of possible decisions, the number of factors considered in making a decision, and the degree of complexity of the interaction of these factors.
- **Technical Skill** required with respect to knowledge, training and actual experience necessary to perform the service.
- **Physical Effort** can be compared by dividing services into tasks and making the direct comparison of tasks. In making the comparison, it is necessary to show that the differences in physical effort are not reflected accurately by differences in the time involved if they are, considerations of physical effort amount to double counting of physician work in the service.
- **Psychological Stress** – Two kinds of psychological stress are usually associated with physician work. The first is the pressure involved when the outcome is heavily dependent upon skill and judgment and an adverse outcome has serious consequences. The second is related to unpleasant conditions connected with the work that are not affected by skill or judgment. These circumstances would include situations with high rates of mortality or morbidity regardless of the physician's skill or judgment, difficult patients or families, or physician physical discomfort. Of the two forms of stress, only the former is fully accepted as an aspect of work many consider the latter to be a highly variable function of physician personality.

Questions 14-19 Directions: For both the surveyed DXA CPT code 76075 and the Reference CPT code you chose from the reference list in Question 10, based on the typical patient described below rate the AVERAGE pre-, intra-, and post-service *complexity/intensity* on a scale of 1 to 5 (1 = low 3 = medium 5 = high).

In questions 14, 16, and 18 rate the complexity/intensity for the surveyed DXA CPT code 76075.

In questions 15, 17, and 19 rate the complexity/intensity for the Reference CPT code you chose from the reference list in Question 10.

Typical Patient: A 66 year old woman had previous bone density demonstrating severe osteoporosis. The patient has been on hormone replacement therapy for one year and a follow-up DXA scan is ordered.

14 Based on the typical patient described previously, rate the AVERAGE complexity/intensity for the surveyed **DXA CPT code 76075** for each of the following:

Mental Effort and Judgment

1	2	3	4	5
Low		Medium		High

The range of possible diagnoses and/or management options that must be considered

1	2	3	4	5

The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed

1	2	3	4	5

Urgency of medical decision making

1	2	3	4	5

15 Based on the typical patient described previously, rate the AVERAGE complexity/intensity for the **Reference CPT code** you chose in Question 10 for each of the following:

Mental Effort and Judgment

1	2	3	4	5
Low		Medium		High

The range of possible diagnoses and/or management options that must be considered

1	2	3	4	5

The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed

1	2	3	4	5

Urgency of medical decision making

1	2	3	4	5

16 Based on the typical patient described previously, rate the AVERAGE complexity/intensity for the surveyed **DXA CPT code 76075** for each of the following:

Technical Skill/Physical Effort

1	2	3	4	5
Low		Medium		High

Technical skill required

1	2	3	4	5

Physical effort required

1	2	3	4	5

17 Based on the typical patient described previously, rate the AVERAGE complexity/intensity for the **Reference CPT code** you chose in Question 10 for each of the following:

Technical Skill/Physical Effort

1	2	3	4	5
Low		Medium		High

Technical skill required

1	2	3	4	5

Physical effort required

1	2	3	4	5

18 Based on the typical patient described previously, rate the AVERAGE complexity/intensity for the surveyed **DXA CPT code 76075** for each of the following:

Psychological Stress

1	2	3	4	5
Low		Medium		High

The risk of significant complications, morbidity and/or mortality

1	2	3	4	5

Outcome depends on skill and judgment of physician

1	2	3	4	5

Estimated risk of malpractice suit with poor outcome

1	2	3	4	5

19 Based on the typical patient described previously, rate the AVERAGE complexity/intensity for the **Reference CPT code** you chose in Question 10 for each of the following:

Psychological Stress

1	2	3	4	5
Low		Medium		High

The risk of significant complications, morbidity and/or mortality

1	2	3	4	5

Outcome depends on skill and judgment of physician

1	2	3	4	5

Estimated risk of malpractice suit with poor outcome

1	2	3	4	5

20 How many times have you personally performed these procedures **in the past year**?

Number of 76075 DXA bone density procedures
Number of Reference CPT code procedures

21 The ISCD and your specialty society are interested in determining whether the physician work for these services has changed over the previous five years.

Has the work of performing this service changed in the past 5 years?
☐ Yes
☐ No

22 This service (DXA CPT code 76075) represents new technology that has become more familiar (i.e., less work).

- ☐ Agree
- ☐ Disagree

23 Patients requiring this service (DXA CPT code 76075) are now:

- ☐ More complex (more work)
- ☐ Less complex (less work)
- ☐ No change

24 The usual site of service has changed (for DXA CPT code 76075):

- ☐ From outpatient to inpatient
- ☐ From inpatient to outpatient
- ☐ No change

Background for Conscious Sedation Questions

Conscious sedation is a service provided by the operating physician or under the direct supervision of the physician performing the procedure to allow for sedation of the patient with or without analgesia through administration of medications via the intravenous, intramuscular, inhalational, oral, rectal or intranasal routes. For purposes of the following two questions, sedation and analgesia delivered separately by an anesthesiologist or other anesthesia provider not performing the primary procedure is not considered conscious sedation.

25 Do you or does someone under your direct supervision typically administer conscious sedation for DXA CPT code 76075?

- ☐ Yes
- ☐ No

26 Do you or does someone under your direct supervision typically administer conscious sedation for Reference CPT code (that you chose in Question 10)?

- ☐ Yes
- ☐ No

27 Question Background

Typical Patient: A 66 year old woman had previous bone density demonstrating severe osteoporosis. The patient has been on hormone replacement therapy for one year and a follow-up DXA scan is ordered.

Is your typical patient for each procedure similar to the typical patient described above? If no, please describe your typical patient below:

- ☐ Yes
- ☐ No

If no, describe:

28 VERY IMPORTANT QUESTION

Based on your review of all previous steps, please provide your estimated physician work RVU for the DXA CPT code 76075. For example, if the surveyed code involves the same amount of physician work as the reference service you choose, you would assign the same work RVU. If the surveyed code involves twice as much (or half as much) work as the reference service, you would calculate and assign a work RVU value that is twice as much (or half as much) as the work RVU of the reference service. This methodology attempts to set the work RVU of the new or revised service "relative" to the work RVU of comparable and established reference services.

What is your estimate of physician work RVU for CPT code 76075 Dual energy x-ray absorptiometry (DXA), bone density study, one or more sites axial skeleton. (e.g., hips, pelvis, spine)?

Estimate of physician work RVU for 76075:

Direct Practice Expense Survey for DXA and VFA

Direct Practice Expense Inputs
In answering these practice expense questions, you may find it helpful to confer with your clinical or administrative staff. In this part of the survey we will be asking about DXA and VFA studies performed either in a facility or non-facility setting (see next page for definitions). We will survey:

- Time spent by health care professional clinical staff providing clinical activities related to DXA and VFA
- Utilization rates of DXA and VFA

Clinical Labor Service Period Definitions

PRE-SERVICE PERIOD:
The pre-service time period begins when the appointment for the diagnostic test is made.

This includes all non-physician clinical services provided to a patient until the beginning of the service period. This may include one or more visits or contacts with the physician's office or facility (hospital) imaging center before the service period.

The pre-service time period ends with arrival at a physician's office or facility imaging center for the diagnostic test.

SERVICE PERIOD:
The service period starts with the patient's arrival at the physician's office or facility imaging center for the diagnostic test.

This includes the preparatory services before the service, assistance provided during the intra-procedural services and all post-procedure services that are provided while in the physician's office, or while the physician is at the facility imaging center. When services are provided in the facility, only staff employed by the physician should be counted.

The service time period ends with departure from the physician's office or facility imaging center.

POST-SERVICE PERIOD:
The post-service period begins when the patient leaves the physician's office or facility imaging center.

The post-service period includes services provided by staff after the service and may include arranging for further services, communicating further with the patient, family, and other professionals which includes written and telephone reports.

The post-service time period concludes when the appointment for the next office visit is made.

Background for Non-Facility and Facility Site of Service Questions

Staff Time
Estimate the staff time providing clinical support in minutes for each category listed. Based on your answer to the "site of service" question below, you will be directed to the appropriate set of questions.

The work of clinical staff should not be counted when it substitutes for work the physician would provide within the definitions of physician work. However, when the clinical staff provides services that are above and beyond the tasks that the physician is usually expected to do and not a substitute for physician services, it should be included. This may include such activities as review of history and test results, recording of notes, measurement of vital signs, review of x-ray or pathology reports, and completion of medical forms and prescriptions.

Include: Clinical labor provided by health care professionals who are paid by your practice and cannot bill separately, such as radiologic technologists (RT), registered nurses (RN), licensed practical nurses (LPN), and certified medical assistants (MA), or other personnel employed in your practice.

Do not include: Clinical labor provided by health care professionals, such as physician assistants (PA) or nurse practitioners (NP), in this survey if they can separately bill for the service and their services are a substitute for the physician service. An example is a PA obtaining a medical history of risk factors for osteoporosis. **Also, administrative activities provided by clerical staff, medical secretaries, or clinical staff should NOT be included.** Administrative activities include activities such as billing for services, scheduling appointments, transcribing, and filing reports and obtaining service authorizations.

Site of Service:
Practice expenses are classified according to the site of service as either non-facility or facility.

Non-Facility settings include physician offices, freestanding imaging centers, and independent pathology labs.

Facility settings include all other settings, such as hospitals, ambulatory surgical centers, skilled nursing facilities, and partial hospitals.

The site of service is the place where the main part of the procedure is performed. It is not based on the actual place of service where a particular pre- or post-service activity occurs. For example, if a procedure is performed in the hospital, then the setting is in the facility, even though services associated with the procedure, such as pre-/post-visits might often occur outside the hospital in the physician's office.

Be sure that you indicate the appropriate site of service where you usually perform the service. If you perform the procedure in both sites of service, answer questions for both the non-facility and facility settings.

29 Site of Service
Select the appropriate site of service where you usually perform the service. If you perform the procedure in both sites of service, select "Both."

- ☐ Non-Facility
- ☐ Facility
- ☐ Both

SITE OF SERVICE: NON-FACILITY
For all questions in the following section, leave any question or portions of questions blank or enter n/a if they do not apply.

Background for Questions in this Section
How much time does the office staff spend providing clinical support for each portion of this procedure in the office? Skip any question or portion of a question that does not apply to your site. If the other category is used, identify staff category. (Base estimates on a typical patient for this procedure.) Only include clinical labor provided by health care professionals who are paid by your practice and cannot bill separately, such as radiologic technologists (RT), registered nurses (RN), licensed practical nurses (LPN), and certified medical assistants (MA), or other personnel employed in your practice. **It is important to include the time associated with clinical activities regardless of the type of staff providing the service, since it is most important to capture the time related to clinical functions.** For example, if you use non-clinical personnel for clinical activities, list the staff type in the "other staff" category below.

However, **administrative activities such as the following should not be included:**

- Obtain referral from referring MD
- Schedule patient/remind patient of appointment
- Obtain medical records/manage patient database/develop chart
- Pre-certify patient/conduct pre-service billing
- Verify insurance/register patient
- Transcribe results/file and manage patient records
- Schedule subsequent post-service E&M services
- Complete DXA or VFA reports and notify the referring MD (cannot complete MDs work and transmit results of DXA/VFA to referring MD)
- Conduct billing and collection activities

Pre-Service – before patient enters office

Enter time (in minutes for each patient) and enter staff type (RT, CNA, RN, LPN, other) for each pre-service item for DXA CPT Code 76075 and VFA CPT Code 76077.

30 Quality control procedures (Total QC time divided by number of patients per day)
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

31 Prepare room, equipment, supplies
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

32 Other non-administrative clinical activity (please specify).
List other clinical activity in "DXA Other" or "VFA Other" as appropriate. Also enter the time and staff for that other clinical activity in the appropriate box.
DXA Other
Specify:
DXA Other Time (in minutes):
DXA Staff Type:
VFA Other
Specify:
VFA Other Time (in minutes):
VFA Staff Type:

Service Period when patient enters the office

Pre-Service

Enter time (in minutes for each patient) and enter staff type (RT, CNA, RN, LPN, other) for each pre-service item for DXA CPT Code 76075 and VFA CPT Code 76077

33 Greet patient and provide gown
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

34 Obtain vital signs which may include height
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

35 Review medical questionnaire for pertinent history and risk factors
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

36 Pre-service patient education
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

Intra-Service

Enter time (in minutes for each patient) and enter staff type (RT, CNA, RN, LPN, other) for each intra-service item for DXA CPT Code 76075 and VFA CPT Code 76077.

37 Position patient and acquire images

DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

38 Review images/compare with prior study(s) if available/manually correct any errors in acquisition/perform image analysis
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

Post-Service
Enter time (in minutes for each patient) and enter staff type (RT, CNA, RN, LPN, other) for each post-service item for DXA CPT Code 76075 and VFA CPT Code 76077.

39 Review with physician/print study/and/or transmit study to physician work station
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

40 Clean room and equipment
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

41 Other non-administrative clinical activity (please specify).
List other clinical activity in "DXA Other" or "VFA Other" as appropriate.
Also enter the time and staff for that other clinical activity in the appropriate box.
DXA Other
Specify:
DXA Other Time (in minutes):
DXA Staff Type:
VFA Other
Specify:
VFA Other Time (in minutes):
VFA Staff Type:

Post-Service – when patient leaves the office
Enter time (in minutes for each patient) and enter staff type (RT, CNA, RN, LPN, other) for each post-service item for DXA CPT Code 76075 and VFA CPT Code 76077.

42 Copy or fax written and/or telephone reports from clinical staff (other than physician) to patient and/or referring physician
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

43 Other non-administrative clinical activity (please specify).
List other clinical activity in "DXA Other" or "VFA Other" as appropriate. Also enter the time and staff for that other clinical activity in the appropriate box.
DXA Other
Specify:
DXA Other Time (in minutes):
DXA Staff Type:
VFA Other
Specify:
VFA Other Time (in minutes):
VFA Staff Type:

44 Site of Service

Do you also perform the procedure in a "Facility" setting?

Facility settings include all other settings, such as hospitals, ambulatory surgical centers, skilled nursing facilities, and partial hospitals.

☐ Yes
☐ No

SITE OF SERVICE: FACILITY

For all questions in the following section, leave any question or portions of questions blank or enter n/a if they do not apply.

Background for Questions in this Section
How much time does the office staff spend providing clinical support for each portion of this procedure in the office? Skip any question or portion of a question that does not apply to your site. If the other category is used, identify staff category. (Base estimates on a typical patient for this procedure.)

Only include clinical labor provided by health care professionals who are paid by your practice and cannot bill separately, such as radiologic technologists (RT), registered nurses (RN), licensed practical nurses (LPN), and certified medical assistants (MA), or other personnel employed in your practice. **It is important to include the time associated with clinical activities regardless of the type of staff providing the service, since it is most important to capture the time related to clinical functions.** For example, if you use non-clinical personnel for clinical activities, list the staff type in the "other staff" category below.

However, **administrative activities such as the following should not be included:**

- Obtain referral from referring MD
- Schedule patient/remind patient of appointment
- Obtain medical records/manage patient database/develop chart
- Pre-certify patient/conduct pre-service billing
- Verify insurance/register patient
- Transcribe results/file and manage patient records
- Schedule subsequent post-service E&M services
- Complete DXA or VFA reports and notify the referring MD (cannot complete MDs work and transmit results of DXA/VFA to referring MD)
- Conduct billing and collection activities

Pre-Service – before patient enters office
Enter time (in minutes for each patient) and enter staff type (RT, CNA, RN, LPN, other) for each pre-service item for DXA CPT Code 76075 and VFA CPT Code 76077.

45 Quality control procedures (Total QC time divided by number of patients per day)
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

46 Prepare room, equipment, supplies
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

47 Other non-administrative clinical activity (please specify).
List other clinical activity in "DXA Other" or "VFA Other" as appropriate. Also enter the time and staff for that other clinical activity in the appropriate box.
DXA Other
Specify:

DXA Other Time (in minutes):
DXA Staff Type:
VFA Other
Specify:
VFA Other Time (in minutes):
VFA Staff Type:

Service Period - when patient enters the office

Pre-Service
Enter time (in minutes for each patient) and enter staff type (RT, CNA, RN, LPN, other) for each pre-service item for DXA CPT Code 76075 and VFA CPT Code 76077.

48 Greet patient and provide gown
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

49 Obtain vital signs which may include height
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

50 Review medical questionnaire for pertinent history and risk factors
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

51 Pre-service patient education
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

Intra-Service
Enter time (in minutes for each patient) and enter staff type (RT, CNA, RN, LPN, other) for each intra-service item for DXA CPT Code 76075 and VFA CPT Code 76077.

52 Position patient and acquire images
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

53 Review images/compare with prior study(s) if available/manually correct any errors in acquisition/perform image analysis
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

Post-Service
Enter time (in minutes for each patient) and enter staff type (RT, CNA, RN, LPN, other) for each post-service item for DXA CPT Code 76075 and VFA CPT Code 76077.

54 Review with physician/print study/and/or transmit study to physician work station
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

55 Clean room and equipment
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

56 Other non-administrative clinical activity (please specify).
List other clinical activity in "DXA Other" or "VFA Other" as appropriate. Also enter the time and staff for that other clinical activity in the appropriate box.
DXA Other
Specify:
DXA Other Time (in minutes):
DXA Staff Type:
VFA Other
Specify:
VFA Other Time (in minutes):
VFA Staff Type:

Post-Service – when patient leaves the office
Enter time (in minutes for each patient) and enter staff type (RT, CNA, RN, LPN, other) for each post-service item for DXA CPT Code 76075 and VFA CPT Code 76077.

57 Copy or fax written and/or telephone reports from clinical staff (other than physician) to patient and/or referring physician
DXA Time (in minutes):
DXA Staff Type:
VFA Time (in minutes):
VFA Staff Type:

58 Other non-administrative clinical activity (please specify).
List other clinical activity in "DXA Other" or "VFA Other" as appropriate. Also enter the time and staff for that other clinical activity in the appropriate box.
DXA Other
Specify:
DXA Other Time (in minutes):
DXA Staff Type:
VFA Other
Specify:
VFA Other Time (in minutes):
VFA Staff Type:

PRACTICE EXPENSE UTILIZATION RATE QUESTIONNAIRE

59 Number and types of machines in practice:
Number of DXA machines:
Number of fan beam:
Number of pencil beam:
Machine model(s):

60 Manufacturer of machine(s) *Choose all that apply*:
☐ GE
☐ Hologic
☐ Norland

☐ Other, please specify

61 Number of DXA procedures done in an average month per machine:

62 Number of hours per week that practice (where machine is located) is open for operation:

63 Average number of days per month that practice (where machine is located) is open for operation:

64 Cost per year of any service contracts for DXA:

65 Cost per year of software upgrades

66 Cost of PAC/DICOM upgrades (ability to transmit radiographic images electronically)

Thank you for your time.

Appendix F

REFINEMENT PANEL PRESENTATION

Andrew Laster MD, FACR, CCD
American College of Rheumatology
September 26, 2006

My name is Andrew Laster. I am a board certified internist and rheumatologist and am here along with Dr. Sanford Baim representing the American College of Rheumatology. I thank CMS for allowing further comments on CPT code 76075, axial DXA of the spine and hip, often referred to as central DXA. I have been in private practice for the past 20 years and am part of a 6 member rheumatology group in Charlotte, NC. I am also a member of the International Society of Clinical Densitometry where I currently chair the Public Policy Committee. The ISCD is a 6000 member multidisciplinary nonprofit group that promotes excellence in the assessment of skeletal health. I would kindly ask that you identify in your packet the letter that ISCD authored to Dr McClellan as I will be referring to tables and figures on pages 12, 14 and 15 in my comments. I should note that The American College of Rheumatology has also authored a letter to CMS in support of the ISCD position.

The American College of Rheumatology objects to the proposed work RVU for central DXA of 0.2 which represents a 33% decline from its previous value of 0.3. As there exists no survey results or any other evidence to support the proposed reduction in work RVU, we will provide the individual panel members with compelling evidence standards that this would grossly under value the physician work component for central DXA. The evidence is based on the following:

- **Work complexity has in fact increased based on 2 separate surveys.**
- **The physician time is greater than originally noted.**
- **The current assigned value would create a rank order anomaly with other reference services.**
- **Incorrect assumptions were made in the valuation of the service. This is based on flawed methodology of the RUC working group and a survey that does not reflect the current composition of physicians performing this service.**

Following my comments Dr. Baim will provide data that supports assigning an RVU of 0.5 to the physician work component of CPT code 76075.

From conversations with the AMA's Department of Physician Payment Policy and Systems, we understand that 76075 was selected for review by CMS because of a marked increase in the number of claims from 1994 to 2004. Table 1 (page 12) documents 77,000 claims in 1994, 1.23 million in 1999 and 2.4 million in 2004.

- **Increases in other imaging services have raised concerns about over-utilization.** Importantly, at current 2004 levels, *DXA is still vastly underutilized* with HEDIS data from 2003 indicating that only 18% of female Medicare beneficiaries who had a fracture received either a BMD test or prescription for drug therapy within 6 months of the fracture date.
    - o **Unlike other imaging services that are specialty driven, central DXA has increasingly been performed by primary care physicians** (internists, family practitioners and gynecologists) as shown in Figure 1 on page 14 and Figure 2 on page 15.
    - o *In Figure 2 the proportion of studies ordered by different specialties is represented.* The percentage of studies obtained by radiology has remained relatively constant, while those obtained by rheumatology and endocrinology have declined. The percentage of studies obtained by primary care has seen a significant increase.

Increases in the number of central DXA studies obtained can be seen as an appropriate response to a number of Federal initiatives. CMS has incorporated central DXA testing as a key preventive

service and it is now part of the "Welcome to Medicare" Exam. The 2002 United States Preventive Services Task Force recommendations, the 2004 Surgeon General's report on Bone Health and Osteoporosis, and the August 2006 Federal Register revisions to Coverage of Bone Mass Measurement all highlight the essential role of central DXA in the diagnosis and monitoring of patients with osteoporosis.

The American College of Radiology which conducted the work survey for 76075 recommended that the 0.3 RVU value be retained. In contrast, the RUC recommended that the value be dropped to 0.2 (which represented the 25th percentile in the ACR survey) because (quote)***"the workgroup believed that the actual work is less intense and more mechanical than the specialty society's description of the work"***(closed quote). In conversation with the AMA, we understand that the workgroup which evaluated 76075 was composed of six physicians (a vascular surgeon, anesthesiologist, general surgeon, pulmonologist, psychiatrist and a family practitioner) only 1 of whom would be expected to be knowledgeable of the procedure. We believe this underscores one of the flaws in methodology used to derive the physician work RVU.

Work intensity for central DXA has in fact increased. In the validated ACR survey, 59% of respondents felt that the procedure had actually *increased in complexity* none indicated that complexity was less. *Only 12% of the respondents agreed with the statement that 76075 represents new technology that has become more familiar (i.e. less work).*In a few minutes, Dr Baim will present data from a larger survey of 453 physicians across multiple specialties with broad primary care representation that supports this aspect of the ACR survey.

The analysis and interpretation of a central DXA study is complex something I fully appreciate having been personally involved in the field for the last 20 years. To serve as a foundation to attain this body of knowledge, the ISCD offers a 10 hour bone densitometry course. **One hour is devoted to principles of DXA scan interpretation** and **one hour to principles of reporting of DXA scans.** An appropriate study involves reviewing images of the spine, hip and or forearm for optimal positioning, placement of bone and soft tissue markers, and regions of interest. Artifacts, degenerative changes and other abnormalities are noted and specific sites excluded from evaluation if appropriate measurements can not be made. The accepted interpretation of the **initial study** performed by the physician includes comments on the diagnosis using the WHO criteria where applicable, fracture risk, consideration of secondary causes, treatment recommendations and if and when the test should be repeated. The ability to provide an appropriate interpretation requires that the physician be aware of the patient's history either from their own medical records or a patient questionnaire regarding past medical history, family history, medications and a directed review of systems. Review of previous radiographs and other medical records may also be necessary.

It is important to note that the clinical vignette used in the most recent ACR survey was of a 66 year old woman who had a previous bone density and now was on hormone therapy. A repeat DXA study has been ordered. As more patients are identified and started on drug therapy, the interpretation and reporting of **follow up studies** increases the complexity even further. In addition to the above analysis, one must also now compare the 2 studies if done on the same machine to make sure that positioning and marker placement is comparable. A precision assessment obtained using the same machine and technologist is essential to determine if the change in BMD identified over time is significant. Interpretations now must also include recommendations on further therapy based on patient compliance, other possible secondary causes or failure of drug therapy to maintain or increase bone density. The complexity of DXA testing was acknowledged in the August 2006 Federal Register which stated that a "quality control system related to both the methodology and reporting of test results is important to ensure the validity of DXA analysis".

I would like to note that if the current physician work value of 0.2 is retained for central DXA, it will create a **rank order anomaly when compared with a far less complex test p (or peripheral) DXA which has a work RVU of 0.22 and radiographic absorptiometry which would have the same physician work RVU of 0.2.** A rank order anomaly exists when a CPT code is assigned an RVU that is inappropriate when compared to another CPT code RVU. **Rank order anomalies**

are evidence that a service is under or over-valued. Peripheral DXA systems measure a single site such as the forearm, finger or heel. Analysis and reporting of results takes far less time and is less intense. WHO criteria do not apply to this technology and determination of fracture risk is limited. The ability to monitor response to drug therapy has also not been demonstrated. **Radiographic absorptiometry** is a technique that is more than 50 years old in which a plain radiograph of the metacarpals and phalanges is obtained with an aluminum wedge included for standardization. A phalangeal bone density is derived.

Finally, we would note that for primary care physicians, who are increasingly performing DXA studies the appropriate reference codes may not be a radiologic exam but an E/M code since the generated report includes more than the densitometric diagnosis of normal, osteopenia or osteoporosis. As such it is helpful to compare 76075 with 99212 which has a physician work RVU value of 0.45 and 99213 with an RVU value of 0.67 in 2006 and a proposed value of 0.92 for 2007.

To summarize, the American College of Rheumatology believes that flaws in methodology have been demonstrated and it is not appropriate to reduce the physician work value of CPT code 76075 to 0.2. The time required to perform this test, coupled with its increasing complexity warrant a work RVU value of greater than 0.3. Central DXA is an imaging test commonly performed by primary care physicians that incorporates many of the elements of Evaluation and Management codes.

Thank you again for your consideration.

Refinement Panel Presentation
Sanford Baim MD, FACR, CCD
American College of Rheumatology
September 26, 2006

Allow me to introduce myself. My name is Sanford Baim. I have been a board certified internist and rheumatologist and member of the American College of Rheumatology for over 28 years and practice rheumatology with 8 colleagues in Milwaukee Wisconsin. During this time I have participated in rheumatology and osteoporosis clinical research and teach medical students and family practice residents from the Medical Collage of Wisconsin and internal medicine residents from the University of Wisconsin School of Medicine and Public Health as an associate clinical professor of medicine. Presently I am an instructor for the ISCD bone densitometry and Vertebral Fracture Assessment educational courses and previously coordinated ISCD activities for procurement of the new CPT code 76077 Vertebral Fracture Assessment using DXA and co-participated with ACR in the VFA work RVU survey that was presented to the RUC in 2004. I am presently Vice President of the ISCD.

I would like to use the next few moments to present objective information from the central DXA 76075 RVU work survey from ACRad in 2005 and the 2006 Clinical Society survey, orchestrated by the ISCD, that will support the American College of Rheumatology's premise as outlined by Dr. Laster.

The 2004 data in figure 1 illustrates that approximately 40% of DXA exams are performed by radiologists and 60% by clinicians. As such, it is important to have both radiologists and clinicians input regarding DXA interpretation. To this end, the American College of Rheumatology, the International Society for Clinical Densitometry, the American Society for Bone Mineral Research, the American Association of Clinical Endocrinologists, The Endocrine Society, and the North American Menopausal Society recently conducted a physician work survey identical to the 2005 ACRad central DXA survey providing supplemental data from clinicians that has been heretofore not available. This clinical society survey was performed to allow CMS to base their reappraisal of the work RVU for central DXA on more inclusive information.

The clinical society survey was sent electronically in August 2006 to 2884 members of the above noted societies with 453 individuals returning completed surveys. The composition of respondents to the survey included 30% primary care physicians (IM, OB/GYN, FM, Geriatricians), 37% rheumatologists and 22% endocrinologists. 16% practiced in rural communities, 42% in suburban communities, and 42% urban centered practices. 28% were in solo, 39% single specialty, 24% multi-specialty, and 9% medical school practice.

Salient results of the clinical society survey are as follows:

1. 68% of respondents felt that the work to perform this service had changed in the past 5 years.
2. 61% felt that this service was more complex (more work) similar to the ACR survey of 59% thus underscoring the increased complexity of CPT code 76075.
3. The median time to perform central DXA was 25 minutes with 5 minutes for pre-service, 10 minutes required for intra-service and 10 minutes for post-service.
4. The E&M code 99213 (established outpatient visit of low/moderate severity 15 minutes) that equates to a **work RVU of 0.67** was selected as the key reference code by the greatest number of respondents at 20%.
5. **The median estimated physician work RVU for central DXA was 0.5. The 25th percentile was 0.35 and the 75th percentile was 1.00.**

The results of the clinical society survey thus substantiate the ACR survey in demonstrating that physician work and complexity has increased over the last 5 years. In contrast to the ACR survey, clinicians felt the time required to perform this service is substantially greater. This would suggest clinicians engage in greater time and effort not fully appreciated by the 2005 ACR survey. As both the physician time to perform the procedure and work complexity have increased, it is appropriate that CPT code 76075 be assigned a higher physician work RVU.

To summarize the key points from the presentations of Dr. Laster and myself:

- Both surveys clearly indicate that the work complexity has increased with time rather than diminished as speculated by the RUC workgroup.
- The clinical society survey disclosed increased time for the interpretative work of central DXA.
- The greatest percent of physicians that provide this service are primary care physicians, rheumatologists, and endocrinologists. Unlike a radiologic study but similar to an E/M visit, a DXA report provides more than just a densitometric diagnosis in that the assessment of fracture risk incorporates the patients medical history and includes treatment and follow up recommendations. As such an appropriate reference code is 99213.
- There are no data to support the lower RVU of 0.2 proposed by the RUC workgroup.
- The ACR survey supports retention of an RVU of 0.3
- The clinical society survey supports a higher RVU of 0.5 that is representative of a broad base of clinicians that interpret DXA exams and should be strongly considered in light of its significant sample size of 453 respondents.
- If the incorrect assumptions by the RUC working group are maintained the RUC recommendation for 76075 central DXA work RVU of 0.2 creates a profound rank order anomaly in respect to 76076 peripheral DXA and 76078 radiographic absorptiometry having work RVUs of 0.22 and 0.20 respectively.

Lastly, the purpose of the 5 year review is to ensure that physician services assigned a CPT code are appropriately valued. The danger of **under valuing** a service as cited in the MEDPAC report to Congress in March of this year is that:

- Physicians may opt not to provide the service which threatens access to care.
- Medicare is not a good steward by not paying enough for the under valued service and thus not spending the taxpayers money wisely.

The American College of Rheumatology in conjunction with our sister societies, the American Association of Clinical Endocrinologists, the American Society for Bone Mineral Research, the International Society for Clinical Densitometry, The Endocrine Society, and the North American Menopausal Society believe that if these short sighted cuts in 76075 central DXA are enacted, the initiatives that CMS has championed to increase the diagnosis and treatment of osteoporosis will be severely undermined. The American College of Rheumatology appreciates this opportunity

to comment on CPT code 76075. We encourage our fellow panelists to very carefully weigh the consequences of the proposed dramatic reductions in reimbursement for central DXA, the only instrument recognized by CMS for both the diagnosis of osteoporosis and monitoring response to therapy.

Appendix G

Effect of Changing Physician Work and PCI on 2008 MPFS

Variable	Work RVU	PE RVU	MP RVU	Total RVU	CF $37.90	CF $30.85
Sum of all direct PE corrections	0.18	2.52	0.18	2.88	**$109.15**	**$88.85**
+ Physician work (2006 MPFS)	0.30	2.52	0.18	3.00	**$113.70**	**$92.55**
+ Physician work (2006 Clinical Society Survey)	0.50	2.52	0.18	3.2	**$121.28**	**$98.72**
+ physician work + new PCI of 0.92	0.50	2.58	0.18	3.26	**$123.55**	**$100.57**

Appendix H

Variable	77080-TC			77080-26	77080	CF $37.90	CF $30.85
	DirectPE	IndirectPE	Total PE	Total PE	Total PE		
Baseline ($41,000)	0.31	0.23	0.54	0.06	0.60	$36.38	$29.62
Baseline ($85,000)	0.41	0.28	0.69	0.06	0.75 (0.79)	$42.07	$35.48
Utilization	0.99	0.60	1.60	0.06	1.66	$76.56	$51.21
Maintenance	0.42	0.29	0.72	0.06	0.78	$43.21	$35.16
Time/study	0.51	0.37	0.88	0.06	0.94	$49.27	$40.11
Minutes/yr	0.43	0.30	0.73	0.06	0.79	$43.59	$35.48
All of above	1.53	0.92	2.46	0.06	2.52	$109.15	$88.48

This slide looks at the effect of changing different direct Practice Expense inputs on the total reimbursement for central DXA (77080) based on the current Conversion Factor, physician work RVU and malpractice RVU. Calculations of direct PE, indirect PE, and total PE are based on a spreadsheet/formula provided by CMS.

Total PE RVU +MP (0.18) + work (0.18) =(total PE RVU + .36) x CF = total reimbursement

- The initial equipment cost was listed as $41,000 but changed in the final document (CMS 1321-FC) to $85,000 based on the fact that fan beam DXA rather pencil beam DXA is the standard.
- Utilization rate changed from 0.5 to 0.13
- Maintenance changed from 0.05 to 0.08
- Time /study changed from 30 minutes to 43 minutes.
- Minutes/year changed from 150,000 to 131,340
- All of above: examines effect on reimbursement if machine cost, utilization rate, maintenance, time/study, and minutes/year are all changed. Even if all the direct PE inputs are corrected the total reimbursement for central DXA remains below the operating cost for most practitioners. This implies that there are additional errors in input for indirect PE.

Submitter : Mr. Bryce Gillespie **Date:** 08/31/2007

Organization : Canby Orthopedic and Sports Physical Therapy

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My Name is Bryce Gillespie ATC, LAT. I have recently graduated from from an undergraduate athletic training program, passed my national certification exam with the NATABOC. I have recently interned at the Nike WHQ, and as of 2 weeks ago I am the Head athletic trainer for Canby orthopedic and sports physical theraphy.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As a certified athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Bryce Gillespie ATC, LAT

Submitter : Dr. Paul Schellhammer **Date:** 08/31/2007

Organization : American Urological Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15110-Attach-1.DOC

1516

American Urological Association

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August 31, 2007

Herb B. Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Kuhn:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, we are pleased to submit comments on the Medicare physician fee schedule 2008 proposed rule. Our comments address resource-based practice expense relative value units (RVUs), physician self-referral and reassignment provisions and the physician quality reporting initiative (PQRI).

RESOURCE-BASED PRACTICE EXPENSE (PE) RELATIVE VALUE UNITS (RVUS)

Discussion of equipment usage percentage

Currently, the Centers for Medicare and Medicaid Services (CMS) utilizes a 50 percent utilization rate for all equipment items that are included in the direct cost inputs used to calculate practice expense relative value units. In the proposed rule, CMS states "we do not believe that we have sufficient empirical evidence to justify an alternative proposal on this issue". CMS then requests comments for alternative percentages and approaches that differentially classify equipment into mutually exclusive categories with category-specific usage rate assumptions and welcomes any empirical data that would assist in these efforts. The AUA strongly supports a differential classification for equipment to reflect different usage rates, as utilization rates of equipment vary dramatically by equipment type depending on the practice type of the physicians using the equipment and the sites of service in which the equipment is used.

We recommend that CMS, in conjunction with specialties, possibly through the American Medical Association (AMA) Relative Value Update Committee (RUC) conduct a survey to gather data on use rates of various equipment. The AUA is willing to assist in such a process. However, until such data is collected, the AUA agrees with CMS's decision to maintain the equipment utilization rate at 50 percent.

Nonfacility Inputs for CPT Code 52327
In the proposed rule, CMS says:

> We received comments from the society representing urologists requesting that we remove all of the nonfacility PE inputs for CPT code 52327, *Cystourethroscopy (including ureteral catheterization); with subureteric injection of implant material.* The specialty society reasoned that the nonfacility PE value is inappropriate since the procedure is never performed in the physician office; it is specific to the pediatric population; and, as such, is always performed with general anesthesia. We agree with the specialty society that this procedure is incorrectly valued for the nonfacility setting and propose to accept their recommendation to remove the nonfacility direct PE inputs and have revised the PE database accordingly.

The AUA is pleased that CMS agrees with our recommendation to remove the direct cost practice expense inputs from the non-facility setting for CPT code 52327. However, based on our review of the data file posted on CMS's website with the proposed rule, it appears that the non-facility inputs for CPT code 52327 have not been removed from the database, so we ask that CMS confirm the removal of the inputs for the final rule.

PHYSICIAN SELF-REFERRAL PROVISIONS

The AUA understands that CMS is responsible for ensuring that appropriate care is provided to Medicare beneficiaries. Many of the sweeping changes proposed in this rule for physician self-referral and reassignment rules, however, will have the effect of potentially hindering quality, decreasing efficiencies, and limiting access to beneficial and convenient care. If these proposed amendments are implemented as suggested, they will require the renegotiation of existing arrangements that were carefully structured to meet current regulations specifically permitting such arrangements. The AUA believes many of these changes could be better implemented through more narrow policy changes and are not needed to protect the Medicare program against fraudulent or abusive arrangements. Below, the AUA offers recommendations to narrow the proposed rules in ways that will limit their impact on low-risk, beneficial arrangements, while still preventing those that are abusive.

I. In-office Ancillary Services Exception

CMS is requesting comments on whether certain services should qualify for the in-office ancillary services exception, including complex tests and services that are not immediately necessary for the diagnosis or treatment of a patient. For many reasons, the AUA feels that

complex tests (such as laboratory tests and diagnostic imaging) and therapeutic services (such as radiation therapy and cryosurgery) should continue to be covered under the in-office ancillary services exception. Performing certain complex tests and therapeutic treatments in a physician's office benefits patients, even where the tests may not provide the physician with an immediate result or the treatment may not be provided immediately.

The AUA feels strongly that government policy should permit the practice of good medicine, rather than thwart advances in healthcare. When the Medicare system was instituted it was specifically designed to allow physicians to retain their autonomy over professional decision making. In fact, the statute provides that "[n]othing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395 (1992). The Senate Finance Committee Report also stated that physicians would retain their autonomy. "The bill specifically prohibits the Federal Government from exercising supervision or control over the practice of medicine, the manner in which medical services are provided, and the administration or operation of medical facilities....The responsibility for, and the control of, the care of the beneficiaries rests with the hospitals, extended care facilities, the beneficiaries' physicians, etc." S. Rep. No. 404, 89th Cong. 1st Sess. 54 (1965) reprinted in 1965 U.S. Code Cong. & Admin. News, 1943, 1965. The Senate Finance Committee also determined that "the physician is to be the key figure in determining utilization of health services—and provides that it is a physician who is to decide upon admission to a hospital, order tests, drugs and treatments, and determine the length of stay." *Id.* at 40-41, 1965 U.S. Code Cong. & Admin. News at 1986. Consistent with Congress' original intent to allow physicians to direct their patients' treatment according to their individual medical judgment, the in-office ancillary services exception should include tests and therapies that physicians believe are beneficial to patients when provided in the physician's office.

The AUA is concerned that limiting the tests and services that qualify for the in-office ancillary services exception undermines a physician's medical judgment and has the potential to create serious, unintended consequences, including jeopardizing patient care. One such consequence is decreasing necessary follow-up care provided to Medicare beneficiaries. Compliance with follow-up tests or treatment falls off dramatically when a patient needs to schedule follow-up tests and treatments with a second medical provider. For example, a patient who comes to see a urologist is significantly less likely to follow-up with urine cultures, renal ultrasounds, and other tests that are ordered by the urologist, if the patient is required to make a second appointment with another provider to perform the testing. Even for a compliant patient, traveling elsewhere for treatment or tests, such as the hospital, almost certainly means increased wait time. This could lead to greater discomfort and pain for a patient. It is much quicker, for example, for a patient with a potential kidney stone to be diagnosed and treated by a urology group that can perform a CT scan in the urology group's office. The urologist can rapidly determine if a stone exists and treat the patient immediately, rather than have the patient go to a hospital, where there is likely to be a long wait before tests can be done to determine existence of a stone and then a further wait before treatment begins.

Limiting tests to only those where results are immediately available and used during the same office visits would decrease the level of service provided to the patient in both convenience and

quality. In modern medical practice, most diagnostic test results are not immediately available after collection of the specimen. In the specialty of urology, three examples are: urine cultures, prostate specific antigen (PSA) blood tests, and prostate pathology. These tests assist in the treatment of the patient condition that was evaluated during the office visit, even if those results are not immediately available. Obtaining these tests from the patient during the visit as opposed to requiring the patient to go to some offsite and frequently distant collection center offers patients a significant advantage and frequently makes the difference as to whether the patient is able to have the test done or not. Having direct access to results and immediate correlation with other patient data improves the quality of care provided. Tests done under the auspices of the physician offer direct control over collection, transportation, and analysis with consistent and enhanced quality.

Complex tests—such as prostate biopsies and biopsy cores—provided under the current exception for in-office ancillary services have led to better patient care. Prostate biopsies, as well as the number of cores taken for each biopsy, is a direct result of the evolving understanding of the nature of prostate cancer rather than, as some allege, the formation of urology specialty lab arrangements between urologists and pathologists. This is borne out by the fact that the number of prostate biopsies as well as the number of cores taken during each prostate biopsy session have increased across all types of urology practice, not just those with these arrangements. These types of services, provided in-office, allow physicians to more effectively monitor their patients.

While it is true that there has been an increase in the number of biopsies and biopsy cores, there are several factors relating to the medical practice of diagnosing and treating prostate cancer that account for these increases, including the following:

- The evolution of using ultrasound guided biopsies to find early, curable prostate cancer;
- Medicare approval of PSA screening, which has led to a greater referral of patients with elevated PSA values;
- Greater medical indications for when to perform biopsies (i.e., lower cut point for PSA, PSA velocity, free PSA, etc.).

Urologist/pathologist arrangements do not cause over-utilization or abuse. Urology practices that specialize in urologic oncology may produce higher numbers of prostate biopsies, for instance, but that should be expected since, as a practice that sub-specializes in urologic oncology, these practices serve a patient population that is more likely to require prostate biopsies. Further, with medical advances, there is ample research supporting the increase in the number of biopsy cores.

Although there is no specific sub-certification for urologic pathology, concentrating experience in the hands of pathologists dedicated to evaluating a high volume of urologic pathology specimens increases the quality of care for Medicare beneficiaries. Such a benefit is evident in the literature, where reproducibility of prostate pathologic diagnoses such as high-grade prostatic intraepithelial neoplasia (PIN) is high among those pathologists who specialize in urology and low among those who do not specialize in urology (Epstein, J. et. al., "Prostate Needle Biopsies

Containing Prostatic Intraepithelial Neoplasia or Atypical Foci Suspicious for Carcinoma: Implications for Patient Care," J. Urol.: 2006;175:820-834). Additionally, the integration of a clinical urologist, who understands the patient's medical history, and a pathologist who communicates regularly with the urologist and has immediate access to the patient's medical record provides a better, more reliable interpretation of the pathology specimen.

Similarly, patients can receive better care when physicians closely collaborate with respect to therapeutic services. Many urology practices have begun to sub-specialize in urologic oncology. Urologists who sub-specialize in urologic oncology often contract or employ radiation oncologists who also specialize in prostate cancer. These physicians are going to have the most in-depth, up-to-date knowledge regarding treatment options for prostate cancer. Additionally, these urology practices find both efficiency and patient care are improved where the urologists have greater interaction with other physicians involved in the patient's care, such as pathologists and radiation oncologists. When urologists work with radiation oncologists, they are able to draw on their individual expertise, while identifying the best treatment modalities for an individual patient as a result of their collaborative approach to treatment. This collaborative approach provides a patient the ability to discuss all potential treatment options with physicians who specialize in those treatments and who will work together to develop a single treatment plan. Otherwise, a patient armed with referrals to separate specialists, may be left discussing various options individually with physicians and then left to decide, among what might be conflicting advice, the best treatment option. Patient satisfaction and patient care benefit where physicians can function as a specialized team devoted to close communication and achieving high quality patient outcomes.

CMS data made available to the public does not support any evidence of fraudulent billing, over-utilization, or abusive billing patterns by urology groups that contract with pathologists for prostate biopsy interpretations or with radiation oncologists for radiation therapies. Urologists operating in these practices report decreased times for their patients between diagnosis and treatment, increased cooperation and information sharing between treating physicians, an overall increase in patient satisfaction, and higher quality patient outcomes as a result of increased physician specialization in the treatment of prostate cancer.

The patient's health needs should always be the driving force behind any medical care. Responsible treatment provided by qualified, board certified physicians should never be forbidden simply because there may be legitimate profit involved. Just as financial incentives should never be the reason behind choosing a particular test or treatment, they should never be used to deny the highest quality care. AUA submits that patients of urology practices, who receive pathology services from pathologists associated with the urology practice and radiation treatment from associated oncologists, receive the same or better care than they would receive if seen by a urologist who sends biopsies to an unknown pathologist or refers patients needing radiation treatment to an unknown radiation oncologist. The relevant tests and therapies are performed in all cases by qualified specialists (i.e., pathologists and radiation oncologists) – the only difference is the quality of the relationship between those specialists, the degree to which those specialists specialize in urological cancers, and the time the patient spends traveling and waiting in between office visits.

When government regulation aimed at protecting Medicare beneficiaries from fraud and abuse spills over into areas that are more efficiently—and appropriately—overseen by professional societies, the result is unsatisfactory to all. The decision of who performs the technical and professional component of a test or a therapeutic service and the setting in which those tests and procedures should be performed are matters of medical judgment best left to professionals and professional societies. CMS should not use regulations aimed at eliminating fraud and abuse to resolve a turf battle between medical specialties.

II. Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)

CMS is proposing to amend the reassignment and purchased diagnostics testing rule. Some of these changes are different from those previously proposed in the 2007 Medicare Physician Fee Schedule. The AUA submitted comments to the 2007 Medicare Physician Fee Schedule noting that the proposed rule was too broad and unnecessarily applied the purchased diagnostic test rules to reassigned claims, thus effectively eliminating some of the billing rights granted under the reassignment rules. The AUA commends CMS for not adopting portions of the previously proposed rule that would have (i) applied the purchased interpretation rules in the context of reassignments, and (ii) changed the definition of "centralized building." Nevertheless, the AUA believes that the rule—as proposed in the 2008 Medicare Physician Fee Schedule—unfortunately remains too broad, thus prohibiting arrangements that benefit patients, pose no risk of abuse and radically change the way physicians practice medicine.

As proposed, the rule would impose an anti-markup provision on the interpretation portion of a purchased diagnostic test to match the anti-markup provision already imposed on the technical component of such tests. The anti-markup provision would apply whether the billing entity purchases the technical or professional component outright or receives a reassignment of the right to bill. The only exception to the anti-markup provision is where the individual performing the test is a full-time employee of the billing entity. To try to avoid what CMS believes will be efforts to "game" these rules by inflating the physician's net charge, CMS is proposing to define the performing physician's "net charge" to exclude costs of equipment and space leased to the performing physician. CMS is also seeking comments as to whether it should include a specific anti-markup provision for the technical component of tests provided in centralized buildings by part-time or leased employees.

The AUA continues to take the position that the proposed rule is an unnecessary change that would alter the standard ways in which physicians provide care to patients. For example, when urologists employ or contract with pathologists to provide pathology services for their patients, the urologists and pathologists have the opportunity to collaborate. Patient care improves because the results of testing are more timely and of higher quality. Taking the time to have tests mailed and then waiting for a faxed result wastes time. As explained in the section above concerning in-office ancillary services, pathologists who routinely review only urological specimens have more accurate results. Faster results, along with the opportunity to collaborate with pathologists, permit urologists to better manage their patients' care.

In addition, the AUA remains concerned that the proposed rule would render meaningless the reassignment rules. By imposing the purchased diagnostic testing requirements onto the reassignment provision these proposed rules effectively eliminate the reassignment rules, including any reassignment pursuant to the contractual arrangement exception expressly created by Congress. Although CMS states that under Section 952 of the Medicare Modernization Act, it only needs to recognize contractual reassignments to the extent that the arrangement meets program integrity and other standards as determined by the Secretary, Congress surely did not mean that this statutory provision could be administratively repealed by merging it into the already existing purchased diagnostic test rules.

Under the proposed rule, if a technical or professional component of a diagnostic test is performed by a part-time employee of, or an independent contractor physician to, a physician group, the physician group would not be able to "mark up" the test. This concept of a "mark-up" is misplaced where a physician is part-time or contracts with a group, and works in the group's location. In this situation, the physician may be paid for many services, not just diagnostic testing, and may be paid a salary, hourly, or other rate that does not take into account the number of tests performed or the reimbursement amounts for such tests. By way of example, a urology group that utilizes a urologist as a part-time employee or an independent contractor, as opposed to a full-time employee, would need to apply the anti-markup requirements. Accordingly, the technical or professional component of an ultrasound performed by a part-time employee or independent contractor urologist during a patient's visit to this urologist would not be able to be "marked up" by the physician group. This standard will be very difficult to meet since, in situations like those described above where each test is not purchased individually from the independent contractor or part-time employee, there will be no per-test charge against which to identify or measure a mark-up.

With respect to applying the anti-mark up rules to part-time employees, the AUA believes that this new proposed standard is excessively broad. The previously proposed rule was limited to part-time, *contractual* arrangements and was, therefore, narrower. The new proposed rule would effectively prohibit part-time employed physicians from participating in a physician group. The new proposed rule is worded in a way that diagnostic tests performed by a physician who is employed by one physician group, but does not practice full-time would fall under the anti-markup rules. Preventing part-time employees from performing or interpreting tests is a discriminatory burden on employees who need/want part-time work and an undue burden on practices that don't require full-time employees. The AUA recommends that with respect to part-time employees or independent contractors, the anti-markup provisions should not apply where the diagnostic test is performed in a location that meets the "same building" test under the in-office ancillary services exception and the physician reassigns his or her right to payment. Further, the anti-markup provisions should be limited to situations where tests are purchased on a per-test basis.

The proposed rule would also have a negative, and potentially unintended, impact on existing shared laboratory and block lease arrangements. For example, the proposed rule would prohibit a "mark-up" under a block lease where equipment, space, and the services of a technician are paid for in set amounts for the exclusive use of "blocks" or units of time. Under these arrangements one group practice has exclusive supervision and control over the equipment,

space and technicians during its "block" of time and the space and services are considered part of the group practice. Services provided under block lease arrangements are generally protected under the in-office ancillary services exception, requiring them to be performed in the "same building" as a medical group's provision of some non-designated health services. Although these arrangements meet a Stark exception, the proposed rule would treat them differently than if the services were performed in a building solely used by the group practice simply because the technicians and professionals interpreting the tests are not full-time employees. CMS has not expressed a fear of abuse with respect to these arrangements, yet this new, broader rule would prevent them. Further, CMS has recognized in previous regulations the permissibility of shared laboratories. However, in a shared laboratory, it is arguable whether the technicians are full-time employees of any of the group practices sharing the laboratory. The AUA seeks clarification that shared laboratories and other shared DHS services, as well as block lease arrangements, would not be subject to the anti-markup provisions.

With respect to testing performed in centralized buildings, such as laboratory tests or diagnostic imaging, in many circumstances there is no difference between the quality and efficiency of testing performed at a group practice's centralized building and those performed in the "same building". In fact, laboratories located in centralized offices allow groups with multiple office sites to perform the services in a consistent way and without unnecessarily duplicating services. However, the AUA acknowledges that there is the possibility that, for example, placing too many laboratories in a single, centralized facility may reduce the ability for the urologists and pathologists to collaborate. Accordingly, the AUA recommends that CMS consider allowing part-time pathologists and laboratory technicians to perform services in centralized buildings where the physicians and technicians, who are either employed part-time, or are part-time leased employees, only perform services for five physician practices or fewer. In Florida, for example, clinical laboratory directors are permitted to supervise up to five laboratories at a time. F.A.C. § 64B3-13.001(4). Allowing part-time pathologists, while limiting the number of labs in which they can provide services to five, permits the collaborative effort that results in timelier, higher-quality results for Medicare beneficiaries.

The AUA is not opposed to the proposed anti-markup provision of the professional component *per se*; however, the proposed definition of "net charge" fails to recognize that there are circumstances under which the costs of equipment and/or rent *should* be included in the net charges. For example, if a urology practice purchases laboratory equipment, employs a laboratory technician to prepare slides, hires a pathologist on a part-time basis to supervise the technical component of pathology services and to perform the interpretation of such services, and performs the billing for all of the services, the regulations remain unclear as to what amount the urology practice can bill Medicare for such services. The group should be able to bill for the pathologist interpretation as well as all of the associated overhead whether the group bears the overhead costs or the pathologist bears those costs and charges the practice. Even without the mark-up, these costs need to be included in the charges; otherwise, these types of arrangements—which are otherwise appropriate and beneficial to Medicare beneficiaries — would become unworkable. The AUA believes that CMS should clarify that the overhead expenses (such as equipment, space, supplies, utilities and billing services) that a physician practice incurs when providing the professional component of diagnostic tests are an appropriate part of the charge to Medicare.

III. Unit of Service (Per Click) Payments in Space and Equipment Leases

CMS is proposing to change the existing language of the space and equipment lease exceptions to prohibit payments based on per-unit-of-service where payments "reflect services provided to patients who were referred by the lessor to the lessee." The AUA strongly opposes this revision.

In the proposed Stark II Rule published in 1998, CMS took a position nearly identical to the one currently proposed, *i.e.*, that time-based – or "per-click" – payments reflect the volume or value of a physician lessor's own referrals and are therefore not permissible. In the final Stark II, Phase I Rule, however, CMS abandoned that view and specifically allowed such arrangements. The AUA feels strongly that CMS's reversion to its 1998 position is erroneous for several reasons.

Most significantly, in light of the legislative history relating to the space and equipment lease exception, CMS lacks the authority to take such a position regarding unit-of-service-based payments. In fact, CMS referred to this legislative history in the final Stark II, Phase I Rule:

> We have reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals.
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> * * *
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> Applying Phase I of this rulemaking to the lithotripter example noted above, the "per use" rental payments would be protected, even for lithotripsies performed on patients referred by the physician owner, provided that the "per use" rental payment was at fair market value, did not vary over the lease term, and met the other requirements of the rental exception. In other words, if the "per use" payment is fair market value, we will not require a separate payment arrangement for use of the equipment on patients referred by the physician-owner.

66 Fed. Reg. 876 (January 4, 2001).

CMS's position in 2001—concluding that per-use payments did not vary with the volume or value—is not surprising given the clear legislative intent to permit payments based on per-unit-of-use, *without any caveat regarding patients referred by the lessor*, as evidenced in the 1993 House Report on the Stark legislation:

> The conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of the time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement.

H.R. Conf. Rep. No 213, 103d Cong., 1st Sess. 814 (1993), *reprinted* in 1993 U.S.C.C.A.N. 1088, 1503.

The AUA believes that CMS's current position regarding unit-of-service-based payments under the lease exception is both in conflict with Congressional intent and unnecessary. First, CMS provided no specific evidence of increased utilization due to the current lease exceptions. Further, payment per-service is the same irrespective of how many patients are referred. In practice, compensation to the physician-owner does not take into consideration the actual number of patients referred, but is based on a per capita distribution or RVUs performed by each physician. In addition, per-click leases are often the best measure of fair market value as it ensures that payment is only made for actual services provided. Furthermore, per-click arrangements are common in the industry, not only for physician-owned entities, but for *non*-physician-owned entities as well. Per-click arrangements also allow fixed-costs to be appropriately spread out over *all* clicks, thus providing a more accurate reflection of fair market value. Per-click arrangements also may reduce over-utilization as a lessee who must pay a fixed amount lease may be more likely to use the equipment to ensure that the lease costs are covered. Finally, per-click arrangements create efficiencies because they permit expensive equipment to be utilized by multiple parties. Without this exception, certain services may be unavailable to patients, particularly in rural areas where practices are too small to independently purchase such equipment.

The AUA would also like emphasize that, for per-click arrangements for lithotripsy services, there is virtually no risk of over-utilization. This is so for two reasons. First, lithotripsy is a *therapeutic*, not a *diagnostic*, procedure. As noted by CMS, "the procedure itself apparently documents the medical necessity to prescribe it. As we understand ESWL, the kidney stone is located, identified, and the progress of the therapy is recorded as part of the visualization process." 63 Fed. Reg. 1682 (January 9, 1998). Second, lithotripsy cannot be over-utilized because of the strict standards of care for the use of a lithotripter. The AUA's Nephrolithiasis Clinical Guidelines Panel has published guidelines on *The Management of Staghorn Calculi* and *The Management of Ureteral Stones*. These publications contain clearly defined guidelines for physicians to follow in the treatment of ureteral and kidney stones—after a stone has been diagnosed—based on the size and location of a stone and the clinical status of the patient. In addition to formal protocols for the appropriate management of stone disease, all accredited lithotripsy facilities have thorough utilization review and quality assurance programs in place to ensure physician treatments are appropriate. Many facilities incorporate physician and staff review of each case prior to treatment to confirm its appropriateness and likely clinical efficacy.

Per-click arrangements involving other non-DHS therapeutic procedures such as green light laser procedures and cryotherapy would also be affected by the proposed change to the space and lease equipment exception. As with lithotripsy, these are therapeutic services, and there is little or no risk that these types of services will be over-utilized.

IV. "Set in Advance" and Percentage-Based Compensation Arrangements

CMS is proposing to add language to the special rules on compensation that would limit the use of percentage compensation arrangements to those that directly result from personally performed

physician services. As proposed, the new rule would effectively eliminate from protection those arrangements involving equipment and office space that are leased based on a percentage of revenues generated by the equipment or space. The AUA opposes such a limitation on the "set in advance" criteria.

CMS has expressed concern that arrangements involving equipment and office space that are leased on the basis of a percentage of the revenues raised by the equipment or space are potentially abusive. However, CMS has not provided any studies that show there to be over-utilization. Moreover, the rule should not apply to therapeutic procedures. First, as is noted above, therapies such as lithotripsy, green light laser procedures, and cryotherapy are *therapeutic*, not *diagnostic* and therefore are not performed unless there is an appropriate diagnosis. Second, these types of services cannot be over-utilized because there are extremely strict standards of care that apply for the use of the equipment used to perform these services.

V. Services Furnished Under Arrangement

CMS is proposing to change the definition of the term "entity" to address its stated concern with over-utilization of services provided "under arrangement." The AUA believes that this rule should be limited to diagnostic imaging services and is also seeking clarification from CMS that such a rule would not implicate arrangements where hospitals and physicians jointly own lithotripters, *i.e.*, that lithotripsy is not considered a DHS. The controversy over whether lithotripsy is a DHS was resolved in a federal court case, *American Lithotripsy Society v. Thompson*, D.D.C., 01-01812, July 12, 2002. The court in that case found that although lithotripsy may be performed "under arrangement" as an inpatient or outpatient hospital procedure, it was not a DHS.

The AUA further believes that the proposed rule would have a negative impact on access to state-of-the-art health care. Physician specialists are more likely than hospitals to obtain and make available new technologies through companies providing services "under arrangement" to hospitals. This is true not just because physicians are motivated by their desire to provide the best care to their patients, but because hospitals—although equally interested in patient care—are motivated by the need to balance the sometimes competing interests of varying specialties. State-of-the-art equipment made available by physician-owned companies fills the critical gap between what advances in technology can offer and what hospitals can afford to provide.

Moreover, when physicians perform therapeutic services in a hospital setting the physician has a particular interest in ensuring that the equipment is available and of high quality. This scenario is analogous to physician ownership in an ambulatory surgical center (ASC) where the physician performs services for his or her patients at the ASC. It is unlike imaging services, where a physician, who may have an ownership interest in an imaging joint venture, refers a patient for a test, but does not perform the technical component of the test or often the interpretation. The reimbursement rules for "under arrangement" services support a differentiation between diagnostic and therapeutic services. Therapeutic services provided "under arrangement" can only be provided in the hospital or a provider-based department of a hospital. 42 CF.R. § 410.27(a)(1)(iii). Thus, CMS's concern that patients are receiving services in a less medically-

intensive setting than the hospital would be eliminated. Accordingly, the AUA recommends that, at most, CMS only apply its proposed rule to diagnostic testing and not therapeutic services.

The AUA understands that CMS is looking for a definition of "entity" that is more "straightforward" than the definition proffered by MedPAC; however, the AUA believes that the term "causes to be submitted" in CMS's proposed definition is unclear and is susceptible to varying interpretations. The AUA believes that if CMS finalizes changes to the definition of "entity" it should be limited to diagnostic tests and incorporate the definition proffered by MedPAC, which would only include an entity which derives a substantial portion of its revenue from a provider of DHS.

VI. Stand in the Shoes

CMS has expressed concerns about the scope of protection afforded indirect financial relationships and has asked for comments regarding a rule whereby a DHS entity, such as a hospital that owns or controls another DHS entity, would "stand in the shoes" of that owned or controlled entity. The AUA is seeking clarification from CMS that such a rule would not implicate arrangements where hospitals and physicians jointly own lithotripters, *i.e.*, that lithotripsy, whether performed in a hospital or elsewhere, is not considered a DHS.

VII. Alternative Criteria for Satisfying Certain Exceptions

In response to comments that even "innocent and trivial" violations of the Stark law could result in huge penalties, CMS has requested comments on amending certain of the current exceptions by establishing a new "alternative method for compliance" provision. The AUA commends CMS for addressing unintentional violations of Stark and attempting to avoid potentially absurd enforcement actions when a provider discovers inadvertent, "technical" violations of the self-referral laws. Nevertheless, the AUA opposes a rule that would require individual determinations—made by CMS at its sole discretion—for *each* self-disclosure. The criteria proposed by CMS for the alternative method of compliance provision are very clear and would provide ample protections against abuse. To avoid the tremendous administrative burden on both CMS and providers, the AUA suggests that, if the criteria under an alternate method are met, and providers self-correct within 30 days of discovery of the non-compliance, self-disclosure should be optional rather than mandatory. Further, the "alternative method of compliance" should be a separate exception that would apply to arrangements that—but for the technical violation—would fall within another exception.

TRHCA-SECTION 101(b): PQRI

Consensus Organizations and Consensus-Based Process for Developing Measures
The 2006 Tax Relief and Health Care Act (TRHCA) states "for purposes of reporting data on quality measures for covered professional services furnished during 2008, the quality measures specified under this paragraph for covered professional services shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that include measures that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures. Such

measures shall include structural measures, such as the use of EHRs and electronic prescribing technology.''

The AUA strongly supports CMS's intention as stated in the proposed rule to interpret the requirements of the TRHCA in the context of the National Institute of Standards and Technology Act (NISTA) (15 U.S.C. 271 et seq.) as amended by the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) (NTTAA) and implemented by OMB Circular No. A–119 (OMB A–119) dated February 10, 1998. As CMS states in the proposed rule, "The NQF has a formal organizational structure and established processes that are intentionally designed to comply with the NTTAA and OMB A–119. Membership is open and includes physicians and other providers, hospital organizations, purchasers, researchers, payers, and employers. In achieving its determination of whether or not to endorse a standard, the NQF uses a formal process that consists of five principal steps that follow a project's conceptualization, prioritization, and planning."

Because the NQF has not reviewed physician-level measures in the past, there are hurdles to overcome and the need to establish uniform processes within the various technical panels to ensure fair and consistent review of physician-level measures. However, the AUA agrees with CMS's discussion in the proposed rule that the NQF is set up to review measures and that rather than creating a new entity, it is sensible to work within the existing NQF structure to deal with any problems that arise from the review of physician-level measures as a new charge for the NQF.

However, we do believe that the requirement that measures for the 2008 program be developed "through the use of a consensus-based process" is too broad. For any reporting system to improve quality, the measures must be meaningful to clinical care and relevant to practicing physicians. Therefore, direct physician involvement in the development, testing and implementation of quality measures is the only way to ensure measures are appropriate and clinically relevant.

While we appreciate that the proposed rule recognizes the American Medical Association's Physician Consortium for Performance Improvement (the Consortium) as a source for the development of quality measures eligible for inclusion in PQRI 2008, we urge CMS to go further and consider the Consortium as the *only* entity appropriate for the development of physician-level quality measures. The Consortium process is consensus-based and physician-led. This characteristic will ensure physician buy-in on measures which is essential for an effective quality reporting program. Further, tasking the Consortium as the only group for developing physician measures significantly reduces the risk of duplicative or contradictory measures and ensures measure harmonization.

Proposed 2008 PQRI Quality Measures

Category #1: Selected Measures from the 2007 PQRI (contingent on NQF endorsement by November 15, 2007):
CMS proposes to retain and include many measures from the 2007 PQRI in the final 2008 PQRI measures. Among those measures is the 2007 PQRI measure #48, Assessment of Presence or

Absence of Urinary Incontinence in Women Aged 65 Years and Older. This is one measure that is part of three urinary incontinence measures:

1. Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older.
2. Characterization of Urinary Incontinence in Women Aged 65 Years and Older.
3. Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older.

Currently, the following office consultation codes are not included in the denominator for measure #48, whereas they are included in the denominator for measures 49 and 50:

- 99241 Office consultation
- 99242 Office consultation
- 99243 Office consultation
- 99244 Office consultation
- 99245 Office consultation

According to the AMA, the consultation codes were removed from any measure that is considered to be for the general population (eg, all patients without a designated diagnosis for that measure) and that for 2007 reporting, they included only those office visits in the denominator where it is reasonable to assume, regardless of the specialty, that the physician would be providing the primary care for the patient. Further, the AMA PCPI workgroup felt that including consultation visits may affect whether a physician achieves the 80% reporting rate needed for each measure selected.

However, the AUA believes that urologists who are seeing a patient from a consult for an unrelated problem (i.e. other than incontinence) should be able to get credit for reporting on measure #48 and requests that this issue be revisited before this measure is finalized for the 2008 PQRI.

Category #2: AMA PCPI Measures currently under development

CMS also proposes to include measures in the final 2008 PQRI selected from all measures that are currently under development via the AMA Physician Consortium for Performance Improvement (PCPI) provided that they achieve NQF endorsement or AQA adoption by November 15, 2007. In addition, CMS proposes to select from among these measures based upon development completion in a sufficiently timely manner that implementation for 2008 would be practical, their importance in relation to quality goals, their meaningfulness as measures of quality, their utility in the PQRI program such as through augmenting the scope of services provided by eligible practitioners to which PQRI measures apply, the degree to which they meet the needs of the Medicare program, and their functionality in terms of their ability to be collected and calculated in the PQRI program.

The AUA was lead organization through the AMA PCPI in a multi-disciplinary process that included radiation and clinical oncology for the development of the prostate cancer measures, which are included in this category, shown in table 17 in the proposed rule. The measures are:

1. Appropriate initial evaluation of patients with Prostate Cancer.
2. Inappropriate use of Bone Scan for staging Low-Risk Prostate Cancer patients.
3. Review of treatment options in patients with clinically localized Prostate Cancer.

4. Adjuvant Hormonal therapy for High-risk Prostate Cancer patients.
5. Three-dimensional radiotherapy for patients with Prostate Cancer

The AUA strongly urges CMS to include the prostate cancer measures in the 2008 PQRI, as they meet the vast majority of the criteria mentioned above. The measures have already been approved by the AQA Performance Measurement Workgroup and are on the agenda for consideration at the AQA meeting on October 18, the CPT-II codes have already been developed and approved by the AMA Performance Measures Advisory Group (PMAG), which is the body that makes recommendations to the CPT Editorial Panel on the language of CPT II codes, the measures can be reported by more than one specialty (urology and radiation oncology) and prostate cancer is a disease of great importance in the Medicare program.

Thank you for considering our comments. If you have any questions or need additional information, please contact Robin Hudson, Senior Manager of Quality Initiatives & Health Policy, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Paul F. Schellhammer, M.D.
President, American Urological Association

Submitter : Dawn Nehls **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15111-Attach-1.DOC

ADVANCED PAIN MANAGEMENT

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August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Dawn Nehls, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Mr. Joseph Whitson** **Date: 08/31/2007**

Organization : **Illinois State University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Joe Whitson. I am a certified athletic trainer at Illinois State University in Normal, IL. I am the head football athletic trainer at the institution. I have a BS in athletic training from East Tennessee State University and a MS.Ed. in Health promotions from Viginia Tech.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not reeeived the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Joe Whitson Ms.Ed., ATC

Submitter : **Miss. Elissa Baldwin** **Date: 08/31/2007**

Organization : **Rebound Rehabilitation**

Category : **Other Health Care Professional**

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam:

My name is Elissa Baldwin. I am a certified athletic trainer working for a hospital-based physical therapy clinic in Vancouver, WA. In addition to working in the clinic, I am sent out to a local high school to provide medical coverage for sports teams. In the clinic, I provide therapy under the guidance and supervision of licensed physical therapists. I do not perform inital evaluations, but take patients though exercises (established by the PT) and provide therapuetic modalities. With each patient I work with and progress, I am under direct supervision of a PT at all times. I am not allowed to provide any services unless a PT is present. In addition, any progressions I give are under the guidance of the primary PT. As a certified athletic trainer, I have a BS in Exercise and Sport Science as well as a MA in Kinesiology. As an ATC, I not only provide medical coverage for any acute injuries on the field, but have also been thoroughly trained to assess and treat many different injuries. In college training rooms, we take athletes through entire rehabilitation programs (including post-operation) under the protocol of the school's orthopedic surgeon. Certified athletic trainers are trained and very qualified to take patients though entire rehabilitation protocols.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available. I see patients turned away because we do not have enough PTs to take care of them throughout their entire rehab and the ATCs in the clinic are not allowed to help when needed.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Thank you for your time and consideration.

Sincerely,

Elissa Baldwin, MA, ATC

Submitter : **Dr. Francis Huber** **Date: 08/31/2007**

Organization : **Self for ASA**

Category : **Physician**

Issue Areas/Comments

Background

Background

Your support for CMS-1385-P is apprciated. An increase is needed to continue the improved safety of anesthesia.

Francis C. Huber, JR. MD
Past President of the West Virginia State Society of Anesthesiologists

Submitter : Mr. Matthew Schulze **Date:** 08/31/2007

Organization : American Society for Clinical Pathology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15115-Attach-1.PDF

15115

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August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
7500 Security Boulevard
Baltimore, MD 21244-8015

Dear Mr. Kuhn:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide comment on the Centers' for Medicare and Medicaid Services (CMS) 2008 Physician Fee Schedule Proposed Rule ("Proposed Rule") [72 FR 38122]. Our comments focus on the anti-markup and reassignment provisions outlined in the section entitled Physician Self-Referral.

The ASCP is a nonprofit medical specialty society representing 140,000 members, including board certified pathologists, other physicians, clinical scientists, medical technologists and technicians. ASCP is one of our nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

I. Reassignment and Physician Self-Referral [72 FR 38179]

ASCP writes in strong support of CMS' efforts to block abusive billing arrangements that profit from the referral of pathology services. CMS has proposed some important patient and programmatic protections, and the Agency is to be commended for its efforts. That said, we believe that these proposals can and should be strengthened. It is our sincere hope that when CMS implements its 2008 Physician Fee Schedule final rule that it include its proposed reassignment and self-referral reforms, at a minimum.

The abuse of the reassignment provisions relating to pathology services is an issue of great concern to ASCP. We have been contacted by hundreds of our members on this issue urging that action be taken to prevent markup on pathology services. They are

acutely aware of the problems associated with these abuses, and many have witnessed them firsthand.

We concur with that the Department when it stated in this year's proposed rule that the 2004 "changes to [CMS'] rules on reassignment concerning the right to receive Medicare payment may have lead to some confusion as to whether the anti-markup and purchased interpretation requirements apply to certain situations where a reassignment has occurred under a contractual arrangement." We agree there is confusion. We do not believe that in most cases where clinicians may be engaging in any activities the Department may describe as "abusive billing practices" that these providers are doing so knowingly and willfully. We have heard that some providers may have been advised that profiting from the referral of certain medical services does not violate Medicare requirements.

A. What's Causing the Billing Abuses

The billing abuses with which ASCP is primarily concerned are those occurring as a result of providers who are profiting from the referral of pathology services. To accomplish this, clinicians are using contractual arrangements to secure the billing rights for pathology services. In part, this is accomplished by entities popularly referred to as "pod" labs. But other entities are seeking to facilitate other types of arrangements, some of which were described in the proposed rule, that can accomplish the same purposes.

Pod labs come in numerous shapes and sizes, but for the most part they are scaled down clinical laboratories, offering a limited menu of services such as analyzing biopsies. These entities, in many cases, may be little more than an office divided by cubicles with a microscope on a cart being wheeled from cubicle to cubicle by a pathologist who examines the specimens. These laboratories exploit a loophole in Medicare's assignment of benefit regulations, enabling referring physicians to profit from pod labs by extracting a portion of the revenue from Medicare designated for the performance of pathology services. These referring providers are engaging in unethical practices by profiting from the referral of the pathology services.

B. Impact of Self Referral

ASCP believes that allowing providers to profit form the referral of pathology services distorts medical decision-making, undermines patient trust in the medical profession, and can adversely affect patient care. As stated in the proposed rule, allowing such profits "may lead to patient and program abuse in the form of higher utilization of services and result in higher costs to the Medicare program." The U.S. Department of Health and Human Services Office of the Inspector General (OIG) has stated that these types of arrangements, which may violate federal anti-kickback statute, "can distort medical decision-making, cause overutilization, increase costs and result in unfair competition." OIG has also pointed out that the markups of Medicare reimbursed services "can also adversely affect the quality of patient care." These abusive billing practices may also adversely affect the practice of pathology and its ability to help diagnose and treat patient conditions and disease quickly and efficaciously.

C. Building a Foundation

Since CMS first warned of the potential for abuse of the reassignment rules in 2004, the specialty of pathology quickly witnessed the increased presence of business arrangements attempting to skirt the agency's physician self referral prohibitions. As this occurred, the U.S. Department of Health and Human Services' Office of the Inspector General (OIG) released a number of publications that stated that these mechanisms *appeared* to violate applicable anti-fraud requirements (OIG advisory opinions do not assess whether certain practices are *per se* illegal), such as the anti-kickback and anti-markup provisions. Not surprisingly, such efforts have had little impact in deterring abusive arrangements.

D. The Data

Despite anecdotal evidence that billing abuses were occurring, the Department lacked, until recently, data to assess the scope of billing abuses by providers seeking to profit from the referral of pathology specimens.

In June 2007, OIG published the results of three audits of physician group practices to examine their recent use of the reassignment provisions to bill for pathology services. While the three audits focused on urology, the same incentive to profit from the referral of pathology services would similarly affect other physician specialties relying on these services. The OIG audits reveal that *all* of the audited physician groups billed significantly more biopsies than the carriers paid on average to other providers—124%, 65%, and 58%.

All of the audited group practices substantially increased utilization after entering into a reassignment arrangements for pathology services—699%, 230%, and 26%. One pod lab went from one jar to almost 9 jars on average per patient. Another increased from an average of just under 4 jars of biopsies tissue to an average of almost 12 jars per patient. It is difficult to justify such significant increases in utilization over a 2 year period on changes in "clinical practice," considering the apparent lack of change in other provider billing behavior.

Compared to the OIG report that resulted in the first Stark physician self-referral restrictions, the recent findings reveal self-referral billing abuses on an even greater scale. That 1989 OIG report found that physicians with a financial interest in the clinical laboratories to which they "referred Medicare patients [ordered] 45 percent more laboratory services than did physicians who did not have such financial interests."[1]

Another report of interest, provided by the Center for Health Policy Studies, adds to this data. This study examined states that have "direct billing laws." Such laws require the pathologist or entity performing the ordered pathology services to bill for these services. These laws help prevent providers from profiting on the referral of pathology services. This study found that laboratory charges per enrollee under private health insurance programs were 41 percent higher in non-direct billing states than in direct billing states.

---

[1] Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress. U.S. Health and Human Services Department Office of the Inspector General Office of Analysis and Inspections. May 1989.

Given the fact that the recent OIG data examines 2004 billing charges, we would encourage the Department to view this data as illustrative of the beginning of the trend, not its apex. Were more recent data available, the increases in utilization may be larger, as the entities promoting arrangements to capture pathology reimbursement appear to have increased their market presence.

In future studies of these practices we would suggest considering using earlier benchmark years to control for possible adjustments group practices may make to their billing practices prior to entering into a contractual arrangement. Such adjustments could mask the extent to which pathology services may be overutilized.

D. Ethical Considerations

The American Medical Association (AMA), through its Council on Ethics and Judicial Affairs (CEJA), has outlined a number of ethical practice policies that are directly or indirectly violated by entities engaged in abusive billing practices that pertain to pathology. For example, CEJA has stated that if anatomic pathology services are provided at a discount, the purchasing physician should not charge a mark-up.

Moreover, while the following opinions do not address markups per se, they do have application to the reassignment arrangements affecting pathology services. Opinion E-8.03 states that "[i]n general, physicians should not refer patients to a health care facility outside their office at which they do not directly provide services and in which they have a financial interest." In opinion E-6.03, CEJA states "clinics, laboratories, hospitals, or other health care facilities that compensate physicians for referral of patients are engaged in fee splitting which is unethical." Additionally, in Opinion E-6.02, CEJA states "[p]ayment by or to a physician solely for the referral of a patient is fee splitting and is unethical." While the later two opinions address fee-splitting, the underlying concern is that profiting from referrals is inappropriate.

Of particular concern is the fact that the financial incentive relied upon by these business arrangements can result in physicians selecting laboratories not on the basis of quality, but on the potential for profit. Consequently, test quality may suffer, increasing the risk of injury to the patient. AMA Opinion E-8.02 addresses this dilemma by stating that a "physician who disregards quality as the primary criterion or who chooses a laboratory solely because it provides low-cost laboratory services on which the patient is charged a profit, is not acting in the best interests of the patient."

E. Responding to Criticism of CMS' Proposed Rule

The arguments used by those opposed to the CMS proposal are insufficient to warrant abandoning or weakening these proposals. It should not be forgotten that those seeking to undermine these proposals desire to profit from referrals. This inherently causes numerous problems, such as overutilization, increased per test costs, etc. Some opposed to CMS' initiatives have argued that they are engaging in these arrangements to provide

necessary services to patients. Nothing in this rule, however, prevents providers from providing patient access to pathology services. It just prevents providers from profiting from these services.

Additionally opponents to the CMS proposals have argued the arrangements are needed to provide for specialized pathology services. This argument is weak as there are many national and regional laboratories and pathology groups that have pathologists who are subspecialty certified and perform pathology services only within those subspecialties. There is no evidence that the diagnostic rates of pod pathologists exceed that of subspecialty pathologists. Pathologists and laboratories should be selected on such criteria as diagnostic capability, quality, turnaround time, and service. Allowing profit to the referring provider or billing entity to serve as a new criterion in selecting the provider of pathology and laboratory services runs in stark contrast to the patients' best interests.

F. CMS's Proposed Reforms

To address abuse of the reassignment provisions, CMS proposes applying the following reforms:

- The PC of a purchased test be subject to an anti-markup provision;
- The anti-markup provision for the TC and PC apply to all arrangements not involving a reassignment from a full-time employee of the billing entity;
- The performing physician's or other supplier's net charge be calculated exclusive of any charge that reflects the cost of space or equipment leased to the performing physician or other supplier by the billing entity; and
- The anti-markup provision not apply to independent labs that have not ordered the TC.

CMS proposes to impose an anti-markup provision of the technical component (TC) and professional component (PC) of diagnostic services. This prohibition would apply irregardless of whether the billing physician or medical group outright purchases the PC or TC, or whether the physician or other supplier performing the TC or PC reassigns his or her billing rights to the billing physician or medical group. ASCP strongly supports this proposal. The only exception that should be allowed under the CMS proposed framework is if the performing supplier of the services is a full-time employee of the billing entity.

ASCP concurs with CMS about the possibility to "game" net charges, and thus we support the agency's proposal to define "net charge" as exclusive of any amount that is inflated to take into consideration the cost of equipment or space leased to the performing physician or other supplier.

We share CMS' concern that overutilization of diagnostic tests could occur in situations where the TC is performed by a part-time or leased employee. We urge the agency to apply the anti-markup provision to the TC performed in a centralized building when the TC is performed by a part-time or leased employee.

ASCP is concerned that the proposed anti-mark-up rule will not eliminate the profit and self referral incentives for a practice principally comprised of physicians ordering pathology tests (e.g., GI practices, Urology practices and Dermatology practices). The proposed language of Section 424.80 is limited to a reassignment. A GI practice, for example, that maintains its own CLIA-certified pathology laboratory staffed by part-time independent contractor histotechnologists or histotechnicians does not typically need a re-assignment of the right of the histotechnologist or histotechnician to bill Medicare, because the histotechnologist or histotechnician cannot bill Medicare for the technical component. Rather, the technical component is billed by the entity that holds the CLIA Certificate for the technical component laboratory.

ASCP suggests that CMS consider an anti-markup provision that would apply to any group practice where at least 90% of the practice is comprised of a single specialty other than pathology that orders the pathology tests billed by the practice. The anti-markup provision should prohibit any mark-up of the direct costs actually incurred by the practice (i.e., compensation paid to histotechnologists, histotechnicians, and pathologists, equipment and supplies utilized).

Moreover, for TCs performed by a "technician" in a "centralized building" we believe it would be useful to clarify that the employee is a bona fide full-time employee of the billing entity. Since there appears to be no definition of what is meant by a "full time," ASCP suggests CMS should define a full-time employee as an individual who works at least 35 hours per week. This is consistent with the agency's 2007 Physician Fee Schedule Proposed Rule. We do not concur with the agency in its proposal not to make changes to the definition of a centralized building. Moreover, we believe entities seeking to take advantage of the centralized building exemption should not be located in other states, unless they are located no farther than 20 miles from the referring office.

ASCP agrees with the need to except the anti-markup provisions for PCs ordered by independent laboratories because these entities pose little risk of program abuse. Independent labs are not ordering the TC.

Moreover, we believe it would be useful to restate that the requirements of subsection 414.50 apply, even if the physician or group billing is acting under the contractual arrangement exception to the rule. Additionally, CMS should require that, for both the reassignment rules in 424.80 and the purchased diagnostic test rules in 414.50, to bill for the TC, the billing physician or medical group must directly perform the PC. That said, we foresee the need to exempt independent labs, because of states where the corporate practice of medicine doctrine is in effect. An exemption for dermatologists that directly perform the interpretation may also be necessary if this proposal is implemented.

We believe that the rule would benefit from application of the purchased test rules to reassignments. Regarding the agency's concern about how this affects multi-specialty group practices, we believe these concerns have merit for "true" multi-specialty groups. But we do not believe that it would be appropriate to allow a group practice to qualify as

a "multi-specialty" group by hiring one or more pathologists. (See aforementioned proposal on percentage composition.)

ASCP believes first and foremost that these proposed physician self-referral provisions must be applied to pathology/laboratory medicine. We believe that application of the anti-markup and reassignment rules to other medical specialties is a concern best addressed by the organizations representing those specialties. Thus ASCP declines to express an opinion whether these proposals should be applied beyond pathology and laboratory medicine. Lastly, ASCP supports CMS's proposals and urges the agency to implement these reforms without delay or grace period.

II. CLINICAL LABORATORY ISSUES

Reconsideration Process
In its proposed rule, CMS proposes to establish a reconsideration process to re-examine the reimbursement of laboratory tests not adequately reimbursed via the "crosswalk" or "gap-filled" process.

CMS' proposal allows for reconsideration under the following circumstances:

- If it determines that the payment amount for a cross-walked code is not appropriate, it may seek public comments on a more suitable reimbursement level. The new payment rate would take effect the following year.

- If after the first year of gap-filling the Agency determines that the carrier-specific gap-filled amounts do not sufficiently pay for the test, it may crosswalk the test during the second year in order to establish a more accurate fee. The new payment rate would take effect the next year.

ASCP supports these recommendations. We believe these changes will start to address a number of the flaws in the current payment process, particularly in regards to gap-filling.

We also encourage CMS to take a more proactive approach in preventing the problems that may result in the need to utilize the above mentioned scenarios. Here ASCP believes that the Agency should require that local contractors develop a transparent, formal process for making gap-fill decisions, including a formal appeals process. Utilizing such a process may help prevent disputes from escalating to the federal level.

III. TRHCA – Section 104: Physician Pathology Services

CMS states in its Proposed Rule that it intends to implement the "grandfather" provision for the TC of pathology services furnished to hospital patients. Currently, an independent laboratory can bill Medicare for the TC of a service furnished to hospital patients if the hospital has a prior relationship with the independent laboratory for this service. CMS states that this will expire at the end of the year.

As Congress has routinely extended this provision each year in the past, ASCP suggests that CMS implement the grandfather on a permanent basis. Even if CMS does not choose to do so, however, we believe that it would be useful for CMS not to implement its proposal for at least six months after the end of the year. In the past, laboratories prepared for the Department's proposed termination of billing rights, and then Congress acted, often just before the year's end, or even thereafter, to extend the provision. This creates difficult billing issues, because laboratories must be poised to implement the new requirements and inform customers of the change. Then if Congress acts, they must go back to customers and explain that the change is not going to occur, after all. CMS has similar issues, as it must inform carriers to implement, only to revoke that instruction shortly thereafter.

As a result, because Congress is again considering extending this provision, we believe it would be useful if CMS stated that, if Congress does not act and extend the provision, it intends to delay enforcement until at least July 1, 2008. That would permit laboratories and hospitals (and CMS) time to determine if Congress was going to act again with regard to the provision and take the necessary action to inform hospitals.

ASCP appreciates this opportunity to provide comment on the proposed rule and looks forward to working with you on corrections to the Clinical Laboratory Technology Practice Act. If ASCP can be of further assistance, please do not hesitate to contact me or Matthew Schulze, ASCP's Senior Manager for Federal and State Affairs, at (202) 347-4450.

Sincerely,

John S.J. Brooks, MD, FASCP
President, ASCP

Submitter : **Ms. Kathleen Ladner** **Date: 08/31/2007**

Organization : **Peak Performance Physical Therapy**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007
Dear Sir or Madam:
I am a certified athletic trainer with ten years experience in the university, clinical and high school settings. I have worked extensively with athletes, workers compensation patients, and back patients in their quest to return to athletics or work. My background has allowed me to educate patients regarding prevention of injury, proper nutrition, and pre and post surgical exercise and rehabilitation. I provide a quality service to patients who often cannot afford other care. I do not seek to provide physical therapy but rather to practice within my own scope of athletic training and provide preventive education and rehabilitation services which I am educated and trained to do. I seek reimbursement for the services that I provide as a medical care giver.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Kathleen N. Ladner, ATC, LAT

Submitter : Dr. Christopher Joyce **Date:** 08/31/2007

Organization : University of North Florida

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am Christopher Joyce and I am a certified athletic trainer and an associate professor of sports medicine at the University of North Florida. I have been teaching in the Athletic Training Education Program for 8 years, and have been a certified athletic trainer for 15 years. I have a BS in Physical Education, a Master s Degree in Athletic Training, and a PhD in Sports Medicine. In addition to being a certified athletic trainer, I am also a certified Strength and Conditioning Specialist, and a certified Clinical Research Associate.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Christopher J. Joyce, PhD, ATC, LAT, CSCS, CCRA

Submitter : Ms. Nancy Kaatz **Date:** 08/31/2007

Organization : Santa Clara Valley Medical Ctr/Santa Clara County

Category : Local Government

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

On behalf of Santa Clara County and Santa Clara Valley Medical Center, I appreciate the opportunity to comment on CMS's proposed changes to the Geographic Adjustment Factor (GAF) for 2008 for Santa Clara County.

Addendum D of the proposed rules shows our GAF decreasing from 1.265 in 2007 to 1.206 in 2008, a 4.63% decrease. Addendum E of the proposed rules shows the Practice Expense Geographic Practice Cost Index (peGPCI) for Santa Clara dropping from 1.543 in 2007 to 1.418 in 2008 and 1.292 in 2009, a 16.27% decrease over 2 years. These reductions are more than twice that of our neighboring counties, yet our review of the factors used to develop the peGPCI (employee wages and office rents HUD FMR) suggests that the variation between Santa Clara and its neighboring counties are not significant. We are concerned that there is an error in the calculation.

Between 2007 and 2009, the GAF for Santa Clara County is set to decline by 9.25%. In contrast, the FMR for 2-bedroom units is set to increase by 0.70%. The contrasts between changes in the county GAF and the FMR for Santa Clara County leads us to believe that the 2009 county GAF for Santa Clara County shown in Table 9 is incorrect.

Santa Clara County, through Santa Clara Valley Medical Center (SCVMC), provides care to approximately 200,000 people, or 1 in 10 residents of the County annually. One in four County residents received care at SCVMC sometime during the last 4 years. SCVMC is the only hospital in Santa Clara County with an open door policy guaranteeing residents access to needed medical care. As the safety net provider in this County, SCVMC has a payor mix of approximately 80% Medi-Cal and unsponsored, 12-15% Medicare and the rest privately insured. SCVMC employs between 300 and 400 physicians. Although Medicare patients make up only 15% of our patients, they are our most vulnerable patients as most are both Medicare and Medi-Cal, have chronic conditions, and have language/cultural needs that are not available elsewhere. We are dependent on our current revenues, and our calculations show that current Medicare rates for physician services do not cover our current cost of physician services. A reduction in the current rates would be devastating, not only for our Medicare volume, but those insurance revenues that are paid based on Medicare payment rates.

The cost of living continues to rise, and Santa Clara County continues to have one of the highest wage indices in the nation. This high cost of living, combined with poor reimbursement from public payors, has created a shortage of physicians in many specialty services and thus created access issues for our County s most vulnerable patients. In the last several years, one hospital has closed, two others have cancelled their Medi-Cal contracts, and another has received 'distressed hospital' funding from the state. Santa Clara County is budgeted to provide over $200 million in funding for Santa Clara Valley Medical Center to support medical services for the medically indigent as well as those under poor paying public programs. Decreasing Medicare payment rates even further would compound this issue.

Given these issues, Santa Clara County urges CMS to review the data used and ensure that there are no errors in the calculations of the Geographic Adjustment Factors for Santa Clara County.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions please contact me at (408) 885-6883 or nancy.kaatz@hhs.sccgov.org.

Sincerely,

Nancy Kaatz, CFO
Santa Clara Valley Health and Hospital System
County of Santa Clara
2325 Enborg Lane, Suite 360
San Jose, CA 95128

Submitter : **Dr. Vesselin Oreshkov** **Date: 08/31/2007**

Organization : **Sangamon Associated Anesthesiologists, SC**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Vesselin V. Oreshkov, M.D.

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August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Barbara Koschak, NP
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Mr. Ron Esteban** **Date: 08/31/2007**

Organization : **Orlando Orthopaedic Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Ron Esteban, and I am a Certified Athletic Trainer and serve as the Director of Marketing for Orlando Orthopaedic Center in Orlando, FL.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for patients.

As an athletic trainer, I am also qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Ron Esteban, MS, ATC, LAT

Submitter : Mr. Michael Van Veghel **Date:** 08/31/2007

Organization : University of Wisconsin Hospitals and Clinics

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To Whom It May Concern,
My name is Mike Van Veghel. I am an athletic trainer who is licensed to perform athletic training services in the state of Wisconsin. I received certification from the NATA in 1991. Over the past 18 years I have worked in a variety of settings providing athletic training and rehabilitation services. Currently I work in an outpatient clinic providing rehabilitative services to a variety of orthopedic and sports medicine patients. I am commenting on these rules as I fear they may limit my ability to practice my profession as well as seriously limit the marketability of future athletic training hiring. Most importantly, these rules will significantly restrict patient access to quality health care even further than the current situation dictates.
Regarding my rehabilitative role, I have significant concerns about how the proposed CMS rule changes could potentially affect the access of our active population to rehabilitation services. The rule changes could work to limit the choices of patients to a small number of qualified rehabilitation providers. There are many other qualified providers whom are safe and effective providers.
As an athletic trainer in Wisconsin, we are licensed in the State of Wisconsin and Certified nationally. Our state practice act allows us to treat and rehabilitate active individuals of all types. Why should age or desired activity level dictate who a provider can see if the respeetive professional is trained properly?
I continually see that we have a shortage of access and allied health providers in this country. In our own clinics wait times for rehabilitative services can extend into a month long period. Yet these proposed changes work to restrict access further. They would also work to keep an athletic trainer in Wisconsin from practicing under their practiee act.
Specifically, I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities as proposcd in 1385-P, including the conditions for hospital participation.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will ereate additional lack of access to quality health care for my patients.
As an athletie trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experienee, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to cireumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effeetive treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Finally, I would like to note that the change for recertification from 30 to 90 days is an excellent idea and do support this along with my PT colleagues.

Sincerely,
Mike Van Veghel LAT, CSCS
UWHealth Rehabilitation Services
Madison Wl

Submitter : Mrs. Stephany Lang **Date:** 08/31/2007

Organization : UPMC

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Stephany Lang and I'm a mother of 3, a certified member of the National Athletic Trainers Association, an NATA-Board of Certification Examiner, an American Red Cross First Aid, CPR, and AED Instructor, and a Silver Sneakers fitness instructor. I've been working in the allied health care profession for 11 years now and find great personal satisfaction and reward in working with my patients, athletes and their families. I currently work part time at two high schools and part time at a professional dance company. I received my Bachelor of Science degree from the University of Pittsburgh and my Master of Education in Health Promotion and Education from the University of Cincinnati.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Stephany Lang, ATC, MEd

Submitter : Mr. Benjamin Loy **Date:** 08/31/2007

Organization : PDX, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

See Attached

CMS-1385-P-15124-Attach-1.DOC

101 Jim Wright Freeway South, Suite 200, Fort Worth, TX 76108-2252, Phone: (817) 246-6760

Comments on the Proposed Rule Concerning Computer Generated Fax Exemption for E-Prescribing

August 31, 2007

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

RE: CMS-1385-P

Dear Sir or Madam:

PDX, Inc. appreciates the opportunity to submit written comments to the Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS) concerning the impact of the proposed Rule changes on our companies, customers and the retail pharmacy industry in general.

PDX, Inc., a major provider of pharmacy management software to the retail pharmacy industry, was established in 1985 in Granbury, Texas and was preceded by pc1, Inc., a software application provider primarily for independent pharmacies. PDX is the most widely distributed single code-based retail pharmacy application used in North America and is licensed primarily by chains and high-volume independent pharmacies. PDX and its affiliated companies provide pharmacy technology to a customer base of over 10,000 retail, clinic and healthcare organization pharmacies. PDX has software installations in all 50 states, District of Columbia, Puerto Rico, and the U.S. Virgin Islands.

PDX has a long history in the development and promotion of electronic prescriptions and was a major contributor in the first large scale attempted implementation of electronic prescriptions in 1996 involving a 500 physician group in Pensacola Florida. Although that initiative failed due to the lack of participation by a major pharmacy chain in the area we have consistently promoted electronic prescriptions to our customers, state boards of pharmacy, professional organizations and anyone else who would listen. We actively participated in the development of the NCPDP SCRIPT standard and were the first software vendor to offer this functionality to retail pharmacies on a nationwide basis. Having worked for over a decade to make electronic prescriptions a reality, our comments are provided in an effort to assist CMS in making the acceptance and implementation of electronic prescriptions as successful as possible. However, we have several concerns and suggestions regarding the proposed CMS rule concerning computer generated electronic faxes which we have detailed below.

It is our opinion that the total elimination of the fax exemption will provide more adverse results than benefits. After a decade, the industry is still educating prescribers and their software vendors on the benefits of e-prescribing. The retail pharmacy segment of the industry has embraced this process as it embraced other technological advances such as on-line real-time claims processing by seeing the advantages provided by such technology. However, the prescriber segment of the industry and the vendors of the practice management systems that service this sector have, to date, been more conservative in their acceptance. The truth is that the majority of the "electronic prescriptions" created today by prescriber practice management

systems are electronic faxes and not true electronic prescriptions utilizing the NCPDP SCRIPT standard. However, such electronic faxes do address many of the same issues that are addressed by true electronic prescriptions. Electronic faxes address the problems with poor handwriting that can result in prescriptions being filled inappropriately or not filled at all if they cannot be deciphered, incorrect spelling of the medication name that can lead to the dispensing of a sound-alike product rather than the medication intended and faxes address the problems with varying dialects that are inherent with telephonically communicated prescriptions. Electronic faxes also provide clearer "directions for use" that can eliminate the possibility of misinterpreted directions and the serious health consequences that can result from such misinterpretations. Electronic faxes help eliminate prescriptions forgeries by photocopying as with today's scanning technology copies cannot always be easily distinguished from the actual originals. Electronic faxes provide a better audit capability than handwritten or telephonic prescriptions and finally help speed the delivery of healthcare services in that prescriptions delivered by this method can be processed before the patient arrives at the pharmacy although admittedly not with the same level of ease and safety as with true electronic prescriptions. Additionally, most pharmacies can accept an electronic fax even those that are still unable to except a true electronic prescription. After more than a decade of working to promote electronic prescriptions we are certainly not advocates for electronic faxes but we do recognize the benefits this process provides to prescribers, pharmacies and to patients themselves. If just one death or life-long disability occurred from a misinterpretation of a handwritten prescription that was issued because the prescriber could not use the electronic fax ability contained in his/her practice management system that, in our opinion, would be one too many.

Another issue is that current DEA regulations prohibit the e-prescribing of a prescription for a controlled substance. This prohibition acts as a tremendous barrier to prescriber adoption of e-prescribing. As currently written, the CMS proposed rule would exacerbate the problems caused by this prohibition. Today it is possible that prescriptions for controlled and non-controlled medications could be processed by the same application with the controlled prescriptions being turned into system generated faxes and the non-control prescriptions being sent as electronic prescriptions. If prescribers could use neither electronic prescribing (because of DEA regulations or contractual issues) nor computer-generated faxes (because of the CMS proposed rule) for controlled substance prescriptions, then many prescribers would have to revert to using paper and telephonic prescriptions for their controlled substances (and possibly others) with all of the inherent problems included in these processes. For these reasons, until the DEA amends its regulations to allow for the electronic prescribing of controlled substances, we believe that prescribers and dispensers need to be able retain the ability to use computer-generated faxes to send and receive prescriptions for controlled substances. In fact, this policy should apply in any circumstance in which a prescriber or dispenser is prohibited from complying with the NCPDP SCRIPT standard for reasons beyond their control.

We certainly agree that in situations where the prescriber's software can generate an electronic prescription that incentives and penalties should be implemented that would encourage all providers to use the electronic prescription process over a computer generated fax or any other method of generating, delivering and receiving prescriptions. We feel that a timeline should be established that requires such capability be included in any computer based practice management system that is used by providers that participate in the Medicare or Medicaid programs. Incentives should be offered to encourage providers to participate in electronic prescribing but ultimately if such incentives do not work then mandates and penalties should be applied to obtain compliance as this is widely recognized as being in the best interest of the general public including beneficiaries of the Medicare and Medicaid programs. The elimination of the exception allowing for computer generated faxes should be measured and follow a 2-3 year timeline established for electronic prescription implementation. Such timeline should

include diminishing incentives and increasing penalties as it reaches its end. It is our option that such a process would be in the best interest of the industry, the general public and beneficiaries of the CMS administered programs.

The concern documented in the original rule published in November, 2005 stated that "absent an exemption, entities transmitting computer-generated faxes would be required to comply with the adopted foundation standards. This would cause computer-generated faxers to revert to paper prescribing". We believe this to be the case as well and that totally eliminating this exemption is not in the best interest of the general public. While we readily support the electronic prescription standard and the move to implement this standard by all physicians and pharmacies, it is not realistic to expect this adoption to happen as quickly as this rule change would require. We should find ways to encourage faster adoption of this standard which may include tax breaks for electronic prescription implementation, increased reimbursement rates to pharmacies and physicians that use electronic prescriptions to a specified level and even encouraging insurance companies to offer discounts on malpractice insurance for practitioners using electronic prescribing to a significant degree.

Unfortunately, there are situations that occur today even when the prescriber and pharmacy are both capable of using the SCRIPT standard but due to restrictions imposed by an intermediary or network are unable to communicate using this standard. Because of the infancy of this service, there are limited connectivity vendors to support the transactions to and from the prescriber and dispenser. Some intermediaries have become actual "road-blocks" to the electronic prescription process in that they require that the prescriber and pharmacy participate ONLY in their network(s). We strongly feel that this should not be allowed and that any pharmacy or prescriber that has the ability to transmit an electronic prescription should be able to route such prescriptions through all available networks in order to provide this service. However, even with a standard there can be implementation differences that could lead to a prescription not being accepted by one party or the other. Therefore, participants in this process may need to certify their implementation with each of the networks being used. Fortunately, most networks are willing to make the accommodations needed to allow for these differences in implementation such that the parties can communicate safely and effectively. Therefore, we recommend that CMS include in its rule a provision that would preempt such restrictive provisions with regard to Medicare and Medicaid prescriptions such that a network would not be allowed to prohibit a prescription from being delivered to a participant in their network that originated from another network as long as the parties have demonstrated compatibility. Additionally, the rule should require that such compatibility testing not be blocked or made prohibitive by either other party or their intermediaries. Failure for comply with or at least work in good faith to achieve these goals should result in the network being decertified for use to transmit Medicaid or Medicare prescriptions.

Another concern with the proposed change relates to the alternative delivery or back up processes. Both prescribers and pharmacies need to have the ability to support an effective alternative process when communication, network or software problems occur. Currently many vendors support a 'failover to fax' feature in cases where electronic prescriptions cannot be delivered. This rule change would eliminate this capability and force hard halts in this communication process. We would recommend that any change in guidance would include the ability to use computer-generated faxes for such cases.

We believe that patients should have free choice to use the prescriber and the pharmacy of their preference. Accordingly, if a patient chooses to use a prescriber that has the capability to electronic prescribe using the NCPDP SCRIPT Standard but chooses a pharmacy that does not have such capability, or vice versa, that prescriber/dispenser should have the right and ability to

send the prescription message by the means that is most efficient and best for the circumstances, including by a computer-generated fax until all parties have been given a fair chance to implement the electronic prescription standard.

Finally, the effective date of this proposed rule is problematic, due to the fact that the industry is working on an implementation timetable built around the requirements of e-prescribing standards adoption spelled out in the Medicare Modernization Act of 2003 (MMA) and associated rules. The MMA requires that providers who write prescriptions electronically use the final standards that are in effect when they conduct e-prescribing transactions as of April 1, 2009. We are concerned that prescribers will be confused if the effective date of this proposed rule is January 1, 2009. We recommend that CMS create a timetable for electronic prescription compliance for participants in the Medicare and Medicaid programs that will allow for a 2-3 year implementation, maybe two years with a built in one year extension. Hopefully, incentives and the extra time to comply will make this requirement more palatable but we understand that in the interest of the public benefit that if incentives do not work penalties may ultimately be required.

Our staff and I would be happy to answer any questions that you have regarding our comments related to this very important issue.

Sincerely,

Benjamin E. Loy, R.Ph.
Sr. Vice President, Industry Relations
PDX, Inc.
Direct: 817-367-4301
Fax: 817-246-0131
Email: bloy@pdxinc.com

Submitter : Kim Litwack **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15125-Attach-1.DOC

1425

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

ADVANCED PAIN MANAGEMENT

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Kim Litwack, NP
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Miss. Carrie Anderson** **Date: 08/31/2007**

Organization : **University of Tennessee Chattanooga**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am currently completing my Master's Degree in Athletic Training at University of Tennessee Chattanooga. After completion of my degree, I plan to work in the collegiate setting followed by work in a clinical setting.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Carrie Anderson
Graduate Athletic Training Student

Submitter : **Dr. Philip Kline** **Date: 08/31/2007**

Organization : **Anesthesiology Group Associates, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

In 1979, the first year of my private practice of Anesthesiology, our Medicare unit value was $14.75. This year, in my area, it is $15.11. Since we are no longer allowed to bill Medicare for extremes of age and physical status, the reimbursement per patient for me has actually decreased since 1979 in absolute dollars. Even more shockingly, Medicare reimbursement is only 25-30% of my 1979 reimbursement in cost-of-living adjusted dollars. I don t know any business which can absorb that kind of financial insult, and that is why it is impossible to attract enough anesthesiologists to areas with a large proportion of Medicare patients. Our Medicare patients get sicker and older, they require more time, competence, effort and expense to care for, and the government continues to cut payments to anesthesiologists. Naturally, fewer and fewer anesthesiologists are willing to sign on to this kind of a deal, placing a constantly increasing stress upon those who do care for Medicare patients. There are less and less of us willing to do this work and take the extra night, weekend and holiday call required, not to mention the necessary investment in continuing medical education. It is an unsustainable situation, and soon there will not be enough qualified anesthesiologists (or enough qualified physicians of any kind) to care for our elderly.

After spending 4 years in college, 4 years in medical school, and 4 or more years in residency, any physician, anesthesiologist included, rightfully insists upon being rewarded for his decades of effort, time and suspension of broader life experiences.

Therefore I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services nationally stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Philip J. Kline, MD
9700 Petersburg Rd.
Evansville, IN 47725-1458

Ptolemy1@prodigy.net

Submitter : **Mrs. Janeen Ramirez** **Date: 08/31/2007**

Organization : **Mrs. Janeen Ramirez**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Janeen Ramirez. I am a Certified Athletic Trainer in the state of Ohio. I work for a hospital based outpatient physical therapy clinic and I am a contracted to a local high school in Maumee, Ohio to provide athletic training services to their athletic teams.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Partieipation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restriet their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients reeeive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the reeommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Janeen Ramirez, ATC

Submitter : **Mr. Steven Carrales** **Date: 08/31/2007**

Organization : **Urorad Healthcare, LP**

Category : **Other Health Care Provider**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Mr. Kuhn:

Urorad Healthcare sent a letter to your office via FedEx that was received today, expressing our concerns pertaining to Docket CMS-1385-P, specifically to the part of the docket addressing physician self referral. We are attaching a copy of this letter to ensure that our concerns are reviewed by your agency.

Urorad Healthcare looks forward to providing CMS any additional information on this topic.

Respectfully,

Steven R. Carrales
President and Chief Operating Officer
Urorad Healthcare, LP
3827 N. 10th Street, Suite 104
McAllen, Texas 78501
Phone: 956-682-9894

CMS-1385-P-15129-Attach-1.DOC

#12529

URORAD
HEALTHCARE

August 29, 2007

Herb B. Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (CMS-1385-P)

Dear Mr. Kuhn:

We thank you for the opportunity to provide comment on *the "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, and other Part B Payment Policies for CY 2008"* published in the Federal Registry on July 12, 2007. Our comments focus on the issue of physician self-referral as it applies to radiation therapy. In particular, we want to address concerns that have been expressed by groups representing radiation oncologists regarding the reliance on the in-office ancillary services exception by medical groups developing comprehensive prostate cancer treatment centers.

As you may know, multi-specialty medical groups are increasingly incorporating radiation therapy into their service offerings. In some cases, the group employs a wide range of physicians from different specialties, and radiation therapy constitutes a very small portion of the services rendered by the group. In other cases, the group focuses largely on the treatment of prostate cancer by employing only urologists and radiation oncologists who specialize in this area. In either case, contrary to the allegations of certain radiation oncology professional associations, the arrangement provides numerous benefits to patients and is not prone to abuse.

A urologist is typically the first physician to diagnose prostate cancer. Once such a diagnosis has been made, urologists desire to treat the cancer with the modality that offers the highest probability of cure and minimizes morbidity, based on the progression of the patient's cancer and the patient's preference. These treatment modalities range from robotic surgery, radiation therapy (i.e. IMRT-IGRT), brachytherapy, cryosurgery etc. When appropriate, watchful waiting is yet another option presented to the prostate cancer patient.
Urologists have referred prostate cancer patients for radiation therapy for the past 30 years. They have managed all of the patient morbidity problems associated with the older forms of radiation treatment delivery. With the advent of modern advanced forms of radiation delivery, urologists are now embracing radiation therapy as an equal treatment modality to surgery with significantly less morbidity.

Some urology and multi-specialty groups have elected to develop their own capacity to deliver radiation therapy treatment rather than refer patients in need of radiation therapy to other medical groups. This enables the group to offer the full range of treatment options available to prostate cancer patients. The capacity to deliver comprehensive prostate cancer treatment is extremely beneficial to patients.

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URORAD
HEALTHCARE

In developing radiation therapy treatment capacity, urologists work with radiation oncologists who may be owners, employees or independent contractors of the group. In many cases, an employee is on a partner track to become a shareholder. This arrangement creates a bona fide multi-specialty group whose core competency is comprehensive prostate cancer treatment. Many groups have "sub-specialists within specialties," meaning some physicians specialize in prostate robotic surgery, incontinence, pediatric urology, laparoscopic surgery, urologic oncology, etc. The radiation oncologist functions as a member of this multi-disciplinary team.

Contrary to the suggestions of radiation oncology professional associations, a medical group's focus on comprehensive prostate cancer treatment will improve rather than undermine the quality of care. Medical groups that focus on treating particular diseases tend to be better educated about the dynamic clinical issues and treatment options relating to that disease. They are more likely to have state-of-the-art equipment. Proven clinical and physics protocols are implemented in these groups that have incorporated radiation therapy, marrying the best in technology with the latest clinical research. This approach has led to greatly enhanced cure rates for prostate cancer patients. In addition, patients are treated in a group that, due to its focus, has experienced virtually every variation of prostate cancer "behavior."

Integrated prostate cancer treatment centers allow patients to be treated in an environment that is conducive to healing. These patients share the experience with other men who have the same anxiety, fears, and concerns regarding their cancer and their lives. These centers tend to spawn prostate cancer support groups where extraordinary relationships are formed, among patients as well as staff.

In contrast to a general radiation oncology practice, integrated groups are also more likely to retain the type of sub-specialists referenced above, who are in the best position to provide the most sophisticated and appropriate care. Moreover, bringing urologists and radiation oncologists together within a single medical group leads to tighter integration and coordination of medical care involving both specialties, such as brachytherapy or radiation therapy, following surgery.

Rather than being used abusively, the multi-specialty radiation oncology/urology integrated practice model has been responsible for bringing advanced community-based prostate cancer care to many areas of the country which previously did not have access to this type of service. In addition, because of this integrated model's economies of scale, and intense focus on the second leading cause of male cancer deaths in the United States, it offers invaluable opportunities for clinical research.

It is misleading to allege that an integrated group skews physician treatment decisions in a way that is inconsistent with optimal patient care. In a Balkanized treatment environment, where radiation oncologists and urologists practice in separate groups, each specialty tends to favor its own form of treatment. In an integrated group, the physicians can collectively determine the appropriate course of care in consultation with the patient, without facing the prospect that a particular treatment decision will cause the care to be provided by another medical group. If anything, integrating the practices of urologists and radiation oncologists minimizes the impact financial considerations may have on treatment advice.

The integration of urologists and radiation oncologists in comprehensive prostate cancer treatment centers is part of a broader trend in the health care industry toward the creation of large multi-specialty medical groups. These groups tend to enhance the level of specialization of their physicians and improve the continuity of care. There is nothing unique about radiation therapy that would support a policy prohibiting the service from being delivered by a multi-specialty group. The

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only rationale for such a policy would be protecting the interests of radiation oncologists by restricting medical groups that include other types of physicians from offering radiation therapy services.

For all of the reasons set forth above, we feel strongly that prostate cancer patients are receiving better care within integrated radiation oncology and urology and broader multi-specialty groups than in other settings, and that such groups minimize rather than exacerbate the impact of financial considerations on treatment decisions. As a result, we believe the current in-office ancillary services exception is serving its purpose and should not be amended in any way that creates an impediment to the continued success of comprehensive prostate cancer treatment centers.

Thank you for the opportunity to comment on the proposed rule. Should you have any questions regarding the issue discussed within this communication, please do not hesitate to contact us at 956.682.9894.

Sincerely,

Mark L. Harrison, MD
Diplomate, American Board of Radiology
Chairman & Chief Executive Officer

Steven R. Carrales
President & Chief Operating Officer

Submitter : **Mr. Chad Clements** **Date: 08/31/2007**

Organization : **Boston University**

Category : **Academic**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Dear Sir or Madam:

My name is Chad Clements. I am a Certified Athletic Trainer, Academic Coordinator of Clinical Education, and Assistant Professor in the Department of Physical Therapy and Athletic Training at Boston University. I have been practicing Athletic Training for 9 years. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Chad A. Clements, MS, ATC

Submitter : **Mr. Marco Boscolo** **Date: 08/31/2007**

Organization : **Gibson Area Hospital**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I work part time providing health care serivces to rual high school through a hospital. I work through a therapy clinic which sees many physical active patients. Patients that need the expertise of an Certified Athletic Trainer.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Marco S. Boscolo, ATC, MA, Doctoral Student

Submitter : **Mrs. Susan Greene** **Date: 08/31/2007**

Organization : **AANA**

Category : **Other Practitioner**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
__Susan Greene__CRNAMS_____
Name & Credential
601 Kroshus Drive_____
Address
__Dilworth,MN 56529_____
City, State ZIP

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Thank you for the opportunity to submit comments on the Physician Self Referral Provisions of CMS-1385-P entitled Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008. I am a board-certified pathologist and a member of the College of American Pathologists. I practicc in Columbus, Ohio as part of a largc pathology group servicing multiple hospitals in urban and rural Ohio.

I applaud CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. I am aware of arrangements in my practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group s patients. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services.

Speeifically I support the expansion of the anti-markup rule to purchased pathology interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. These revisions to the Medicare reassignment rule and physician self-referral provisions are necessary to eliminate financial self-interest in clinical decision-making. I believe that physicians should not be able to profit from the provision of pathology services unless the physician is capable of personally performing or supervising the service.

Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. I agree that the Medicare program should ensure that providers furnish care in the best interests of their patients and restrictions on physician self-referrals are an imperative program safeguard to ensure that clinical decisions are determined solely on the basis of quality. The proposed changes do not impact the availability or delivery of pathology services and are designed only to remove the financial conflict of interest that compromises the integrity of the Medicare program.

Sincerely,

Randall C. Hastedt, M.D.

Submitter : **Mrs. Corrine Tate** **Date: 08/31/2007**

Organization : **Institute for Athletic Medicine**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To: The Center for Medicine and Medicaid Services

Over the past 33 years in practice, I have witnessed many incidents of unethical procedure regarding referrals to facilities where the referring physician has a vested interest.

In the early 1980 s, the pendulum swung in favor of the independent clinics and referral for profit was no longer condoned. Many physician groups sold or closed their physical therapy clinics at that time.

In recent years, thc number of physician owned clinics and surgery centers with therapy services has risen dramatically. This allows doctors to refer to their own therapists, and also get a kickback from each referral as the owner of the clinic. Their clinics have been allowed to bill for these services.

If this wasn t enough, the physicians push the patient to go to their clinics and often down play or speak against the hospital owned or privately owned physical therapy clinics. Thc loop hole in the Stark Law allowing physicians to own and refer to their own physical therapy clinics causing a lucrative cash flow to the physicians and thc opportunity to abuse.

Plcase sec this for what it is, a huge conflict of interest and a potential drain on health care dollars.

Please vote against thc practice of physician owned physical therapy practice.

Thank you for your consideration.

Corinnc J Tate, PT
Institutc for Athletic Medicinc - Burnsville

Submitter : Dr. Gregory Thomas **Date:** 08/31/2007

Organization : American Society of Nuclear Cardiology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15135-Attach-1.DOC

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

4550 Montgomery Avenue
Suite 780 North
Bethesda, Maryland 20814
Telephone: 301-215-7575

Website: www.asnc.org
Email: admin@asnc.org
Fax: 301-215-7113

August 30, 2007 DRAFT

Submitted Electronically: http://www.cms.hhs.gov/eRulemaking

Herb Kuhn, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1385-P

Re: Medicare Program; Proposed Revisions to Payment Policy under the Physician Fee Schedule for Calendar and other Part B payment Policies for Year 2008; Proposed Rule

Dear Mr. Kuhn:

The American Society of Nuclear Cardiology (ASNC) is pleased to provide comments on the proposed notice for Medicare payments in the Physician Fee Schedule for calendar year 2008, published in the Federal Register on July 12, 2007 by the Centers for Medicare & Medicaid Services (CMS).

As you know, ASNC is a greater than 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

Medicare Physician Payment Rate for 2008

ASNC shares the extreme concern of the rest of the physician community over future payment cuts that will result from the severely flawed Sustainable Growth Rate (SGR) formula. Clearly, the medical community, and the Medicare patients they serve, will be adversely impacted by the 9.9 percent reduction in the conversion factor for 2008 as well as cuts of nearly 40% over the next eight years.

Earlier in the year, ASNC joined over 70 medical organizations in urging CMS to adopt policy changes that will reduce the severity of these future payment cuts. These changes included: application of the entire $1.35 billion Physician Assistance and Quality Initiative Fund to the 2008 conversion factor update; reduction of the productivity adjustment to the Medicare Economic Index to be in line with those productivity rates recommended for other Medicare providers; removal of Part B drug costs from all of the agency's SGR calculations, retroactive to the 1996 SGR base year; and exclusion of services affected by national coverage determinations from its SGR calculations for a period of least two years to better understand the actual experience with these services as a basis for adding their spending to the SGR in third year of coverage.
A ten percent payment cut in 2008 will only compound many of the other changes that are facing nuclear cardiologists resulting from the phase-in of new practice expense values and continuing effects of the recent Five Year Review of work values. These payment cuts will surely impact physicians' ability to adopt information technology and quality initiatives, as well as to continue accepting new Medicare patients as they prepare for the influx of baby boomers.

Resource Based Practice Expense Relative Value Units

Equipment Usage Percentage Assumptions – Equipment Utilization Data & Equipment Interest Rate Assumptions – Cost of Capital Assumptions

ASNC applauds CMS for not changing the equipment utilization assumption of 50 percent or the 11 percent equipment interest rate assumption. Regarding the former, we are pleased by CMS comments that they "do not want to create disincentives for the use of equipment by arbitrarily increasing the equipment usage percentage." And more importantly, that the agency "does not believe they have sufficient empirical evidence to justify an alternative proposal on this issue." Regarding the latter, ASNC agrees with CMS's belief that "11 percent continues to be an appropriate assumption."

Physician Self-Referral Rules Relating to Diagnostic Tests

ASNC appreciates the opportunity to provide its views on the CMS proposed rules on the self-referral provisions of the Physician Fee Schedule. ASNC believes that the agency's latest attempt at refining these provisions will yet again force physicians and health care entities to re-structure longstanding relationships previously thought to be acceptable, driving up the cost of health care at the very time we should be looking for ways to make it more affordable. The Stark laws already pose significant obstacles to physicians, group practices, and integrated health systems despite the fact that referrals between the components of integrated systems are often times in the best interest of patients.

Therefore, ASNC urges CMS to withdraw these proposals and focus on refining the regulations to simplify compliance, reduce the risk of making illegal many physician relationships that have nothing to do with self-referral, and protect certain physician arrangements that create efficiencies and better quality patient care.

Changes to the In-Office Ancillary Services Exception

CMS is requesting comments on amending this exception due to the agency's growing concern regarding anecdotal evidence of an increasing frequency of abuse by physicians who provide services "not closely connected to the physician practice" that exceed the original intended scope of the exception. ASNC is concerned that a lack of specificity with regard to the arrangements and participants targeted by CMS prevents meaningful assessment by commenters.

Further, if meant to address certain types of diagnostic imaging arrangements, we strongly recommend CMS carefully consider the potential impacts of any proposed changes to the exception in the interest of preventing any unintended and potentially destructive consequences to medical practices. ASNC believes that any changes made without thoroughly consulting stakeholders could: cripple beneficiary access to imaging; lower the promptness and quality of care in cardiology; and inadvertently benefit (financially) other stakeholder specialties without any clinical or economic justification for doing so.

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)

Current Medicare rules prohibit the markup of purchased diagnostic—technical component—services and limit which entity may bill for the professional component of such services. CMS proposes to prohibit the markup of both technical component and professional component services if the diagnostic tests are performed by "outside suppliers," i.e., anyone other than a full-time employee of the physician or group practice billing for the diagnostic services.

While we understand that CMS is concerned that the anti-markup and purchased interpretation requirements have led to confusion where a reassignment of payment has occurred under a contractual arrangement, and that they believe that certain arrangements that permit physician groups to bill for services provided by a contractor in a centralized building may lead to program abuse, ASNC does not think that the proposed changes represent an appreciation of the realities of group practices and how physicians are compensated.

Under the proposed rule, the only technical or professional services a medical group could mark-up would be those performed by the group's full time employees. This would significantly impact the ability of small nuclear cardiology practices, which cannot afford to purchase their own gamma camera, to utilize

independent contractors and part-time employees to perform technical component services. This is because these practices would be limited to billing Medicare no more than the amount actually paid to the independent contractor or part-time employee, even though the practice must, in addition to paying the imaging facility, also cover the costs and assume the business risk for billing for the technical component services. We feel that CMS' proposed policy on this issue will encourage less efficient use of equipment with this type of policy – resulting in reduced access for Medicare beneficiaries and increased costs for the Medicare program.

With regard to the reassignment proposal, CMS appears unconcerned with how reassignment of the right to bill and receive payment for the professional component occurs throughout the health care system. Many physicians reassign for their professional interpretations to other medical groups as independent contractors. Often, physicians are paid an aggregate monthly or annual amount for their services and therefore there is no "charge" to report on a claim. The proposed rules do not address how the billing physician or medical group can determine the amount to declare on the claim as the charge for any single specific interpretation, causing confusion as well as potential exposure to false claims liability, as practices would be required to include a "charge" for all diagnostic test services.

Unit-of-Service ("Per-Click") Payments in Space and Equipment Leases

CMS is proposing to require that space and equipment leases may not include "Unit-of-Service (Per-Click)" payments to a physician-owner for services rendered by an entity-lessee (e.g. hospital, ASC) to patients who are referred by a physician-owner to the entity. In addition, CMS is seeking comments on whether to prohibit similar arrangements where one entity owns the space/equipment, and the physician pays the owner/entity on a time- or unit-of-service basis for use of the space/equipment to the extent that such payments reflect services rendered to patients sent to the physician by the owner/entity.

ASNC is concerned that CMS' proposal approaches this issue from a position that is critical of such arrangements based on "inherent susceptibility" to fraud and abuse, even if the arrangements meet the standards of leasing requirements described in the regulation. We think this approach to reviewing such arrangements misses the opportunity to evaluate the potential cost savings realized through competition between available providers of space and equipment that previously were only offered by larger providers.

It is our understanding that the proposed change would only apply to individual physician lessors and would not apply to arrangements between the "physician group and the hospital," and in arrangements where the hospital (or other DHS entity) is the lessor. The proposed limitations could ultimately result in reduced competition and cost savings through increased inefficiency in any given market

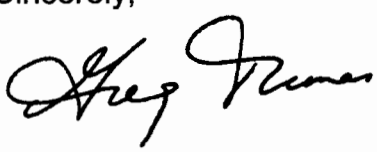
for the services provided through space/equipment leases using this method of payment.

Coding - Additional Codes from the Five-Year Review

Finally, ASNC supports the comments of the American College of Cardiology (ACC) and the American Society of Echocardiography (ASE) regarding CMS's proposal to bundle CPT code 93325 (Doppler echocardiography color flow velocity mapping) because the agency believes that color flow Doppler is "intrinsic" to all echocardiography services. We are disappointed and concerned that CMS has chosen to reject the recommendation of the AMA RVS Update Committee (RUC), which earlier this year referred 99325 to the CPT Editorial Panel. Therefore, ASNC strongly urges the agency to recognize that the CPT/RUC process is working to resolve the agency's concerns, while ensuring that the resources required to provide this service are accurately reflected in CPT and the RBRVS.

Again, ASNC appreciates the opportunity to provide comments regarding these important issues. Should you have any questions, please feel free to contact Christopher Gallagher, ASNC Director of Health Policy, at 202-375-6641 or via email at Gallagher@asnc.org. Thank you.

Sincerely,



Gregory S. Thomas, MD, MPH, FACC, FACP, FASNC
President

Submitter : Mr. Christopher Eastlee **Date:** 08/31/2007

Organization : Association of Air Medical Services (AAMS)

Category : Other Association

Issue Areas/Comments

Beneficiary Signature

Beneficiary Signature

See Attachment

GENERAL

GENERAL

See Attachment

CMS-1385-P-15136-Attach-1.PDF

Association of Air Medical Services

August 30, 2007

The Honorable Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
P.O. Box 8012
Baltimore, Maryland 21244-8012

Re: CMS-1385-P; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.

Re: "BENEFICIARY SIGNATURE"

Dear Ms. Norwalk:

The Association of Air Medical Services (AAMS) would like to take this opportunity to offer comments on the recent rule change proposed by the Centers for Medicare and Medicaid Services (CMS). AAMS represents over 90% of the air medical transport community throughout the United States, including both helicopter and fixed wing operations. The proposed rule would have a direct impact on the operation of air medical services and the high quality health care our members provide to Medicare beneficiaries. We therefore greatly appreciate this opportunity to submit comments on the proposed rule.

Air medical services are often called upon to transport critically ill and injured patients in a myriad of situations and environments: from interfacility transports to direct response to the scene of an accident. These services are called upon when the speed of the aircraft, the distance or travel conditions to the facility, and the level of care provided by air medical crews may be the determining factor in a patient's condition.

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ALEXANDRIA, VA
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(703) 836-8732
FAX (703) 836-8920
www.aams.org

Leading and Serving Transport Medicine

The Proposed Rule referenced above would require air medical personnel to obtain, at the time of transport, a document signed by hospital indicating the name of the patient, and the time and date the patient was received by the facility in lieu of a beneficiary's signature. Since the beneficiaries transported by air medical services are almost always under duress according to CMS, the Proposed Rule essentially creates a new requirement of air medical and ambulance services. AAMS believes, in accordance with the positions of other medical transport organizations, that requiring these individuals to obtain a beneficiary's signature is not only an onerous requirement, but also an unnecessary burden on individuals who must direct their focus to the condition of the patient and the safety of themselves and their

fellow crew members. Due to the fact that air medical crews are equally unable to obtain a signature from the beneficiary or from the healthcare facility personnel, AAMS respectfully requests that CMS remove entirely the beneficiary signature requirement for ambulance services

Beneficiary Signatures Not Valid in Emergency Transports

CMS has long held that signatures obtained under duress are not valid. Further, CMS has indicated that in the case of a medical emergency, BOTH the beneficiary and their authorized representatives are under duress, and are therefore incapable of providing a valid signature. This guidance can be found in *Transmittal AB-02-11 dated July 31, 2002 (attached):*

> *"A person under great duress is not able to understand and act on his or her rights."*

And

> *"In genuine emergencies, the beneficiary/victim and his or her family/friends (authorized representative) are under great duress by the emergency circumstances, to sign anything in order to obtain help."*

And specific to ambulance services obtaining signatures:

> *"Ambulance companies may not give ABN-G's to beneficiaries or their authorized representatives in any emergency transport because such beneficiaries are under great duress."*

New Regulation Unnecessary

The original requirement for a beneficiary signature was to obtain authorization of the assignment of benefits, to ensure that the ambulance service did not bill both the patient and Medicare for the same transport. Since the implementation of the national ambulance fee schedule in 2002 requiring ambulance services to accept Medicare assignment, there is no longer any valid reason to require any signature at all for an emergency ambulance transport, and most certainly not one from a hospital representative who played no role in the transport. Further, now that claims are submitted electronically, there is no opportunity to electronically forward these signatures along with the claim.

Emergency Department Efficiency

The recently released report from the Institute of Medicine Committee on the Future of Emergency Care cited hospital emergency department overcrowding as one of the biggest issues in emergency health care, and recommend that hospitals improve efficiency to combat emergency department overcrowding. Numerous instances of patient parking and extended waiting periods when handing over patients have also become serious issues for ambulance staff. Numerous efforts are currently underway at the local, state, and federal levels to help facilitate

efficiency in emergency departments. The requirements listed above would have the opposite effect on hospital procedures and may actually lead to further issues of patient parking and overcrowded emergency departments.

Additionally, many ambulance and air medical crews report difficulties when asked to obtain signatures from a hospital or other medical facility staff. The very nature of signing documents, especially in the healthcare community, has taken on an extremely negative connotation that is difficult to overcome. Healthcare facilities may develop policies as to which individuals are qualified or maintain the responsibility of signing these forms, and those policies and the individuals responsible would be different at the various facilities. This is especially troubling when considering that the information obtained from this new requirement already exists and remains on file. In short, this proposal would drastically decrease efficiency while increasing delays, all to obtain information that is already collected and available.

No Recourse for Air Medical Service Providers

The Proposed Rule also offers no recourse for air medical and ambulance providers in cases where the facility's employee refuses to sign the form or the crew is otherwise unable obtain the signature. Air medical and ambulance crews have no ability to require that hospital or other medical facility personnel sign any document. It is unfair to require ambulance and air medical service crews to obtain signatures from individuals who are not required to give those signatures, and then make those signatures a requirement for reimbursement in lieu of the beneficiary's signature when that signature is also impossible to obtain.

Conclusion

Based on the above comments, AAMS, in coordination with other organizations representing the medical transport community, respectfully requests that CMS consider the following:

- Amend 42 C.F.R. §424.36 and/or Pub. 100-02, Chapter 10, Section 20.1.1 and Pub. 100-04, Chapter 1, Section 50.1.6 to state that "good cause for ambulance services is demonstrated where paragraph (b) has been met and the ambulance provider or supplier has documented that the beneficiary could not sign and no one could sign for them OR the signature is on file at the facility to or from which the beneficiary is transported".
- Amend 42 C.F.R. §424.36 to add an exception stating that ambulance providers and suppliers do not need to obtain the signature of the beneficiary as long as it is on file at the hospital or nursing home to or from where the beneficiary was transported. In the case of a dual eligible patient (Medicare and Medicaid), the exception should apply in connection to a signature being on file with the State Medicaid Office.
- Amend 42 C.F.R. §424.36(b) (5) to add "or ambulance provider or supplier" after "provider".

For these reasons, AAMS urges CMS to forego creating a limited exception to the beneficiary signature requirement for emergency ambulance transports, especially as proposed, and instead

eliminate the beneficiary signature requirement for ambulance services entirely if one of the exceptio ns listed above is met.

Thank you for your consideration of these comments.

Sincerely,

Edward Eroe
AAMS President
Partner, CEO
MedServ Air Medical Transport

Dawn M. Mancuso, CAE
Executive Director/CEO

Submitter : **Dr. Peter Mazzara** **Date: 08/31/2007**

Organization : **American Society of Anesthesiologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter
Peter R. Mazzara, M.D.

Submitter : Mr. Frank McKinney **Date:** 08/31/2007

Organization : Achieve Healthcare Technologies

Category : Health Care Industry

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Achieve Healthcare Technologies, a leading supplier of financial, clinical and E-prescribing software to the long-term care industry, appreciates the opportunity to comment on the Exemption to Foundation Standard Requirements for Computer-Generated Facsimiles contained in proposed rule CMS-1385-P, dated July 12, 2007.

Through its participation in the 2006 CMS E-prescribing pilot, and its continued leadership in the development of electronic prescribing standards, Achieve possesses a unique perspectivc on the use of electronic prescribing in the long-term care setting.

Thc comments below rcflect our support for rulings that encourage the adoption of electronic prescribing. They also represent the interests of customers who utilize computer-generated faxes today whilc transitioning to SCRIPT-based electronic processes.

It is our understanding that the proposed rule does not apply currently to long-term care, due to the rule s reference to use of the SCRIPT standard, from which long-term care settings were previously exempted (CMS E-prescribing final rule published November 7, 2005: &we exempt from the requirement to use NCPDP SCRIPT Standard prescription transactions between prescribers and dispensers where a non-prescribing provider is required by law to be a part of the overall transaction process).

That notwithstanding, Achieve has reviewed the proposed rule with great interest. We wish to bring forward certain considerations that apply to multiple care settings, in addition to others that are unique to long-term care.

Our comments focus on three points: (1) clarification of the rule with respect to controlled substances, (2) permission for use of computer-generated faxes when transmitting to pharmacies or other providers without E-prescribing capabilities, and (3) proposal for inclusion of long-term care in E-prescribing regulations, incorporating the appropriate version of SCRIPT (10.1 or higher).

Wc recommend specifically exempting controlled substances from the elimination of computer-generated faxed prescriptions. It is currently not legal to issue written prescriptions for controlled substances using E-prescribing systems. While Schedule II prescriptions are generally required to be in writing and manually signed by the prescriber, certain exceptions apply for residents of long-term care facilities and patients in Medicare-covered hospice programs, enabling electronic faxes to play a role in an effective and secure prescription process. Removing the computer-generated fax exemption for controlled medications will necessitate the addition of manual steps, potentially reducing reliability and security.

We also recommend that CMS allow prescribers and facilities to transmit prescription orders via computer-generated fax to pharmacies that do not use systems that are able to rcceive SCRIPT transactions in the version appropriate to the care setting (version 10.1 for long-term care). LTC pharmacy support for E-prescriptions is not yet commonplace, and currently lags behind support in the retail setting. Without this allowance, providers will be forced to introduce manual printing and faxing steps into their process--increasing the opportunity for errors and resulting patient safety impacts.

Lastly, Achieve strongly encourages the adoption of NCPDP SCRIPT version 10.1 as the foundation standard for long-term care E-prescribing. The 2006 CMS pilot testing of the currently-named foundation standard, SCRIPT 8.1, identified several additions needed to enable use by long-term providers. Those additions have subscquently been made to the standard, and SCRIPT version 10.1 supports E-prescribing in long-term care settings.

Thank you for the opportunity to comment. Please do not hesitate to contact Achieve if you have further questions or require clarification.

CMS-1385-P-15138-Attach-1.PDF

Submitter : Erika Palmtag **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15139-Attach-1.DOC

1/6139

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August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Erika Palmtag, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Mr. Mike Pirbyl **Date:** 08/31/2007

Organization : Iowa Western Community College

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Mike Pribyl, Head Certified Athletic Trainer, Sport Science Program Chair, Iowa Western Community College, Council Bluffs, IA. I have been an athletic trainer for 14 years and have been trained to perform orthopedic rehabiliation through the National Athletic Trainers' Association.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Mike Pribyl, M.Ed, ATC (and/or other credentials)

Submitter : **Tracy Zombar** **Date: 08/31/2007**

Organization : **Tracy Zombar**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Tracy Zombar. 1 have a masters in athletic training and have been running a spine rehabilitation clinic for over three years.

1 am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

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Sincerely,

Tracy Zombar, MAT(and/or other credentials)

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam:

My name is Tracy Zombar. I have been running and working for a spine rehabilation clinic for over 3 years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

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Sincerely,

Tracy Zombar, MAT (and/or other credentials)

Submitter : Nancy Spangler **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15142-Attach-1.DOC

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August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

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RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Nancy Spangler, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Mrs. Kimberly Stento **Date:** 08/31/2007

Organization : Mrs. Kimberly Stento

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a certified and licensed athletic trainer in the state of Indiana. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Kimberly C. Stento, MS, ATC, LAT

Split fees and Space sharing

Incident to and Ancillary reimbursement is forcing orthopedic surgeons in to unwilling fee splitting and space sharing both are violations of the law in spirit and practice. When a surgeon provide ancillary service of an occupational therapist he would initially hire the therapist on a part time basis as an independent practitioner. He then bills for reimbursement at ancillary billing rate every time patient receives therapy in his office. In other words he is forced to share and office and even supervise another professional on a regular basis.

Economic Disadvantage of dis-Intermediation

Imagine a situation in which surgeons practice only in a hospital. Every surgery or visit will attract a large overhead of hospital for the surgeons services. By having surgeon in a private practice medicine has enjoyed major cost savings – advantage of intermediation. If one were to combine two independent professions you will cause disintermediation. Lose financial efficiency due to intermediation. Thus increasing the economic cost of medical service to the public at large and medicare patients in general.

All medicine is experiential

Medicine is highly focused and experience based profession. Some of our smartest students study medicine. Early medical education emphasizes general education and later education is focused in to a specialty of choice. Private practice begins after many years of experience treating patients.

Profession is divided in to specialties and sub specialties. Even among the orthopedic surgeons a hand surgeon will refer a foot'knee injury to foot/knee surgeon. Why or how can it be suggested that another professional specialty such occupational therapist be organized under a surgeon for which the surgeon has no formal training or experience. An occupational therapist today, has extensive therapy education and training and uses special instruments, such as laser or electrotherapy. Correct dosage and location of application of laser is critical to the success for a therapy plan learnt after years of experience.

Rural Clinics Argument

The state law in New York encourages rural clinics to be organized as multi speciality clinics and do not require CMS's in-service reimbursement. As a matter of fact there is not a portion of therapy service that can be delayed so the care can be provided by a true expert such as an occupational therapist.

Immediacy of care

On rare occasions when a therapist may needed after completion of treatment, physician or surgeon

In-service occupational therapy may be warranted. In these cases, just like a specialist is on call, a therapist can be on call as well. Furthermore certain emergency treatment is allowed under the present laws

Loss of independent professionals

Patient recovering from trauma or specialized care in a geographic area other than their place of residence are unable to receive therapy in many areas because there are no independent therapist or practices. Since the are therapists may all be a part of orthopedic surgeons practice. A common problem in the tri-state area.

Trend towards private pay

Since many surgeons, in high cost of living areas, do not accept medical insurance, a practice trend that encourages mingling of orthopedic surgery and therapy would further jeopardize the ablility to receive insurance paid therapy benefit. Thus sharply reducing the benefits of after surgery and non invasive therapy.

Non Invasive treatment

There is a general trend towards non invasive treatment and therapists receive and may continue to receive increasingly, physician prescription for treatment prior to surgery. In recognition of this and other trends the state of New York Dept of Education now allows occupational therapists to perform evaluation without a physicians' prescription. This usually results in non invasive and lower cost non invasive treatments to take precedence over surgery. This emerging trend and practice does and will continue take a beating when either there are no independent therapists available (all are working for surgeons to support their practice) or patients have no chance to receive non invasive treatment to delay surgery , if necessary.

Observed stages in Surgical Practice with embedded therapist practice

Stage I

The surgeons truly requires a therapist for ancillary service. Patients returns to practice to receive surgical treatment but also expects to receive occupational therapy. Surgeon for patient convenience provide therapy via a COTA or an independent part time therapist. But he has to bill the service as ancillary or incident to.

Stage II

The surgeons hires an office manager to help with the growing practice and office manager recommends additional revenue by ancillary or incident to reimbursement.

Stage III

The surgeons must supplement his growing incident to billing practice with more staff and hires additional therapists to supervise the COTA.

State VI

To supplement revenues the surgeon practice hires a PT to supervise Occupational Therapists and COTA to partially meet the supervision requirements. Un-willingly violates the law, PT supervising Ots. Further complicates the issue by providing PT partial ownership of practice.

Stage V

The practice contracts with equipment and supplies company to provide supplies and equipment for patients. The equipment supplier trains OT/PTs in the home use of their equipment. The supplier supplies equipment(electrotherapy and electrodes) directly to patient on surgeons prescription and bills insurance for reimbursement.

Submitter : Shawna Wheeler **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15146-Attach-1.DOC

F,146

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August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Shawna Wheeler, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Ms. Debra Rislow** **Date: 08/31/2007**

Organization : **Gundersen Lutheran - La Crosse, WI**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Our comment is in regard to the Proposed Elimination of the E-Rx Exemption for Computer-Generated Faxes.

While we believe that fully electronic prescription writing and communication is highly desirable for its safety and security benefits, we know through experience that this deadline is premature and that many us who fax prescriptions today will experience undue hardship fully implementing ePrescribing solutions by that January 1, 2009.

We recommend that the deadline in the final rule be changed to January 1, 2010.

Thank you,
Deb Rislow, CIO

Submitter : **Deanna Errico** **Date: 08/31/2007**

Organization : **Clarkson University Dept of Physical Therapy**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am concerned that these proposed changes to the hospital Conditions of Participation have not been fully considered.I am especially concerned that these proposed rules will creatc additional lack of access to quality health care for patients from athletic trainers. Athletic Trainers are qualified to perform physical medicine and rehabilitation serviccs. State law and hospital medical professionals have deemed athletic trainers qualified to perform these services and these proposed regulations attempt to circumvent those standards. I work as both an athletic trainer and a physical therapist and I feel strongly this and I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility

Thank you

Deanna M Errico

Submitter : **Patricia Ellis** **Date: 08/31/2007**

Organization : **NATA**

Category : **Other Health Care Provider**

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Aug. 31, 2007

Re: Docket ID CMS-1385-P

Dear Sir or Madam:

I am a certified professional coder previously employed by a large hospital/clinic. I contend that the physician is the most qualified person to determine who is capable of providing a service to his/her patients. The burden that this regulation places on facilities is not in the best interest of Medicare beneficiaries nor does it benefit the Medicare program.

It appears that a certain CMS staffer is on a crusade to facilitate the APTA s vision 2020. The rules and regulations that she has initiated are a perfect match to the goals of the APTA. These include; physical therapists as the sole provider of physical medicine services, direct access to physical therapists, i.e. no referral from a physician needed, (the time between re-certification of the plan of care has been extended), no physician owned physical therapy clinics.

This monopolization of service does not improve the quality or the costliness of physical medicine. Like most monopolies, they tend to drive costs up not down, they restrict choice and limit innovation. This goes against the movement towards patient directed healthcare, quality based initiatives and access to care.

No evidence has been brought forth that shows non-physical therapists do not provide quality care.
The only conclusion from the Medpac report was that providers need to do a better job of documentation.
Government employees should have the best interests of the public for which their programs were developed in mind, not the financial gains of the physical therapists.

Submitter : Mrs. Mary St.Pierre **Date:** 08/31/2007

Organization : NAHC

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attached"

CMS-1385-P-15150-Attach-1.DOC

1450

NATIONAL ASSOCIATION FOR HOME CARE & HOSPICE
228 Seventh Street, SE, Washington, DC 20003 • 202/547-7424 • 202/547-3540 fax

Elaine D. Stephens, RN, MPH
Chairman of the Board

Val J. Halamandaris, JD
President

August 31, 2007

Herb Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Filed Electronically

Re: CMS-1385-P, RIN 0938-A065: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

The National Association for Home Care (NAHC) is the largest trade association in the United States representing providers of home health and hospice care and the patients they serve. We appreciate the opportunity to provide comments on Medicare Program: Proposed Revisions to Payment Policies Under the Physician Fee Schedule, specifically on the proposed regulations related to qualifications for physical and occupational therapists and assistants.

NAHC is pleased that the Centers for Medicare & Medicaid Services (CMS) has acted on the need to update the current therapy and therapy assistant qualification language to reflect the current names of professional and credentialing organizations and to address foreign and military trained individuals. NAHC strongly supports the delivery of Medicare services by qualified therapists. However, we strongly urge CMS to keep regulations as simple as possible to ensure compliance. In addition we believe that, in light of the continuing problem with therapy and therapy assistant shortages, care must be taken not to exclude individuals who have been providing quality therapy services to Medicare beneficiaries based on current requirements.

At this point in time most states have licensure, or comparable professional requirements, for controlling the practice physical and occupational therapist and physical and occupational therapy assistants. State regulatory bodies have established consistent qualifying criteria based on standards established by the professional organizations that oversee education and practice of therapists and therapy assistants.

Recommendations

1. Establish, as the Medicare requirement, that all physical, occupational, and speech language pathologists and physical and occupational therapy assistant who are licensed, or meet other state regulatory requirements to practice in a state(s), meet Medicare requirements.

2. Require compliance with the current 42CFR §484.4 qualifications for therapists and therapy assistants in those states that do not regulate the practice of physical or occupational therapists or assistants.

3. Add qualifications for foreign trained and military therapists and therapy assistants not currently covered by state requirements, but ensure that any new qualifications do not exclude experienced therapists currently practicing.

4. Update the references to professional and credentialing organizations to reflect the current names.

The conditions at §§410.43, 410.59, 410.60, 482.56, 485.705 and 491.9 all include the requirement that qualified therapists and therapy assistants who meet the qualifications in §484.4 or otherwise recognized by the State in which practicing prior to January 1, 2000 "...continue to furnish Medicare (physical, occupational) therapy services at least part time without an interruption in furnishing services for more than 2 years." Should this regulation be finalized many very capable and competent therapists who provide therapy services to populations other than Medicare patients, or therapists who have taken a hiatus from practice but continue to engage in educational programs, could be inappropriately barred from furnishing Medicare services.

To establish a blanket uninterrupted practice requirement leaves too much room for controversy. Determination of what constitutes "part time" is subjective. State regulatory bodies have established both educational and employment requirements for professional practice.

Recommendation

1. Eliminate the language referencing "interruption in furnishing services of more than 2 years" from the provider conditions.
2. Add a reference to ongoing practice or educational requirements in the qualifications for therapists and therapy assistants and apply these only in those states that do not have professional licensure or other credentialing.
3. Refrain from referring to the provision of "Medicare" services as a qualification.

Again, thank you for the opportunity to comment on these proposed rules. If you wish to discuss our comments further I can be reached at (202) 547-7424

Thank you,

Mary St.Pierre
Vice President for Regulatory Affairs

Submitter : **Mrs. Donna Zastoupil-Hartze** **Date: 08/31/2007**

Organization : **AIM Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am personally opposed to physician owned physical therapy practices. I have personal experience in which physicians who would normally not have referred for physical therapy are now doing so since they personally benefit. In addition, I have been a witness to the pressure of billing a certain number of units in order to meet financial goals. It is my personal opinion that objectivity has been lost in these cases.

Donna Zastoupil-Hartze, PT

Submitter : Jennifer Murphy **Date:** 08/31/2007

Organization : Orthopedic Rehabilitation Services

Category : Other Health Care Provider

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
BRIEF INTRO ABOUT SELF ie. Where you work, what you do, education, certification, etc.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Jennifer Murphy, M.S., ATC, C.S.C.S

Submitter : Rachel Groman **Date:** 08/31/2007

Organization : AANS/CNS

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

TRHCA--Section 101(d): PAQ1

TRHCA--Section 101(d): PAQ1

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

CMS-1385-P-15153-Attach-1.PDF

1153

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS
THOMAS A. MARSHALL, *Executive Director*
5550 Meadowbrook Drive
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President
JON H. ROBERTSON, MD
University of Tennessee
Memphis, Tennessee

American Association of Neurological Surgeons

CONGRESS OF
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info@1CNS.org

President
DOUGLAS KONDZIOLKA, MD
University of Pittsburgh
Pittsburgh, Pennsylvania

August 31, 2007

Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue
Washington, DC 20201

Re: Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 72 Fed. Reg. 38,122 (July 12, 2007) (file code CMS–1385–P)

Dear Mr. Kuhn,

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), we appreciate the opportunity to comment on the above referenced proposed rule published in the *Federal Register* on July 12, 2007. We will focus our comments on two issues:

- Tax Relief and Health Care Act of 2006--Section 101(b): Physician Quality Reporting Initiative; and
- Tax Relief and Health Care Act of 2006--Section 101(d): Physician Assistance and Quality Initiative

TRHCA—SECTION 101(b): Physician Quality Reporting Initiative

In the proposed Medicare Fee Schedule, CMS confirmed that the 2007 PQRI will be renewed in January 2008 for at least one year. The AANS and CNS are very concerned that the process for developing the 2008 PQRI is advancing despite the fact that the 2007 PQRI just started on July 1, 2007. The 2008 program is being developed without any attempt to evaluate the most basic elements of the 2007 PQRI program, such as impact on patient care, physician participation rates, and implementation challenges and costs. While we understand that CMS is required by the Tax Relief and Health Care Act of 2006 (TRHCA) to implement the 2008 program, we urge the agency to use its discretion to closely review the 2007 program before moving ahead.

2008 Measure Development Process

The AANS and CNS are concerned that the requirement that measures be developed "through the use of a consensus-based process" is too broad. For any reporting system to improve

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725 Fifteenth Street, NW, Suite 500 Washington, DC 20005
Phone: 202-628-2072 Fax: 202-628-5264 E-mail: korrico@neurosurgery.org

quality, the measures must be meaningful to clinical care and relevant to the specific specialty physicians. Therefore, direct physician involvement in the development, testing and implementation of quality measures is the only way to ensure that measures are appropriate and clinically-relevant. While we appreciate that the proposed rule recognizes the American Medical Association's Physician Consortium for Performance Improvement (PCPI) as one source for developing quality measures eligible for inclusion in PQRI 2008, we urge CMS to go further and require that the PCPI be deemed the *only* entity to development physician-level quality measures. The PCPI process is consensus-based and is physician-led. This characteristic will ensure physician buy-in on measures, which is essential for an effective quality reporting program. Further, tasking the PCPI as the only group for developing physician measures significantly reduces the risk of duplicative or contradictory measures and ensures measure harmonization. All stakeholders, including individual specialty societies, quality improvement organizations, CMS, NCQA, AQA and others have the opportunity to collaborate and participate in the PCPI process; thus ensuring that the PCPI meets CMS's goals to obtain a broad spectrum of input as physician quality measures are developed in the future.

In establishing this quality reporting program, the statute requires that the quality measures "shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA)." In its proposed interpretation of this requirement, CMS offers the AQA and NQF as examples of "consensus organizations." The AANS and CNS believe that the NQF plays an increasingly important role in evaluating, endorsing and promulgating quality performance measures. Although physician organizations continue to have a minority voice, we appreciate the positive steps the NQF has taken in recent months to improve its voting structure and to ensure that all stakeholders are equally represented on it board and councils. The AQA, on the other hand, continues to have a flawed and unpredictable process. The AQA currently lacks a standardized voting and governance structure and does not allow surgical specialty societies to effectively participate in the quality measurement process. While the AQA may to a certain extent serve a useful function in deciding whether measures are ready for implementation by health plans and other payers, it should not be perceived as, or become a substitute for, the more rigorous NQF endorsement process. The measure developers (which should be identified as the PCPI), the NQF, and the AQA each have distinct roles at distinct points in time in the measure development process. It is critical that CMS preserve this sequential process by limiting the functions of the AQA as an entity that implements measures once they have been endorsed by the NQF, rather than expanding the charter of the AQA to include measure endorsement.

2008 Proposed Measures

In the proposed rule, CMS proposes seven categories of measures that it will consider for the 2008 PQRI. The agency also seems to indicate that the 2007 PQRI reporting requirements will be carried over to the 2008 program and apply equally to each of the different categories of measures. The AANS and CNS request that CMS clarify how it plans to apply the same rules across the seven categories of measures. We are particularly curious about how the newly proposed structural measures, which are currently under development by Quality Insights of Pennsylvania, will be treated compared to other process measures. For example, could a physician report on a mix of structural and process measures to meet the three measure requirement? Furthermore, the intent and applicability of these structural measures remains unclear. Are they intended for physicians and non-physicians, or for non-physicians only?

Use of Registries

The proposed rule also includes language outlining CMS's plan to test models through which providers could report claims-based process measures to CMS via registries or electronic databases. AANS and CNS strongly support the concept of the use of clinical data registries for purposes of improving health care quality, and we commend CMS for considering the feasibility and utility of accepting clinical quality data submitted from registries, databases, and electronic health records. However, we are deeply disappointed by CMS's continual reliance on a one-size-fits-all approach to measurement. The registry proposal outlined in the rule simply offers a new option for funneling flawed process measures to CMS through the existing claims-based system. By doing so, CMS ignores the fact that process measures alone have little relevance to measuring the quality of care provided by acute care specialties, since they do not measure surgical outcomes – the more relevant test of surgical quality.

For the past year, AANS and CNS members and staff have met with CMS officials to discuss the value of collecting clinical outcomes data. We urged CMS to look at ways in which a physician could qualify for bonus payments by reporting prospective outcomes data to a registry or database that has the capability to compare outcomes on regional and national level. The registry reporting proposal set forth in the proposed rule in no way recognizes that clinical outcomes data collection is the most appropriate way to report and measure surgical quality. The AANS and CNS continue to urge CMS to structure Medicare quality programs in a way that more accurately reflects the needs of different medical specialties. The AANS and CNS also request that any registry reporting proposal include the following criteria:

1) Physicians must have access to and control of the data being submitted and/or reported;
2) Transparency should be incorporated such that patients and physicians are informed of the policies and processes for use;
3) Data should be stripped, whenever possible, of patient identifiers;
4) Patients and physicians should have the option to "opt out" of the system.

TRHCA—SECTION 101(d): Physician Assistance and Quality Initiative

The proposed rule also outlines CMS's plans to continue to pay bonus payments to physicians who successfully participate in the PQRI program using the $1.35 billion fund (the "Fund") created in the TRHCA, rather than using these funds to reduce the Medicare physician payment cuts. As a result, physicians still face an almost 10 percent payment rate cut on January 1, 2008. The AANS and CNS strongly believe these funds should be used to minimize cuts in the physician reimbursement, rather than to continue to fund the PQRI program. In April, the AANS and CNS, along with over 80 other physician and health professional organizations, sent a strong letter urging the Administration to use this money to help Medicare physician payments keep pace with increases in practice costs. Organized neurosurgery is disappointed that CMS did not incorporate these concerns into its proposed rule and would greatly appreciate if CMS would reconsider its decision.

CMS claims there are "fundamental legal and operational problems" associated with applying the funds to the negative update. For instance, if CMS were to use the Fund to reduce the negative update for 2008, actual physician spending could be above or below CMS's estimate of the reduction to the update since Medicare is an entitlement program and total annual costs

cannot be predicted in advance. CMS is concerned, therefore, that it would have to estimate an amount by which to reduce the update that is low enough to ensure that the $1.35 billion funding cap is not exceeded. If this amount is too low, however, it could leave money in the Fund, and CMS is concerned that it may not have the statutory authority to spend the remaining funds in future years.

The AANS and CNS believe there are ways to overcome these "legal and operational" challenges. For example, CMS could explore applying the $1.35 billion to past year's SGR debt. This would reduce the slated cuts to the 2008 conversion factor. Furthermore, the Congressional Budget Office (CBO), in providing Congress with a cost estimate for this provision of the TRHCA, anticipated that CMS could develop a plan by which 90 percent of the Fund could be used in calendar year 2008 and the remaining funds in 2009. CBO also noted that "the funds will remain available until spent."

CMS's decision to use the Fund entirely for quality improvement purposes is also counter to the intent of Congress and the recommendation of the Medicare Payment Advisory Commission (MedPAC). Congress intended that this Fund be established to benefit all physicians. Use of the Fund to establish bonus payments for the PQRI will allow only a limited number of physicians to qualify for these funds, while applying the Fund to the conversion factor will allow all physicians to benefit. Furthermore, MedPAC has recommended that Medicare payment rates for physicians' and other health professionals' services be updated by 1.7 percent to reflect its forecast of practice cost increases in 2008 and that the $1.35 billion fund "be directed entirely toward a conversion factor update for 2008." While using the Fund toward the 2008 payment update will not be enough to achieve a full 1.7 percent update, it would help mitigate the disastrous effects of the 9.9 percent payment cut and also lower the costs of Congressional action aimed at preventing these cuts.

Finally, CMS states in the proposed rule that implementing the Fund through an extension of the quality reporting program is the best way to ensure physicians get the greatest benefit from the Fund's resources. Neurosurgeons are committed to improving the quality of health care by participating in meaningful quality measurement programs. However, with the looming payment cut, many physicians will not be able to invest the time and financial resources needed to participate in the 2008 PQRI, and thus would not even be eligible for the potential 1- 2 percent bonus payment. The payment cut also would seriously hinder a physician's ability to invest in health information technology and other practice improvements that lead to high quality care in general.

It is therefore imperative that CMS use the $1.35 billion to buy down the physician payment cut, which will have a positive impact on all physicians, rather than apply it all towards a future quality reporting program whose value has not yet been assessed or demonstrated.

CONCLUSION

Thank you for considering our comments. As we have stated in previous comments, the AANS and CNS appreciate the dedication and hard work of individual CMS staff members. We urge CMS to explore every avenue within its regulatory authority to mitigate this year's physician payment cuts and to ensure that the Medicare quality reporting program is meaningful and relevant to clinical care and mindful of the current economic environment under which physicians practice. The ability for neurosurgeons to continue to treat Medicare beneficiaries in

the face of increased costs, expanded administrative burdens, and plummeting reimbursement is rapidly becoming unsustainable.

Sincerely,

Jon H. Robertson, MD, President
American Association of Neurological Surgeons

Douglas Kondziolka, MD, FACS, President
Congress of Neurological Surgeons

Robert E. Harbaugh, MD, Chairman
AANS/CNS Quality Improvement Workgroup

Staff Contact:
Rachel Groman, Senior Manager
Quality Improvement and Research
AANS/CNS Washington Office
725 15th St., NW Suite 500
Washington, DC 20005
Office: 202-628-2072
Fax: 202-628-5264
Email: rgroman@neurosurgery.org

Submitter : **Dr. Harvey Plosker** **Date: 08/31/2007**

Organization : **Broad Anesthesia Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Mrs. Kimberly Jaramillo** **Date: 08/31/2007**

Organization : **Hope International University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Kimberly Jaramillo. I work at a small college in Fullerton, CA. I am a Certified Athletic Trainer with a Masters in Physical Education and Athletic Training education. I currently supervise the Prevention, Evaluation, Treatment, and Rehabilitation of all athletic injuries that occur within our nine intercollegiate athletic teams.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed ehanges to the hospital Conditions of Partieipation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Kimberly Jaramillo, MA, ATC

Submitter : Carrie Voss **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15156-Attach-1.DOC

ADVANCED PAIN MANAGEMENT

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August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Carrie Voss, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Mr. Shawn Allender** **Date: 08/31/2007**

Organization : **STAR Physical Therapy**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Shawn Allender and I am a Certified Athletic Trainer that works in an Outpatient Physical Therapy.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Shawn Allender MS,ATC
Clinic Director
STAR Physical Therapy
Franklin, Tennessee

Submitter : **Mr. Benjamin Medlin** **Date: 08/31/2007**

Organization : **Guilford COunty Schools**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Benjamin Medlin. I am employed with Guilford County Schools as an educator and as a Certified Athletic Trainer where I assume responisibility for the health care of the student-athletes. I hold a Masters Degree in Athletic Training, a certification as an Emergency Medical Technician, and a license and certification as an Athletic Trainer.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
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Sincerely,
Benjamin Mcdlin, MA, LAT, ATC, EMT-B

Submitter : Mr. Russ Corvese **Date:** 08/31/2007

Organization : BioScrip

Category : Health Care Industry

Issue Areas/Comments

CAP Issues

CAP Issues

CAP Issues

Submitter : **Ginger Fenter** **Date: 08/31/2007**

Organization : **F S**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.

Mr. Weems,

My purpose is to draw your attention to an abusive situation continuously occurring within our region because of physician-owned physical therapy services.

My name is Ginger Fenter. I am a physical therapist in private practice in Arkansas providing care since 1989. My partners and I have successfully provided physical therapy services in hospitals as well as home health services in four different rural areas. The drive from any of our hospital serviced areas to the nearest large city is approximatcly an hour.

I submit this information because I feel a blatant abuse of the in-office ancillary services exception occurs in this city. Two large multi-specialty and family practice physician owned groups exist in this city. Both of these groups have physical therapy clinics in the same building. The common practice of the larger group is to strongly recommend that patients drive three times week to their office for physical therapy. The other group more frequently refers their rural patients back to their homc town clinic.

Consider: A patient is seen by a physician in the larger group. They are immediately sent to the physical therapy department for a physical therapy evaluation and treatment at which time they are strongly encouraged to continue treatment at the physician-owned facility. They are not offered any other option.

Occasionally, we will bc contacted requesting our services but the patient has not been seen by a physician. We explain the Medicare requirement of physician referral and the patient chooses to see a physician in this group. When we follow up on the patient, we are told that they would rather come to us but have to go to the larger city to see their doctor s physical therapist.

I must disclose that if the patient adamantly refuses to return after their evaluation and treatment, they are then given our facility information with instructions to contact us for an appointment. The patient is usually told at that time that we provide a good service and work closely with the physicians in their practice. Once we finally receive the referral, we have a good working relationship with the physicians of both groups. Please note, an unnecessary duplication of the evaluation charge must occur when the patient changes physical therapy providers after one visit.

The problem exists when a patient simply wants to do what they feel their doctor wants them to do. That should be positive. But, when the financial interests of a group dictate that a patient, especially an elderly patient, drive more than an hour one way, three times a week, it obviously is not a positive. Most of these patients either do not know they have an option or are too afraid to say they would rather see a local therapist. Many of the ones that finally reach our clinic out of exasperation are tearful and apprehensive because they fear repercussion from not attending their doctor s therapy service. They explain to us that they simply cannot afford the drive, have no one to take them that far consistently or are hurting worse from the drive than if they didn t attend at all.

I have attempted to state the facts and remove any emotional component from this submission. However, after hearing this from patient after patient and realizing that the vast majority of Medicare recipients in our area find themselves in this difficult position, not being incensed would constitute apathy.

Thank you for your consideration of my comments.

Sincerely,

Ginger Fenter, PT
F S & V Physical Therapy, Inc.
479-632-0321

Please note: The attempt to attach the former in letter format on our letterhead was unsuccessful.

Submitter : Mr. Arthur Cassot **Date:** 08/31/2007

Organization : AANA

Category : Other Health Care Provider

Issue Areas/Comments

Background

Background

As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

This increase in Medicare payment is important for several reasons.

ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.

ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.

ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.

Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).

America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.

Submitter : Ms. Jocelyn Moody **Date:** 08/31/2007

Organization : Henderson State University

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:
I am an assistant athletic trainer at Henderson State University, which is a Division II university, in Arkadelphia, AR. I received my Bachelor of Science degree at the University of Arkansas at Fayetteville in May 2003 and my Master of Arts degree at San Jose State University in California in August 2006. I have been a certified athletic trainer since November 2003. It is vital for athletic trainers to have an opportunity to work in these settings. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Jocelyn A. Moody, MA, ATC

Submitter : Dr. Watson Fung **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15163-Attach-1.PDF

Watson Fung, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : **Mr. Michael Ribar** **Date: 08/31/2007**

Organization : **Froedtert Hospital**

Category : **Hospital**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

As a LAT, I am in direct oposition to the proposed medicare legislation that would limit LAT's to work for Medicare provider hospitals. I feel this is an infringement on my rights to practice as a LAT and my rights for the persuit of a better life guaranteed through the constitution. I am writing to voice my opinion and ask for help in defeating this legislation.
Thank you
Michael Ribar LAT,PES

1565

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Josh Keller, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Mr. Robert Taylor **Date:** 08/31/2007

Organization : Lakeland Rehabilitation Center

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Robert Taylor and I am a certified athletic trainer, certified strength and conditioning specialist, and certified performance enhancement specialist. I work in an outpatient physical therapy center, which I have done since 1993, treating patients of every age. I also work at local school districts, performing clinical outreach programs and educational programs.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Robert Taylor ATC,CSCS,PES
Lakeland Rehabilitation Center
Niles, MI

15161

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

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The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

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		(Non-Facility)
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I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

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***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Karen M. Eller, MD
Interventional Pain Specialist
Palmetto Pain Center
41A Marshellen Drive
Beaufort, SC 29907

1503

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

John Samuels, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : Christina Domino **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15169-Attach-1.DOC

1169

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

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I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
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64479 (Inj foramen epidural c/t)	58%	21%
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The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

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I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

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Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

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Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Christina Domino, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Mrs. Serina Bowen** **Date: 08/31/2007**

Organization : **Self-employed**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer with a master degree in Kinesiology. I am currently self-employed, but in the past have worked for physical therapist in physcial therapy clinics.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Serina Bowen, M.Ed, ATC/LAT

Submitter : Mr. Robert Bianchi **Date:** 08/31/2007

Organization : Bianchi, Kasavan & Pope, LLP

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Our office in San Benito County California is very dependent on a very limited health care provider services. We employ over 30 people and their families. We request that you use option #3 under the proposed rules. We would also like for your office to use correct county figures. We understand that the GAO has updated the figures and if CMS used them , then our service providers would be more in line with neighboring counties.
My number is 831.801.0351

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am requesting the CMS to remove physical therapy from the "in office ancillary services" exception to the federal self-referral laws citing the following points:
1. The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to practices that they have a financial interest in and to over utilize these services. By eliminating physical therapy as a designated health service furnished under the in-office ancillary services exception, CMS would reduce a significant amount of abuse and over utilization, and enhance the quality of eare for the patient.
2. Physician direct supervision is not needed to administer physical therapy services. Many physicians are using "office staff" to provide physical therapy. A Physical Therapist is not evaluating the patient or providing treatment. Physical Therapists are currently educated for an average of seven plus years, receiving a Master's degree or Doctorate in Physical Therapy. With these requirements as well as a state license required for practice, why would "office staff" be able to provide physical therapy in a physician's office? It is ridiculous to me that this can be allowed. It is a disservice to the patient. Treatment can not be proper, effective and cost efficient. I have treated patients that have received prior "physical therapy" treatment in a physician's office that have had little or no progress. Treatment is continued in these offices because of financial incentive of the owner (physician), without re-assessment or improvement. Skilled manual therapy can not be provided by "office staff". This, again is a great disservice to the patient.

I thank you for your consideration in this matter.

Submitter : **Mr. Brian Murphy** **Date: 08/31/2007**

Organization : **Shelbourne Knee Center @ Methodist Hospital**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I have been a certified athletic trainer for 12 years. I have been employed in the clinical setting for the last 9 years and currently work as an athletic trainer providing rehabilitation services in a physician owned clinic. I work with patients before surgery providing rehabilitation guidelines in efforts for them to improve and avoid surgery. I also work with patients following surgery to provide post operative rehabilitation guidelines in efforts to help them return to their desired level of physical activity. I have a Bachelor of Arts Degree from Purdue University and a Master of Science Degree from the University of Iowa. I was certified by the National Athletic Training Association Board of Certification in 1995.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Sincerely,

Brian Murphy, MS, ATC
Athletic Trainer
Shelbourne Knee Center @ Methodist Hospital
Indianapolis, IN
317-924-8638

Submitter : Mr. Erin Stave **Date:** 08/31/2007

Organization : St. Mary's/ Duluth Clinic Health Systems

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Regulation Committee,

I am a Certified Athletic Trainer in Duluth, MN and the passing of these new provisions may greatly effect my role in the clinic and career.

Certified Athletic Trainer's have the educational competencies and professional attributes which physician's and patients of all ages need. I believe that the treating physician should be able to make up their own mind, within reason, as to which allied health care professional can help treat their patients. I understand that there needs to be limits on treatment protocols for some patients, however, this provision may end up costing insurance companies and Medicare/ Medicaid more money in the long run. As the demand for physical medicine and rehabilitation goes up with little to no room for patients to schedule, costs will rise. This is just like business. More demand equals higher cost! If this provision doc snot go through than access for patients will go up. This will also equal happier patients, and quicker return to noraml daily living. This in turn can create less costs for the payors.

Please support certified athletic trainer's across the nation by not passing this provision.

Thank you for your time,

Erin Stave, M.A., A.T.,C
St. Mary's/ Duluth Clinic Orthopedics
Duluth, MN

Submitter : Tiffany Frazier **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15175-Attach-1.DOC

15175

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

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RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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Sincerely,

Sincerely,

Tiffany Frazier, PA-C
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Dr. Enrique Via-Reque **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15176-Attach-1.PDF

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Chris Phillips** **Date: 08/31/2007**

Organization : **Compete Performance**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Chris Phillips and I am a certified Athletic Trainer and Strength and Conditioning Coach. I currently run an Athletic Performance business, as well as the Head Athletic Trainer with the Los Angeles Avengers of the Arena Football League. I have spent the last 15 years treating injuries occurring to professional athletes including eight years in the National Hockey League.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Chris Phillips ATC, CSCS
Compete Performance
www.competeperformance.com

Submitter : Mr. John Sullivan **Date:** 08/31/2007

Organization : Sisters of Mercy Health System

Category : Health Care Provider/Association

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

On behalf of Sisters of Mercy Health System (Mercy) we would like to thank you for the opportunity to provide the following comments regarding the July 7, 2007 notice (CMS-1385P) regarding the proposed elimination of the E-Rx exemption for computer-generated faxes.

Mercy operates hospitals, physician practices, outpatient clinics, health plans and related health and human services in a seven-state area, including Arkansas, Kansas, Louisiana, Mississippi, Missouri, Oklahoma, and Texas. Its members include 19 acute care hospitals, providing nearly 4,500 licensed beds, a heart hospital, a managed care subsidiary (Mercy Health Plans), physician practices, outpatient care facilities, home health programs, skilled nursing services, and long-term care facilities. Services are provided by approximately 27,000 co-workers and 3,300 physicians who are employed or practice at Mercy facilities. Mercy is the 10th largest Catholic health care system in the U.S. based on net patient service revenue and is sponsored by the Sisters of Mercy-St. Louis Regional Community.

In 2006, Mercy launched the Genesis Project in response to compelling factors facing the healthcare industry. Once completed in 2011, the Genesis project will result in a large implementation of an integrated electronic medical record across the physician/clinic and hospital settings including computerized physician order entry, patient monitoring, patient care documentation, radiology, pharmacy, emergency, surgery and the ICU. This project is the single largest project in our health system s history representing almost a half a billion financial commitment in the next few years.

We believe that e-prescribing is the safest and most secure method for communicating prescriptions to pharmacies. We support the push to make electronic prescriptions the standard for the country. However, we believe that eliminating the ability to fax prescriptions by January 2009 is too soon and that a date of January 2010, at the soonest, would remove undue hardship on many healthcare providers who are still planning for and implementing the new technology.

The proposed date of January 2009 will likely have the unintended consequence of moving an electronic faxed prescription to a handwritten prescription. Computer-generated faxes are in almost all cases safer, more secure, and more convenient than printed prescription.

Furthermore, it is our experience that the electronic prescribing network is not currently ready in all markets. Third-party intermediaries required for robust electronic prescription communications, such as SureScripts and RxHub, often have inaccurate or missing data about local pharmacies because they rely on the pharmacies themselves to provide this information. This inevitably results in failed ePrescribing transactions. Also, not all pharmacies, have implemented the receiving side of the ePrescribing solution. It is highly unlikely, that these gaps could be completely eliminated in the short timeframe allowed in the proposal. Mercy has 18 integrated retail pharmacies as a part of our delivery network. None of these pharmacies are able to accept electronic prescriptions today.

In a significant number of cases, ePrescription transactions fail for a variety of reasons. In these situations, computer-generated faxing has been an invaluable back-up mechanism. Eliminating faxing as a back-up would result in delayed and missed prescriptions, which presents an unnecessary risk to patient safety. We recommend that even after the final ePrescribing requirement date that computer-generated faxing still be allowed as a back-up for communicating prescriptions in the event that the fully electronic system fails for any reason for a particular transaction.

Thank you for your consideration of these recommendations.

CMS-1385-P-15179-Attach-1.PDF

MERCY
SISTERS OF MERCY
HEALTH SYSTEM

August 30, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244

Dear Ms. Norwalk:

On behalf of Sisters of Mercy Health System (Mercy) we would like to thank you for the opportunity to provide the following comments regarding the July 7, 2007 notice (CMS-1385P) regarding the proposed elimination of the E-Rx exemption for computer-generated faxes.

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Thank you for your consideration of these recommendations. We look forward to a time in the near future when patients have the safety, security, and convenience benefits that fully electronic prescription writing promises.

Once again, Mercy is grateful for this opportunity to provide our comments. If you should have any questions or concerns, please feel free to contact me at (314) 628-3806 or at Jon.Lakamp@mercy.net.

Sincerely,

John Sullivan
President / Chief Executive Officer

Submitter : **Dr. wayne wallender** **Date: 08/31/2007**

Organization : **Dr. wayne wallender**

Category : **Physician**

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Wayne Wallender,D.O.

Submitter : Dr. Louis Serpico **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15181-Attach-1.PDF

15181

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Louis Serpico, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Louis Serpico, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : Dr. Susan Gutierrez **Date:** 08/31/2007

Organization : Dr. Susan Gutierrez

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"see Attachment"

CMS-1385-P-15182-Attach-1.TXT

CMS-1385-P-15182-Attach-2.TXT

15182

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05	Interventional Pain Management Physicians

	(Non-Facility)	- 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Susan Gutierrez, M.D.
5601 Norris Canyon Road
Suite 340
San Ramon, CA 94583
Ph: 925-855-5525
Fax: 925-277-1557

Submitter : Dr. Suzanne Serpico **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15183-Attach-1.PDF

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Suzanne Serpico, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : **Mrs. Karyn Gentile** **Date: 08/31/2007**

Organization : **Baldwin-Wallace College**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Dear Sir or Madam:

As an allied health profession, a certified and licensed athletic trainer and a faculty member in higher education, I am very concerned with the new proposed therapy standards in regards to staffing provisions. I am disheartened about the negative impact this will have on the profession of athletic training as well as the unwarranted message of disrespect for the skills and abilities of athletic training professionals being conveyed to the public, to current athletic training students to insurance carriers, and to fellow allied health professionals.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Karyn A. Gentile, MS, ATC, LAT

Submitter : Amanda Ely **Date:** 08/31/2007

Organization : Carle Foundation Hospital Sports Medicine

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Amanda Ely and I am a certified athletic trainer employed by Carle Foundation Hospital Sports Medicine in Champaign, Illinois. I do outreach athletic training to Parkland College. I have a BS in Kinesiology-Exercise Science from the University of Wisconsin and a MA in Educational Psychology from the University of Arizona. I have been working as a certified athletic trainer for 6 years. I have been employed in Division I athletics, Division III athletics, and the clinic-outreach setting.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Amanda Ely, ATC, MA

Submitter : Dr. Charles Tuma **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15186-Attach-1.PDF

15186

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Charles Tuma, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : Mr. Jason Cobb **Date:** 08/31/2007

Organization : Q1 Training and Consulting Inc.

Category : Health Care Industry

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I have worked in a variety of settings, with outpatient physical therapy, industrial injury management and prevention and DME fitter with an Orthopedic Physician practice over the last 8 years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jason Cobb MS, ATC

Submitter : **Andrea Bender** **Date: 08/31/2007**

Organization : **Elon University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Andrea Bender and I am a Certified Athletic Trainer and Professor at Elon University in Elon, NC. Not only do I teach our young students to be successful Allied Health Care Professionals, I am a clinician providing high quality health care to roughly 300 Division I student athletes.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Andrea L. Bender, MS, LAT, ATC

Submitter : Jorena Simpkins **Date:** 08/31/2007

Organization : Campbell County Schools

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer working in a secondary school environment at this time, however I have five years of experience in an out-patient physical therapy clinic working with patients of all ages and medical issues. This working environment, as well as the one I am involved in now, allows me to do the work I was educated for and completely enjoy doing. In becoming an ATC almost 20 years ago I have been able to fulfill the desire to help others regain mobility and in some cases their livlihood. That is the reason I do what I do for a living.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Sincerely,

Jorena B. Simpkins, ATC

Submitter : Mrs. Dianne Cortese **Date:** 08/31/2007

Organization : Golden Gate Physical therapy

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Self referral by physician should be elimated in order to avoid abuse of services and health benefits.I am in favor of stopping this loophole and believe PT services should be rendered by professional and licensed PT and PTA.

Submitter : **Mr. Chad Vaughn** **Date: 08/31/2007**

Organization : **Gibson Area Hospital**

Category : **Hospital**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Chad Vaughn and I am an athletic trainer in the hospital outpatient setting. I have worked in the outpatient setting now for 12 years anbd have coordinated sports medicine programs for 5 years total.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Sincerely,
Chad Vaughn, MS, ATC, CSCS

Submitter : Dr. Gina Montague **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15192-Attach-1.PDF

15192

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Gina Montague, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : Mr. Robert Schultz **Date:** 08/31/2007

Organization : University Of Colorado Hospital

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I have provided quality health care to athletes at the collegiate level and people whom are medicare insured. My skillls and knowledge allow these people to benefit from my expertise. Please consider that there are very talented people who can help improve the health of our society with an ATC behind their name.

Sincerely,

Robert G. Schultz PTA, ATC

Submitter : **Dr. Curt Gramlich** **Date: 08/31/2007**

Organization : **Dr. Curt Gramlich**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor inerease as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Curt Gramlich, MD Anesthesiologist

Submitter : Kathy Borrelli **Date:** 08/31/2007

Organization : Kathy Borrelli

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Administrator-Designate,
I wish to comment on the July 12th proposed physician fee schedule rule, specifically the issue surrounding physician self referral and the "in-office ancillary sevices" exception.
I have been practicing physical therapy for 27 year, most of those in physical therapist owned private practices. I have had several patients in the past that have come to my office for physical therapy after receiving physical therapy at physician's offices and felt that their care was superior at our office. The main reason the patient had gone to their physician's office was because the physician suggested it. Thc physician-patient relationship is strong with the physician able to influence the patient's decisions on his or her care. Physicians who own practices that provide physical therapy services have an inherent financial ineentive to refer their patients to the practices they have invested in, with the possibility of over-utilization those services for financial reasons. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exemption CMS would reduce a significant amount of programmatic abuse, overutilization of physical therapy services under the Medicare program, and enhance the quality of patient care.
Thank you for your consideration in this matter.
Sincerely,
Kathy Borrelli, PT

Submitter : Dr. John Paggioli **Date:** 08/31/2007

Organization : Eastern CT Pain Treatment Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15196-Attach-1.DOC

CMS-1385-P-15196-Attach-2.DOC

1516

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05	Interventional Pain Management Physicians

	(Non-Facility)	- 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

John Paggioli, M.D.
Eastern CT Pain Treatment Center
190 W. Town Street
Norwich, CT 06360

Submitter : Mr. Michael Carr **Date:** 08/31/2007

Organization : Meritcare

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
Michael Carr CRNA MS
4101 54th St S
Fargo ND 58104

Submitter : **Robin Palesano** **Date: 08/31/2007**

Organization : **Robin Palesano**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Robin Palesano

Submitter : Dr. Ellen Bodner **Date:** 08/31/2007

Organization : Council of Licensed Physiotherapists of NYS,Inc.

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am a member of the Council and a PT in private practice for over 30 years. I am in support of measures taken by CMS to assure the quality of physical therapy treatments provided to the public in all settings and look for further regulation of settings that are quasi-legal,fraudulent and self-referring.I am extremely concerned that when ancillary services are provided by physicians that they are exempt from self referral laws and create an environment fraught with fraud and abuse. It is nothing more than referral for profit and self-interest and works against the best interest of the patient. I have had many situations where physicians outrightly tell their patients that they must come to their facility because their care will be monitored directly by the physician, full-knowing that they are never on premise. I have been told personally by several orthopedists and neurologists that by opening their own PT facility it was the best thing they ever did since it helps them maintain their high incomes otherwise diminished by managed care. In addition, other specialists to whom they refer their patients feel obligated to send back the referred patients to these physician- owned facilites even if the location and care is not suitable to the patient. The patients are not being directly informed that these facilities are physician- owned and when they mention that they would like to go elsewhere, they are actively discouraged. With the exception of board certified physiatrists, these settings should not be allowed by Medicare regardless of the geopgraphuc setting of the PT services relative to the phsycian-owner referrer. The only exception should be for diagnostic and evaluation purposes but not treatment. Also of concern are multi-specialty facilities that offer a variety of services without specifying ownership. They should be closely monitored to assure thar a quality specialist is delivering the services.
Referral for profit in any form is wrong and should not be tolerated by an agency concerned about overpayment for unnecessary care. Respectfully yours,
Ellen Bodner, PT, DPT

Submitter : Mr. Chuck Conner **Date:** 08/31/2007

Organization : Mr. Chuck Conner

Category : Other Health Care Provider

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Chuck Conner and I have been a certified athletic trainer since 1994. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Chuck Conner, ATC, LAT, M.A.

Submitter : Dr. philip glengary **Date:** 08/31/2007

Organization : Dr. philip glengary

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1385-P-15201-Attach-1.DOC

CMS-1385-P-15201-Attach-2.DOC

1520

Philip J Glengary, MD
72 Estate River #16
Kingshill, USVI 00850
August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations. For instance, in Michigan where I practice primarily, the senior citizens are often sent to institutions which do not offer the highest quality care. This shunting or shuffling occurs in the ER's and primary care physician offices. A second effect seen here in Michigan is the poor recruiting that we encounter to meet our future manpower needs to serve all of the citizens here. Why become an anesthesiologist, a profession known to be extremely high stress when a less stressful medical specialty beckons at often a higher reimbursement.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Philip J Glengary, MD

Submitter : Mr. James Crook **Date:** 08/31/2007

Organization : The Reg. Med.Cent. - Orangeburg/Calhoun Counties

Category : Hospital

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer and Chief Petty Officer in the Navy Reserve in Orangeburg, SC. I have been in the medical field for over 23 years. Over the years I have practiced in a wide variety of settings from inpatient to outpatient and urgent care to rehabilitation. My current employment is with the Regional Medical Center (tRMC) here in Orangeburg, SC. tRMC is a small community hospital that serves a mostly rural population with a very high percentage of medicare and medicaid patients. This proposal would directly affect my work and career.

I am writing today to voice my strongest opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am extremely concerned that these proposed rules will create additional lack of access to quality health care for my rural SC patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical cxpericncc, state certification and national certification exams ensure that my patients receive quality health care. State law and hospital medical professionals deem me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. Is it not irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas like mine, to further restrict their ability to receive those services?! These people must have access to more services, not less. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I strongly encourage the CMS to consider the recommendations of professionals tasked with overseeing the day-to-day health care needs of their patients. I earnestly request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
James M. Crook,
M.Ed., ATC, CSCS, HMC(FMF)USNR
Athletic Trainer

Submitter : **sneed shadduck** **Date: 08/31/2007**

Organization : **sneed shadduck**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sneed P. Shadduck, MD

Submitter : **Ms. Cathy Trenkle** **Date: 08/31/2007**

Organization : **Northeast Louisiana Ambulance**

Category : **Individual**

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

Cathy Trenkle
1514A Bosworth Ave.
Winnsboro, LA 71295
(318) 669-4928
bentleyandtanna@yahoo.com

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Re: CMS-1385-P: Geographical Price Cost Indices

Dear Mr. Kuhn:

PLEASE HELP US!!!! Our healthcare professionals that work on these ambulances, i.e. all levels of Emergency Medical Technicians - Paramedics, Intermediates and Basics (you probably have heard them called ambulance drivers which translates to taxi cab drivers or just plain drivers, without any education or certification) are already the lowest paid provider in the health care food chain. For example, an Emergency Medical Technician Basic goes through 3-6 months of training to become certified and some of them earn as little as $6.00 per hour in the rural northeast part of our state. Did you hear that? $6.00 per hour to perform life saving interventions on you or your family member to keep you alive until you arrive at the hospital. $6.00 per hour to carefully move and position your body so that your back or neck injury doesn t become complete irreversible paralysis.

It takes the same two year Associate Degree to become a nurse or a paramedic. Paramedics earn approximately $10 per hour in the Northeast and Nurses with the same time invested can earn up to $50 per hour, hence our shortage of new paramedics. This is a very serious problem which will only be compounded by this decrease.

This letter serves as my comments on the Geographical Price Cost Indices section of the Proposed Rule (CMS-1385-P). I strongly oppose any reduction in Medicare reimbursement for ambulance service providers which would have an adverse impact on their already strained EMT staffing. The Proposed Rule would unfortunately increase already massive difficulty providers are facing with staffing issues as they would receive lower reimbursement as a result of the updated Geographical Price Cost Index (GPC) figures.

While I recognize the statutory requirement for CMS to update the GPCI, any reductions in reimbursement would be in direct contradiction to the findings of the May 2007 Government Accountability Office (GAO) report entitled Ambulance Providers: Costs and Expected Medicare Margins Vary Greatly (GAO-07-383) which determined that Medicare reimburses ambulance service providers on average 6% below their costs of providing services and 17% for providers in super rural areas. For those ambulance service providers who would receive lower reimbursement as a result of the changes to the GPCI, the Proposed Rule will further exacerbate the problems already caused by below-cost Medicare reimbursement.

The GAO recommended that CMS monitor the utilization of ambulance transports to ensure that negative Medicare reimbursement does not impact beneficiary access to ambulance services particularly in super rural areas. I believe that the Proposed Rule would have a considerable impact on beneficiary access in all areas adversely affeeted by the changes in the GPCI. I implore CMS to take this into consideration as it finalizes the Proposed Rule and alleviate any harmful impact these changes in the GPCI will have on providers while ensuring that those providers who would benefit from the changes receive the proposed increases which are desperately needed.

Thank you for your consideration of these comments.

Sincerely,

Cathy Trenkle
EMT-B

Submitter : **Dr. Ronald Kufner** **Date: 08/31/2007**

Organization : **Dr. Ronald Kufner**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15205-Attach-1.DOC

1205

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Ronald P. Kufner MD

Submitter : Mr. Ken Ferry **Date:** 08/31/2007

Organization : iCAD, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment, Duplicate

CMS-1385-P-15206-Attach-1.PDF

1520

Never stop looking™

iCAD

August 30, 2007

Herb Kuhn, Acting Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS–1385–P
P.O. Box 8018
Baltimore, MD 21244–8018

Re: Proposed CY 2008 Physician Fee Schedule; CMS-1385-P
Section: IMPACT

Dear Mr. Kuhn:

On behalf of iCAD, Inc., I appreciate the opportunity to comment on the Proposed Notice published by CMS in the *Federal Register* of July 2, 2007 which describes proposed changes to payment for services to Medicare patients under the Physician Fee Schedule.

iCAD, Inc. is headquartered in Nashua, NH and manufactures mammography Computer-Aided Detection (CAD) systems used for the early identification of breast cancer. CAD systems incorporate advanced pattern recognition and image analysis capabilities to aid radiologists in the detection of abnormalities on mammography images. The use of CAD provides a targeted second review. The clinical efficacy of CAD in the early detection of breast cancer with mammography is well documented and based on strong peer-reviewed clinical evidence.

ICAD is extremely concerned about the impact of the proposed changes to the Medicare payments for Computer Aided Detection (CAD) systems used with mammography (Codes 77051 and 77052)[1]. This proposal:

- Continues the transition of the new calculated practice expense Relative Value Units (RVUs) that were originally published in the 2007 Final Physician Fee Schedule Rule.
- Reduces the conversion factor by 9.9% for 2008.

---

[1] 77051Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; diagnostic

77052Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; screening mammography

98 Spit Brook Road, Suite 100 Nashua, NH 03062 USA
+1 866 280 2239 toll free +1 603 882 5200 phone +1 603 880 3843 fax
www.icadmed.com

Never stop looking™

iCAD

Should the conversion factor reduction be initiated and the practice expense calculation be applied as is, by 2010, CAD payments would not cover the cost of providing this important service. The impact to technical payments for codes 77051 and 77052 is projected to be a decrease of about 57% by 2010.

CAD systems for mammography are important diagnostic tools, which enhance the ability of mammography to detect breast cancer in its early stages. The use of CAD requires the purchase and maintenance of medical equipment that is operated by certified mammography technologists.

The 2007 Medicare PFS final rule altered the Practice Expense (PE) RVUs for CAD. The 2007 technical component reimbursement rate for CAD is $14; with PE cuts, this will be reduced to $7 in 2010 (based on the 2007 conversion factor).

With the addition of the proposed 9.9% cut to the conversion factor for 2008, CAD technical component reimbursement would be reduced to $12 in 2008 and $6 by 2010. Based on the published direct cost inputs for CPT codes 77051 and 77052, the payment amount of $6-$7 does not cover the average cost per procedure of providing CAD.

Under these circumstances, we are concerned that reductions of this magnitude will have an adverse impact on the overall quality of mammography services provided to patients at the very time that the federal government is seeking to improve quality through various quality-related initiatives. Moreover, efforts to increase the utilization of screening mammography (with CAD) may be slowed. Reports of mammogram units closing as a result of payment reductions and other cuts to medical imaging may also have a harsh impact on beneficiaries.

We ask that CMS impose a delay of at least one year in implementing the conversion factor reduction so the impact of the various changes in the physician fee schedule can be assessed. We urge you to reconsider the practice expense reduction for CAD and welcome the opportunity to work with you on clarifying the cost data.

We appreciate the opportunity to comment on this proposal.

Sincerely,

Ken Ferry
President and Chief Executive Officer
iCAD, Inc.

98 Spit Brook Road, Suite 100 Nashua, NH 03062 USA
+1 866 280 2239 toll free +1 603 882 5200 phone +1 603 880 3843 fax
www.icadmed.com

Submitter : **Judy Palesano** **Date: 08/31/2007**

Organization : **Judy Palesano**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Judy Palesano

Submitter : **Ms. Alison Lane** **Date: 08/31/2007**

Organization : **Fairfax County Public Schools**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am a certified athletic trainer, nationally certified and licensed by the Department of Health Professions in the Commonwealth of Virginia, currently working as a high school athletic trainer. I have worked previously under a regional hospital health care system in an orthopaedic surgeons office, as well as physical therapy clinics as an athletic trainer. While employed with this health care system, I provided rehabilitation services to both young athletes and older patients covered by Medicare or Medicaid.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P, particularly in Therapy Standards and Requirements , and in Part 482.56 Condition of Participation: Rehabilitation Services.

I am quite concerned that these proposed rules will create additional lack of access to quality health care providers for Medicare/Medicaid patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which, while it is not the same as physical therapy, our techniques, practices, equipment, and knowledge of musculoskeletal conditions are very similar and many of our skills overlap with physical therapists. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards. When I worked in an orthopaedic surgeons office and in a physical therapy clinic, I worked alongside physical therapists under the guidance of physicians.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Why is CMS insisting on ignoring certified athletic trainers and blocking us from providing healthcare? We are recognized by the AMA as allied health care professionals, and have more education than PTAs and OTAs whom you deem as authorized to provide services.

I fail to see where CMS benefits and improves the health of Americans by restricting their access to health care providers such as myself, especially with the baby boomers rapidly approaching a time where their health needs will increase. I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Thank you for your time and consideration.

15207

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Dalia Garunas, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : **Miss. Marie-Helene McAndrew** **Date: 08/31/2007**

Organization : **Golden Gate physical therapy.**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am in favor to get rid of the Stark physician self-referral law in order to protect our PT profession and assure maintenance of high quality care rendered under licensed PT and PTA.This loophole favors abuses of services and fraud and is misconstrued w/i the population of our clients and professionals as well.Thank you.

Submitter : Dr. Vito Gulli **Date:** 08/31/2007

Organization : College of American Pathologists

Category : Physician

Issue Areas/Comments

CAP Issues

CAP Issues

August 30, 2007
Thank you for the opportunity to submit comments on the Physician Self-Referral Provisions of CMS-1385-P entitled Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008. I am a board-certified pathologist and a member of the College of American Pathologists. I practice in New Jersey with the Robert Wood Johnson Medical School Department of Pathology which provides professional services to four central and southern NJ hospitals and currently has 15 group Pathologists. Our practice is both University and Community hospital based and offers services in New Brunswick, Holmdel, Hamilton and Manahawkin New Jersey.
I applaud CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. I am aware of arrangements in my practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group s patients. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services.
Specifically I support the expansion of the anti-markup rule to purchased pathology interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. These revisions to the Medicare reassignment rule and physician self-referral provisions are necessary to eliminate financial self-interest in clinical decision-making. I believe that physicians should not be able to profit from the provision of pathology services unless the physician is capable of personally performing or supervising the service.
Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. I agree that the Medicare program should ensure that providers furnish care in the best interests of their patients, and, restrictions on physician self-referrals are an imperative program safeguard to ensure that clinical decisions are determined solely on the basis of quality. The proposed changes do not impact the availability or delivery of pathology services and are designed only to remove the financial conflict of interest that compromises the integrity of the Medicare program.
Sincerely,

Vito M. Gulli, MD, MBA, FCAP

Submitter : Dr. Deborah Wexler **Date:** 08/31/2007

Organization : Immunization Action Coalition

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15214-Attach-1.PDF

15214

Immunization Action

COALITION

1573 Selby Avenue, Suite 234
St. Paul, MN 55104-6328
(651) 647-9009 • Fax: (651) 647-9131
admin@immunize org
www.immunize org
www.vaccineinformation org

August 31, 2007

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Sir or Madam:

RE: Open Comment Period for CMS-1385-P

I am the Executive Director of the Immunization Action Coalition (IAC), a 501(c)3 nonprofit organization that works to increase immunization rates and prevent disease. Thank you for the opportunity to review CMS-1385-P.

Preventing potentially life-threatening diseases with vaccination has been proven to be effective and cost saving. IAC strongly recommends that the 2008 Physician Quality Reporting Initiative (PQRI) measures include the following:

(1) Universal influenza screening and counseling and influenza vaccination for persons age 50 years or older (Tables 18 and 21).

In the United States, the number of influenza-associated deaths has increased since 1990. This increase is due in part to the substantial increase in the number of persons age 65 years or older who are at increased risk for death from influenza complications. An average of 36,000 influenza-associated pulmonary and circulatory deaths per season occurred during 1990-1999, compared to 19,000 such deaths per influenza season during 1976-1990.

The Advisory Committee on Immunization Practices (ACIP) recommended lowering the age for routine influenza vaccination from 65 to 50 beginning with the 2000-01 vaccination season in order to increase vaccination levels in the 50-64-year-old age group. From 24%–32% of persons in this age group have a chronic medical condition that places them at high risk for influenza-related hospitalization and death.

One of the national health objectives for 2010 is to achieve an influenza vaccination coverage level of 90% for persons age 65 years and older (objective no. 14-29a). Estimated national influenza vaccine coverage in 2004 among persons age 65 years and older and age 50-64 years was 65% and 36%, respectively, based on 2004 National Health Interview Survey (NHIS) data. Estimated vaccination coverage for persons age 65 years and older varied by race: 67% among non-Hispanic whites, 45% among non-Hispanic blacks, and 55% among Hispanics (CDC, unpublished data, 2006).

(2) Pneumoccoal vaccination for persons 65 years and older (Table 21).

Pneumococcal disease kills more people in the United States each year than all other vaccine-preventable diseases combined. More than 50,000 cases and more than 10,000 deaths from invasive pneumococcal diseases (bacteremia and meningitis) are estimated to have occurred in the United States in 2002. More than half of these cases occurred in adults for whom pneumococcal polysaccharide vaccine was recommended.

Case-fatality rates are highest for meningitis and bacteremia, and the highest mortality occurs among the elderly and patients who have underlying medical conditions. Despite appropriate antimicrobial therapy and intensive medical care, the overall case-fatality rate for pneumococcal bacteremia is about 20% among adults. Among elderly patients, this rate may be as high as 60%.

In 2005, the overall proportion of respondents age 65 years and older reporting ever having received pneumococcal vaccine was 63.7% (BRFSS data).

(3) Hepatitis A and B vaccination in patients with HCV (Table 17).

Experts estimated that 4.1 million (1.6%) Americans have been infected with HCV, of whom 3.2 million are chronically infected. Many of those infected are older adults who came of age in a time when HCV infection was not well understood and risks abounded (drug experimentation, contaminated blood supply, etc.).

Chronic liver disease puts HCV-infected patients at risk for serious complications if he/she becomes infected with the hepatitis B or hepatitis A virus. Simply vaccinating these individuals against HBV and HAV can help protect them against additional liver damage.

Hepatitis A and hepatitis B vaccination is now part of the routine childhood vaccination schedule. However, vaccine coverage of at-risk adults (including those infected with HCV) remains less than optimal. Hepatitis B vaccination coverage (at least one dose of vaccine) among adults who answered "yes" to any one of a broad selection of risk factors as surveyed by NHIS, increased from 30% in 2000 to 45% in 2004. However, hepatitis B vaccination coverage of adults with small levels of risk remained lower than vaccination coverage of children (92%) and adolescents (86%).

Thank you for considering adding these vaccination measures to the 2008 PQRI measures. Prevention via immunization is an easy and cost-effective way to measurably reduce morbidity and premature mortality among U.S. adults.

Sincerely,

Deborah L. Wexler MD

Deborah L. Wexler, MD
Executive Director

Submitter : **Miss. Christela Fabio** **Date: 08/31/2007**

Organization : **Miss. Christela Fabio**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Christela Fabio and I am a certified athletic trainer at a community college in California.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Christela Fabio, MA, ATC.

Submitter : **Mr. Michael Ruggiero** **Date: 08/31/2007**

Organization : **Astellas Pharma US**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Sec attachement, and please accept this submission in lieu of the submission earlier today.

CMS-1385-P-15216-Attach-1.PDF

15216

astellas
Leading Light for Life

August 31, 2007

BY HAND DELIVERY AND ELECTRONIC SUBMISSION
(http://www.cms.hhs.gov/eRulemaking)

Mr. Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS 1385-P; Comments Regarding the Proposed Physician Fee Schedule Rule for Calendar Year 2008

Dear Mr. Kuhn:

Astellas Pharma US, Inc. (Astellas) appreciates the opportunity to comment on the Medicare Physician Fee Schedule Proposed Rule for 2008 published by the Centers for Medicare and Medicaid Services (CMS).[1] Astellas is among the top 20 global research-based pharmaceutical companies, with global sales of approximately $8 billion, and the number two Japan-based pharmaceutical company. Our fundamental goal is to use our expertise in key therapeutic areas to improve the health of Americans by developing and marketing cures for unmet medical needs. Our North American product lines, which focus on the therapeutic areas of infectious disease, immunology, cardiology, dermatology, and urology, are used by Medicare beneficiaries in a variety of settings, including physician offices and other outpatient settings.

Our detailed comments are set forth below, and focus on three important goals: developing clear ground rules that produce consistency and accuracy in manufacturers' Average Sales Price (ASP) calculations; refining the Part B Competitive Acquisition (CAP) so that it can better serve the needs of physicians and patients; and ensuring patient access to important diagnostic procedures.

* * *

[1] Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed rule, 72 Fed. Reg. 38122 (July 12, 2007).

Astellas Pharma US, Inc.
Three Parkway North, Deerfield, IL 60015-2537
Tel: 847-405-1640 www.us.astellas.com

I. ASP Calculations and Bundling

Because of its importance in setting providers' payment rates for Medicare Part B drugs, Average Sales Price (ASP) should be calculated by rules that are clear, free of unnecessary complexity, and designed to produce accurate figures. Clear ground rules are essential for allowing manufacturers to calculate ASPs in a consistent manner that accords with CMS' expectations.

Given these principles, we have concerns about CMS' proposal to extend to ASP calculations the new bundling provisions in the Medicaid prescription drug rule.[2] These provisions define a "bundled" sale and require that manufacturers proportionately allocate discounts on bundled sales across the drugs in the bundle. The definition of a "bundled sale" in the Medicaid rule (which is substantially similar to the "bundled arrangement" definition CMS proposes to adopt in the ASP context) is confusing and potentially overbroad.[3] Both definitions define bundling to include arrangements that involve unspecified "performance requirements," even if such requirements relate to the "same drug." We are concerned that without additional clarifying guidance from CMS, this language will apply too broadly. Specifically, CMS should avoid a construction of "bundled sale" that sweeps in arrangements that do not involve attempts to use the discount on one drug to reduce the effective price of another. For example, CMS

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[2] 72 Fed. Reg. 39142 (July 17, 2007). More specifically, CMS proposed to extend to ASP the approach to bundling that it had adopted in the proposed Medicaid rule (which is substantially identical to the language adopted in the final Medicaid rule), and stated that it intended to "remain consistent with the final policy in the Medicaid final rule on this issue, as appropriate." 72 Fed. Reg. 38122 at 38151.

[3] The Medicaid rule defines a "bundled sale" as "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle." 42 C.F.R. § 447.502. In the ASP context, CMS proposes to define a "bundled arrangement" as "an arrangement, regardless of physical packaging under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), or where the resulting discounts or other price concessions are greater than those that would have been available had the drugs or biologicals sold under the bundled arrangement been purchased separately or outside of the bundled arrangement." 72 Fed. Reg. at 38151. CMS also proposes to require that "all price concessions on drugs sold under a bundled arrangement must be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement." Id.

should clarify that a "bundled sale" only occurs where there is a purchase or market share requirement in exchange for the discount, and not in an arrangement that merely conditions the discount for one drug on the formulary inclusion or placement of another drug. Avoiding such an overbroad construction of "bundled sale" is appropriate both to reduce the confusion faced by manufacturers, and because such a definition would require the reallocation of discounts on a larger set of sales that would tend to undermine, rather than improve, the accuracy of ASP calculations.

We agree with CMS that, other things being equal, adopting consistent rules for ASP calculations and Medicaid rebate calculations is a desirable step that should increase the efficiency of manufacturers' pricing calculations. As noted above, however, extending the Medicaid rule's bundling provisions to ASP calculations could potentially produce greater confusion and complexity, more errors, and reduced consistency between manufacturers. If CMS wishes to adopt this approach in the ASP context, the Agency should provide manufacturers with clear guidance on the many questions that remain unanswered regarding how to apply the Medicaid bundling definition and the related allocation procedures. Among other things, CMS should explain how the bundled discount allocation procedure intersects with the 12-month rolling average methodology for estimating lagged price concessions, and how manufacturers should handle any cases where the information needed to reallocate discounts was unavailable before the deadline for ASP submissions. CMS also should specify how manufacturers should allocate discounts for bundled sales involving a combination of drugs that are ASP-eligible and drugs that are not.

We strongly encourage CMS to study these kinds of issues carefully and, if CMS ultimately decides to require allocation of bundled discounts, to commit itself to giving manufacturers the clear guidance that they would need to understand and implement these requirements.

II. Competitive Acquisition Program Issues

CAP has significant potential to improve Medicare beneficiaries' access to Part B drugs as the program attains higher levels of physician participation. Consequently, Astellas encourages CMS to adopt refinements to CAP that will help make the program more "user friendly" for physicians and increase their CAP participation rate.

Along these lines, Astellas supports the effort by CMS to explore "narrowing the restriction on [the physician] transporting CAP drugs where this is permitted by State law and other applicable laws and regulations."[4] Allowing physicians to transport CAP drugs to a

[4] 72 Fed. Reg. 38122 at 38158.

satellite office or to the patient's home, when this can be done safely and in accordance with other applicable laws and regulations, could give physicians participating in CAP a degree of increased flexibility that would make CAP participation more attractive, and increase patients' access to needed medicines.

Astellas also supports the proposal by CMS to define additional exigent circumstances in which physicians could withdraw from CAP,[5] since we believe that this could ease physician concerns about enrolling in CAP in the first instance and thus ultimately boost participation in CAP. To that end, CMS may wish to consider liberalizing the proposed procedures for physicians to withdraw from CAP due to "significant burden," by giving physicians a period longer than 30 days in which to submit a written request to withdraw from the program.

Finally, CMS should also consider encouraging physicians to participate in CAP by eliminating the current requirement that CAP-participating physicians submit claims for drug administration services for CAP drugs within 14 days of administering the drug. There may be many physician practices that do not customarily submit claims within this window, and eliminating the 14-day claims submission requirement could therefore make CAP participation a more attractive prospect for those practices. CMS initially adopted the 14-day claims submission requirement because, at that time, it was necessary to match the physician's drug administration claim with the CAP vendor's drug claim before the CAP vendor could be paid; imposing the 14-day claims submission requirement on CAP-participating physicians was therefore the only mechanism to enable the CAP vendor to be paid relatively promptly. However, due to recent statutory changes the claims matching requirement (and the related 14-day physician billing requirement) are no longer necessary for this purpose; under Section 108 of the Medicare Improvements and Extension Act (Division B of the Tax Relief and Health Care Act of 2006) payment for drugs and biologicals supplied by the CAP vendor must be made upon receipt of the vendor's claim, and a separate post-payment review process confirms that the drugs have in fact been administered to beneficiaries. CMS therefore has the opportunity to remove an administrative requirement now imposed on CAP-participating physicians that likely has been an impediment to CAP participation for some physician practices. We encourage CMS to take this step, and any other steps it identifies that can make it simpler and more convenient for physicians to participate in CAP.

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[5] Currently physicians can withdraw from CAP early (before their one-year commitment expires) in certain "exigent circumstances," i.e.: (1) if the physician's CAP vendor ceases to participate in CAP; (2) if the physician leaves the group practice that selected the CAP vendor; (3) if the physician moves to another competitive acquisition area (if multiple CAP areas are created); or (4) for other exigent circumstances defined by CMS. CMS now proposes to define an additional exigent circumstance in which a physician could opt out of CAP if he or she submitted a written request to do so within 30 days of entering the CAP physician election agreement and if CMS granted the request due to remaining in CAP being a "significant burden" on the physician.

III. Payment for Certain Diagnostic Imaging Services

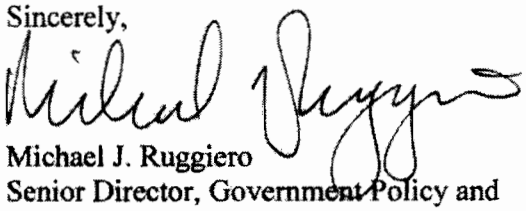
In the Proposed Rule, CMS proposes no longer to provide separate payment for Doppler echocardiography color flow velocity mapping (CPT code 93325) when performed in conjunction with several echocardiography codes. We urge CMS carefully to consider comments submitted in response to this proposal by interested physician specialty societies, and to ensure that the issue has been fully considered by the CPT Editorial Panel and all relevant stakeholders who participate in the CPT process before CMS finalizes any proposal in this area.

* * *

* * *

Astellas appreciates the opportunity to provide these comments. If you have any questions or would like additional information, please contact me at 202-812-6162 or via e-mail (michael.ruggiero@us.astellas.com).

Sincerely,



Michael J. Ruggiero
Senior Director, Government Policy and
External Affairs

Submitter : Mrs. Kimberly White **Date:** 08/31/2007

Organization : Sandy Rose Ins., A Branch of PDI

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am supporting option #3 under the proposed rule for the pending physicians fee schedule. As a memeber of the San Benito Busines Council, I beleive it is the best option for our community, if it's used in conjunction with the correct calculation of county figures. The June 2007 GAO would bring San Benito Countys fee schedule in line with the surrounding counties. It would go along way to help us to keep the fine doctors that we have, as well as the possibility of atracting new doctors in the future. Our county needs the revised calculations to be applicable so that we have a fighting chance as a viable community with professional health care providers. Thank you, Kim White, Member At Large, San Benito Business Council

Submitter : Mr. Mark Kander **Date:** 08/31/2007

Organization : Amer. Speech-Language-Hearing Assoc.

Category : Speech-Language Therapist

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

ASHA appreciates CMS agreeing that the services of audiologists in connection with CPT codes 92557, 92567, 92568, 92569, 92579, and 92601-92604 should be valued through the professional work component of the fee schedule as opposed to the practice expense component. We agree with the recommended values approved at the April meeting of the Relative Value Update Committee (RUC) and endorsed by CMS in the proposed rule except for the values proposed for Codes 92557 and 92579.

ASHA firmly believes that the relative value units assigned to CPT codes 92557 and 92579 are not appropriate considering the time and intensity involved in performing these services. If left uncorrected, we think this will lead to substantial rank order anomalies with other audiology codes. We had an informal discussion with the RUC about our concerns and were advised that we could request a review of the values assigned to CPT codes 92557 and 92579. ASHA intends to request this review and plans to resurvey these two codes with our colleagues at the American Academy of Audiology assuming we are given that opportunity by the RUC.

TRHCA– Section 201: Therapy CapS

TRHCA-- Section 201: Therapy CapS

ASHA supports the continuation of the exceptions process as a short-term solution to the therapy cap but understands that, absent congressional action, CMS must reinstate the therapy cap in January 2008. The Association continues to work with Congress to extend the exceptions process while CMS develops alternatives but is concerned with the growing frustration in Congress that long-term options have not been put-forward by the agency. For this reason, ASHA urges CMS to implement the recommendations of the Computer Science Corporation (CSC) Outpatient Therapy Service Pilot Report of 2006.

Both the Medicare Payment Advisory Commission (MedPAC) and CSC support a CMS pilot to review four patient assessment tools, including ASHA's National Outcomes Measurement System (NOMS), for the purposes of gathering data in the development of alternatives. NOMS is the most appropriate tool for tracking and collecting speech-language pathology outcomes for many reasons, including:
" NOMS robust database, initiated in 1998, from which to establish national risk-adjusted quality benchmarks;
" NOMS wide acceptance by the speech-language pathology community;
" NOMS design to address the continuum of care for patients in all settings; and
" CMS inclusion of NOMS as the recommended speech-language pathology outcomes measure, effective January 1, 2007, in the Medicare Benefit Policy Manual.

In 2006, NOMS was reviewed and reported on in both the June 2006 MedPAC Report to Congress and the July 2006 Computer Science Corporation (CSC) Outpatient Therapy Services Pilot Report. Both studies found NOMS suitable for measuring the effectiveness of speech-language pathology services. In addition, according to both MedPAC and CSC studies, NOMS is the only patient assessment tool currently available to measure outcomes related to dysphagia, one of the most frequently billed Medicare SLP services.

While it is our understanding that there may be overarching concerns within the agency regarding the use of proprietary tools, the development of a CMS-owned treatment assessment tool would take many years and utilize already limited CMS research and development funds. We see no reason why CMS would want to spend valuable resources in the development of new therapy outcomes tools, when therapy specific tools already exist in the market and have been recommended by two external organizations as viable tools for CMS consideration. In addition, these tools are currently being used by clinicians to satisfy documentation criteria for the therapy cap exceptions process. In implementing the pilots, CMS could move quickly in accessing and analyzing data collected by these tools and make significant strides in developing alternatives, thereby proving to Congress that progress is being made.

ASHA believes that moving forward on the CSC recommendations is the most expeditious means by which to gather not only patient characteristic data but also outcomes data that is instrumental in the development of therapy cap alternatives. We urge CMS to implement the outpatient therapy payment pilots as recommended by CSC as the most efficient and cost effective means by which to develop therapy cap alternatives.

Therapy Standards and Requirements

Therapy Standards and Requirements

Personnel Qualifications. Section 409.17(a)(1)(ii) [Inpatient Hospital Services] should omit speech-language pathology from the grandfather clause (practicing before January 1, 2008) because the current definition in ?484.4 has not changed.

Section 482.56(b)(2) [Optional Hospital Services] requires the addition of services as indicated below:
(2) The physical therapy, occupational therapy, or speech-language pathology services must be in accordance with a written plan of treatment that meets the requirements of paragraphs (b)(3)(i) through (b)(3)(iv) of this section.

Section 484.4 Speech-Language Pathologist. In item (1) that follows in the definition of a speech-language pathologist, a second hyphen is required in the name of our professional association: American Speech-Language-Hearing Association

Section 485.705(a)(3)(ii) [Personnel qualifications Clinics, Rehabilitation Agencies] should omit speech-language pathology from the grandfather clause (practicing before January 1, 2008) because the current definition in ?484.4 has not changed.

Conversion to 90-Day Therapy Certification Period. ASHA recommends adoption of the 90-day therapy certification period because the length may be changed to 30 days at the physician s discretion. Allowance of a 90-day certification means less paperwork for the physician and staff when clinically appropriate.

Submitter : **Dr. John Rask** **Date: 08/31/2007**

Organization : **Univ of New Mexico**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Ancsthesia Coding (Part of 5-Year Rcview)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When thc RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionatcly high Medicare populations. This is particularly critical at our institution which provides care to an especially high percentage of Medicare patients.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implemcnting thc anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : Mrs. Lori Shuart **Date:** 08/31/2007

Organization : Mrs. Lori Shuart

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

RE: Dockct #1385-P Therapy Standards and Requirements, Physician Self-Referral Provisions

BRIEF INTRO ABOUT SELF:
My name is Lori Shuart I am a Kinesiotherapist praticing in the state of Virginia. I have been working in the field for 10 years. I recieved by undergraduate in exercise science and masters degree in exercise physiology. I have been a registered Kinesiotherapist under the Counsel on Porfessional Standards for Kinesiotherapy since 1999. I have also been very active on the professional boards and educational comittees for the profession of Kinesiotherapy.

I am writing today to voice my opposition to the proposed therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and other facilitics proposed in Federal Register issue #1385-P. As a Kinesiotherapist, I would be excluded from providing physical medicine and rehabilitation services undcr these rules.

I am concerned that these proposed rules will create additional lack of access to quality health care for my patients. This is particularly important because my colleagues and I work with many wounded Veterans, an increasing number of whom are expected to receive services in the private market. These Medicare rules will have a detrimental effect on all commercial-pay patients because Medicare dictates much of health care business practices.

I believe these proposcd changes to the Hospital Conditions of Participation have not received the proper and usual vetting. CMS has offered no reports as to why these changes are necessary. There have not been any reports that address the serious economic impact on Kinesiotherapists, projected increases in Medicare costs or patient quality, safety or access. What is driving these significant changes? Who is demanding these?

As a Kinesiotherapist, I am qualified to perform physical medicine and rehabilitation services. My education, clinical experience, and Registered status insure that my patients receive quality health care. Hospital and other facility medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards and accepted practices.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the health care industry. It is irresponsible for CMS to further restrict PMR services and specialized professionals.

It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to rceeive those services. Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to reconsider these proposed rules. Leave medical judgments and staffing decisions to the professionals. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Lori V. Shuart, MS, RKT

Submitter : Dr. JAMES SCULLY **Date:** 08/31/2007

Organization : AMERICAN PSYCHIATRIC ASSN.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

PLEASE SEE COMMENTS IN ATTACHED MSWORD FILE. TRIED SUBMITTING MULTIPLE TIMES VIA REGULATIONS.GOV 8/30/07 AND 8/31/07 BUT IT DID NOT FINALIZE SUBMISSION TO THE POINT OF SHOWING THE RECEIPT. THANK YOU. A.F.

CMS-1385-P-15221-Attach-1.DOC

American Psychiatric Association

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Arlington. VA 22209
Telephone 703.907.7300
Fax 703.907.1085
E-mail apa@psych.org
Internet www.psych.org

August 30, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid
Services, Department of Health and Human Services
File Code CMS–2268–P RIN 0938–AO96
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions;" [CMS–1385–P] RIN 0938–AO65, July 12, 2007

Dear Administrator Kuhn:

The American Psychiatric Association (APA), the national medical specialty society representing more than 38,000 psychiatric physicians, appreciates the opportunity to submit these comments in response to the proposed rule by the (A), entitled "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions," concerning 42 C.F.R. Parts 409, 410, 411, 413, 414, 415, 418, 423, 424, 482, 484, 485, and 491, published in the Federal Register on July 12, 2007.[1] There are several areas of this proposed rule that are of concern, as detailed below.

Budget Neutrality and Work Adjuster

[1] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007).

As the American Medical Association points out, '(d)ue to the SGR, physicians now face drastic Medicare payment cuts totaling almost 40% over the next eight years. Yet, during this same time period, the Medicare Economic Index (MEI), which measures increases in medical practice costs, is expected to increase by about 20%.'[2] These ever-decreasing reimbursements are discouraging physicians from participating in Medicare, as verified by a recent AMA survey.[3] APA is concerned with CMS' intent to use a budget neutrality (BN) adjustor (a "work adjuster") to the Medicare Physician Payment Schedule, effective for services performed on or after January 1, 2008.[4], [5] *(See Appendix 1: Example- New York Impact of Budget Neutrality Adjustor)* APA had expressed concern about this approach in prior comments to the proposed CY 2007 PFS rule.[6] CMS adopted this method in the CY 2007 PFS final rule (Dec. 1, 2006) to ensure budget neutrality under the Omnibus Budget Reconciliation Act of 1989. This use of a "work adjuster" impacts psychiatrists more strongly than many other specialties because

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[2] Paraphrased from the American Medical Association (AMA) draft comments of August 31, 2007, to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 1. (AMA's final comments were unavailable by the filing date of these comments.)

[3] From American Medical Association (AMA) draft comments of August 31, 2007, to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007): "AMA physician surveys have demonstrated that forecast rate cuts to the Medicare fee-for-service program also have a negative impact on physicians' willingness to participate in MA plans." at 2. (AMA's final comments were unavailable by the filing date of these comments.)

[4] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38126.

[5] APPENDIX 1: Example- New York Impact of Budget Neutrality Adjustor

[6] APA Comments filed October 10, 2006, to CMS Proposed Rule: "Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology.;" CMS-1512-PN [Federal Register, June 29, 2006 (Volume 71, No. 125)], at 1-2:

"Other Issues- Budget Neutrality

APA is concerned primarily with CMS' proposal in this notice to create a new "work adjuster" to the Medicare Physician Payment Schedule, effective for services performed on or after January 1, 2007, to ensure budget neutrality under the Omnibus Budget Reconciliation Act of 1989. CMS previously used the method of applying a "work adjuster" to physician work relative value units (RVUs) in order to gain budget neutrality but found that it did not work well. In fact, this caused problems sufficient to prompt CMS to reject this methodology entirely, take a different tack and apply this adjustment to the conversion factor, as of 1999. APA agrees with this revised approach. As CMS admitted:

> We did not find the work adjustor to be desirable. It added an extra element to the physician fee schedule payment calculation and created confusion and questions among the public who had difficulty using the RVUs to determine a payment amount that matched the amount actually paid by Medicare. (*Federal Register*, Vol. 68, No. 216, Pg. 63246)."

psychiatrists' work is highly service-intensive with a relatively low use of material resources.

APA agrees with the view of the American Medical Association (AMA) Specialty Society Relative Value Update Committee (RUC) that CMS should apply any necessary adjustments to the conversion factor, rather than to physician work relative value units (RVUs). We also agree with AMA's statement that "CMS must work with Congress to avert Medicare fee-for-service physician pay cuts by enacting positive physician payment updates that accurately reflect increases in medical practice costs, as indicated by the Medicare Economic Index (MEI). In addition, over the long-term, CMS must work with Congress to repeal the SGR and replace it with a system that keeps pace with increases in medical practice costs."[7]

Medicare Economic Index (MEI)

The Medicare Economic Index (MEI) measures the annual price change for inputs for physicians' services using a weighted average. CMS adjusts MEI downward to account for physicians' productivity. CMS' estimates an MEI for CY 2008 of 1.9% that includes a 1.5% productivity offset. We agree with AMA's recommendation that it would be appropriate for 'CMS to reconsider applying a 1.5% productivity adjustment to the MEI.'[8] As AMA points out, this 1.9% downward adjustment related to physicians' productivity is more than twice the 0.65 % payment update reduction for inpatient and outpatient hospital services, hospices and ambulance services in the President's 2008 budget proposal.[9] We agree with AMA's recommendations that CMS include any other inputs to appropriately measure the costs of physicians' practice of medicine and reduce

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[7] Paraphrased from the American Medical Association (AMA) draft comments of August 31, 2007, to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 2. (AMA's final comments were unavailable by the filing date of these comments.)

[8] American Medical Association (AMA) draft comments of August 31, 2007, to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 2. (AMA's final comments were unavailable by the filing date of these comments.)

[9] Paraphrased from the American Medical Association (AMA) draft comments of August 31, 2007, to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P], at 3. (AMA's final comments were unavailable by the filing date of these comments.):
'The President's budget proposal for 2008 recommends that the payment update for inpatient and outpatient hospital services, hospices and ambulance services be reduced by 0.65 percentage points each year to offset productivity increases. Unlike updates for these other providers, in measuring increases in practice costs, the MEI includes an automatic reduction for presumed increases in productivity. As stated above, in 2008, this downward adjustment in the MEI is slated to be about 1.5%—or more than twice as much as the proposed reduction for other services. Surely CMS does not believe that physicians' and other health professionals' productivity is increasing at twice the rate of other health care providers.'

the physician MEI productivity adjustment to 0.65 %, to be equitable and consistent with that of other types of providers.[10]

Neuropsychological Testing as a Telehealth Service

Per the request of the American Telemedicine Association (ATA), CMS intends to revise Sections 410.78 and 414.65 to include neurobehavioral status examinations as a category 1, Medicare-covered telehealth services.[11] This is a commendable addition. A neurobehavioral status exam is furnished by a physician or psychologist and includes an initial assessment and evaluation of mental status for a psychiatric patient.

However, CMS did not agree with ATA that neuropsychological testing (as described by HCPCS codes 96118 through and 99620) should be added as a category 1 Medicare telehealth service. Neuropsychological testing falls within the statutory definition of telehealth services and should be covered on that basis: "Section 1834(m)(4)(F) of the Act defines telehealth services as professional consultations, office visits, and office psychiatry services, and any additional service specified by the Secretary."[12]

CMS proposes not to add neuropsychological testing to the list of telehealth services because CMS considers it a category 2 service. CMS does not consider it a category 1 service because "(t)hese are a unique series of test instruments that are not similar to other services on the list of telehealth services."[13] Other specifics CMS provides to support this distinction are that neuropsychological testing:

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[10] From American Medical Association (AMA) draft comments of August 31, 2007, to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P], at 3-4. (AMA's final comments were unavailable by the filing date of these comments.)

[11] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38143-38145:
"Category #1: Services that are similar to office and other outpatient visits, consultation, and office psychiatry services. In reviewing these requests, we look for similarities between the proposed and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment.
Category #2: Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the face-to-face ''hands on'' delivery of the same service. Requestors should submit evidence showing that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to a face-to-face delivery of the requested service."

[12] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38143.

[13] *Ibid.*, CMS Proposed Rule [CMS–1385–P], at 38144:

1) "requires administration by a trained professional and involves a unique interactive dynamic between the physician, practitioner (or technician) who administers the test and the patient. For example, to assess tactual performance the patient may be blindfolded for portions of the test; to assess sensory perception, the practitioner who administers the test touches the patient's fingers, assigning a number to each finger.;" and

2) "In some cases a significant amount of time is necessary to complete a neuropsychological test battery. . . "

It is unclear why an off-site patient could not have these testing dynamics easily reproduced, such as being blindfolded or having numbers assigned to fingers, with the help of someone on-site with them, while the testing is done via telecommunications. These testing functions are already largely computerized, so the differences between on-site and off-site testing should be minimal and not prohibitive of Medicare coverage.

CMS also has doubts as to patients' ability to facilitate such testing:

"We question whether a patient with suspected or confirmed brain damage or mental illness such as schizophrenia can be taught how to use a computer by a practitioner who is in a remote location. Therefore, we also request specific comments as to whether a neuropsychological patient could be instructed and supervised adequately to take the Wisconsin Card Sorting Test through an interactive audio and video telecommunications system."

Cognition and other basic brain processes of neuropsychiatric patients vary broadly across a spectrum, as evidenced in the diverse expression of symptoms in such disorders as schizophrenia, Alzheimer's dementia, major depression, and mental retardation. Neuropsychological testing may be more challenging for some patients than others but that would be true whether this is done face-to-face or by telecommunications. Patients who require immediate help in person can arrange to have someone, such as a nurse or medical technician, to assist them at their location during the tele-testing. Medicare coverage should be available for those patients who can accomplish neuropsychological testing via telecommunications. The determination as to whether or not a given patient is capable of participating in telecommunications testing should be within the discretion of the treating provider.

We would agree with ATA that neuropsychological testing by means of telecommunications, especially that which is primarily or completely computerized anyway is not significantly different than that done in-person, nor impeded by use of telecommunications. Existing telehealth services for psychiatric patients include office visits, consultation, and office psychiatry. The minor alteration in patient-provider

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"We believe that neuropsychological testing services are category 2 services because, as explained further below in this section, the roles of and interaction among the physician or practitioner at the distant site and beneficiary at the originating site are not similar to existing telehealth services (for example, office visits, consultation, and office psychiatry)."

dynamics for these services would not appear to be significantly different than those for neuropsychological testing, so as to justify their non-coverage.

As the population advances in age and as more brain trauma patients enter the Medicare program, the need for neuropsychological testing will be higher. Dementia, including Alzheimers' disease, in older adults had an overall prevalence of 5 to 10 percent among persons ages 65 and older, according to 1994 world-wide survey data.[14] "Dementia is characterized by cognitive decline and a normal sensorium (ie, delirium is absent). The prevalence of dementia doubles every 5 yr after age 60 until about age 90. Dementia affects only 1% of people aged 60 to 64 but 30 to 50% of those > 85. In the US, about 4 to 5 million people are affected. Dementia is the leading cause of institutionalization among the elderly; prevalence among elderly nursing home residents is estimated to be 60 to 80%."[15] One way it can be detected in early stages through neuropsychological testing.[16]

Approximately 1.5 million people sustain a traumatic brain injury (TBI) per year in the United States, both civilians and military personnel. "There is increasing evidence

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[14] The Agency for Health Care Policy and Research (AHCPR) "Recognition and Initial Assessment of Alzheimer's Disease and Related Dementias," Clinical Practice Guideline No. 19; AHCPR Publication No. 97-0702, November 1996. Retrieved August 30, 2007, from AHCPR website http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat6.chapter.30948

"The panel conducted a second literature search on risk factors and epidemiology. It found that extensive surveys in various populations throughout the world report the rate of moderate-to-severe dementia as approximately 2 percent among persons ages 65 to 69; about 4 percent among those ages 70 to 74; 8 percent among those ages 75 to 79; and 16 percent among those ages 80 and older. These data show an overall prevalence of 5 to 10 percent among persons ages 65 and older (Henderson, 1990; Morris, 1994)."

[15] "The Merck Manual of Geriatrics, Section 5. Delirium and Dementia, Chapter 40. Dementia;" Retrieved August 30, 2007, from http://www.merck.com/mkgr/mmg/sec5/ch40/ch40a.jsp (last updated February 2006.)

[16] The Agency for Health Care Policy and Research (AHCPR) "Recognition and Initial Assessment of Alzheimer's Disease and Related Dementias," Clinical Practice Guideline No. 19; (AHCPR Publication No. 97-0702, November 1996). Retrieved August 30, 2007, from AHCPR website http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat6.chapter.30948

"**Functional Assessment Instruments.** Because dementia symptoms usually appear first in IADL tasks that reflect cognitive deficits (e.g., inappropriate dressing for occasion or weather) rather than physical deficits, measurement of functional performance is warranted. Information on functional performance contributes importantly to the assessment of dementia, particularly the detection of mild forms of disease (Morris, McKeel, Storandt, et al., 1991). Assessment instruments that measure higher order social and instrumental activities are considered especially helpful when used in the context of a comprehensive evaluation for early dementia (Barberger-Gateau, Commenges, Gagnon, et al., 1992; Wilder, Gurland, Chen, et al., 1994).
Formal assessment of functional health emerged in the 1960s with the Index of Activities of Daily Living (Katz, Ford, Moskowitz, et al., 1963) and the Physical Self-Maintenance Scale (PSMS) and Lawton-Brody Instrumental Activities of Daily Living Scale (Lawton and Brody, 1969). More recently developed instruments include the Functional Activities Questionnaire (FAQ) (Pfeffer, Kurosaki, Harrah, et al., 1982) and the Structured Assessment of Independent Living Skills (SAILS) (Mahurin, DeBettignies, and Pirozzolo, 1991)."

that clinically and pathophysiologically relevant neurologic injury occurs after even mild traumatic brain injury (MTBI) or concussion, and may have long term neurologic sequela... Mild traumatic brain injury has been recognized by Congress as a public health issue in the past."[17] *(See Appendix 3: August 11, 2006, Letter from Armed Forces Epidemiological Board to Assistant Secretary of Defense for Health Affairs)*

Appropriate testing at earlier stages of brain injury or disease is likely to elicit a more accurate patient profile that will lead to more targeted interventions and better patient outcomes. While the Epidemiological Board addressed military patients, principles of their findings apply to civilian assessment and treatment of brain injuries and other impairments. "A standardized follow-up using appropriate clinical assessment techniques to recognize neurologic and behavioral effects of TBI following acute injury is important. Such advancement will enable the initiation and improvement of prevention strategies, patient management and surveillance, and basic and clinical research."

The Epidemiological Board also recommended "post-deployment screening to help ensure that those who remain impaired or are suffering persistent TBI-related health problems are identified for follow-up care. This is recommended because mild-to-moderate TBI symptoms can be subtle with no apparent stigmata."[18] Clearly, clinical assessments and screening, which can include neuropsychological testing, are essential for identifying and treating brain damaged patients appropriately. Accurate assessment of a patient's condition may well lead to optimal treatment and better outcomes that may, in turn, confer overall cost-savings to the Medicare program.

Comprehensive Outpatient Rehabilitation Facility (CORF) Issues

In the proposed rule, CMS merges Sections 410.100(h) and (i) of the regulations into a single definition of CORF social and psychological services, under Section 410.100(h), due to the similarities in those services.[19] Those services have strong components of case management and patient assessments, as they relate to the patient's rehabilitation treatment plan. As CMS notes, CORF services are not meant to be

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[17] August 11, 2006, letter from Armed Forces Epidemiological Board to Assistant Secretary of Defense for Health Affairs about traumatic brain injury in military service members, with recommendations to the Department of Defense on handling these injuries, at 1.

[18] August 11, 2006, letter from Armed Forces Epidemiological Board to Assistant Secretary of Defense for Health Affairs about traumatic brain injury, at 2.

[19] 42 C.F.R. § 410.100 Included Services

"(h) *Social and psychological services.*

Social and psychological services include the assessment and treatment of an individual's mental and emotional functioning and the response to and rate of progress as it relates to the individual's rehabilitation plan of treatment, including physical therapy services, occupational therapy services, speech-language pathology services and respiratory therapy services."

treatment services for mental illness.[20] CMS invites comments on which CPT codes would be appropriate for CORF social and psychological services.

We do not support CORF personnel having access to the full range of CPT codes to describe the social and psychological services they provide. We think that it would be preferable for CMS to develop one or more HCPCS codes to describe these services, rather than for CMS to use any of the existing CPT codes, none of which were intended to describe these particular services. Codes 96150 through 96154 were developed for health and behavior assessment and treatment, while CORF services do not include mental health treatment. We believe that use of CPT codes within the 99XXX series and the 90801 – 90899 range is inappropriate, given the services described, especially given that these services may be provided by minimally trained personnel. APA agrees that CPT codes for non-physician rehabilitation case management services such as these should be clearly distinguishable from those used to denote treatment services for mental illness.

In response to CMS' interest in comments on the topic, one way to define CORF personnel qualifications within the conditions of participation for social workers and psychologists would be to use an existing set of federal qualifications for these positions, established by the Office of Personnel Management (OPM).[21]

Physician Self-Referral Provisions

We note that CMS' final rule on self-referral prohibitions, "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)" CMS-1810-F was just released to the Federal Register with an anticipated publication date of September 5, 2007. It is to become effective 90 days after publication. To the extent that this final rule may conflict with proposed self-referral

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[20] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38174.

[21] Example: "United States Office of Personnel Management Operating Manual: Qualification Standards for General Schedule Positions," from Section IV-B (p.IV-B-31); OPM website, http://www.opm.gov/qualifications/index.asp *"Updated 06 November 1998:"*
"Individual Occupational Requirements for GS-180: Psychology Series
Use these individual occupational requirements in conjunction with the "Group Coverage Qualification Standard for Professional and Scientific Positions."
Basic Requirements:
Degree: major or equivalent in psychology for all specializations except clinical psychology and counseling psychology. These two specializations have additional educational requirements, as stated below:
Clinical psychology-- For positions at grades GS-11 and above, satisfactory completion of all the requirements for the doctoral degree (Ph.D. or equivalent) directly related to full professional work in clinical psychology is required.
Counseling psychology-- For positions at grades GS-9 and above, satisfactory completion of 2 full academic years of graduate study directly related to professional work in counseling psychology, or satisfactory completion in an accredited educational institution of all the requirements for a master's degree directly related to counseling psychology is required."

regulations in the proposed rule at issue, the final rule will be determinative. Physician self-referral is prohibited by Section 1877 of the Social Security Act (the Act).[22]

CMS proposes to add Section 411.353(g) to shift the burden of proof to a provider to prove that his or her claim was not furnished pursuant to a prohibited referral, once CMS denies payment for the claim on the basis that it violated Stark self-referral prohibitions. We agree with AMA that this is inappropriate. It reverses the usual and customary due process approach in United States jurisprudence. In both criminal and civil law, the longstanding tradition is that the burden of proof is on the party making the allegation of a legal violation, not on the person accused. The burden of proof is on the federal government to demonstrate that a provider violated fraud and abuse laws, such as Stark statutory prohibitions against self-referral.[23] For the sake of consistency, the approach here should be no different where Stark violations are alleged with regard to reimbursement claims.

CMS certainly should not create any regulations that establish burden-of-proof requirements that conflict with legal traditions, including with existing requirements for proof related to federal program violations. To do so could create bizarre results, such as a fraud and abuse action and a claims denial based on the same alleged Stark violation where the government and the provider simultaneously have the burden of proof as to the same elements of an alleged violation. Requiring providers to prove that they are in compliance with federal programs in order to get paid is exceptionally onerous and is another disincentive to physicians to participate in such programs. We believe that this burden-of-proof regulation Section 411.353(g) should be eliminated from the proposed rule.

Elimination of the SCRIPT Exemption for Computer-generated Prescription Faxes

CMS plans in the proposed rule to stop allowing providers and dispensers to use computer-generated faxes for prescriptions with software that does not use the SCRIPT

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[22] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)] at 45140:
"Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership interest or compensation arrangement), unless an exception applies; and (2) prohibits the entity from submitting claims to Medicare or billing the beneficiary or third party payor for those referred services, unless an exception applies. The statute establishes a number of exceptions and grants the Secretary the authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse."

[23] From American Medical Association (AMA) draft comments of August 31, 2007, to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 17. (AMA's final comments were unavailable by the filing date of these comments.)

standard.[24] The 2005 final rule exempted computer-generated prescription faxes from the requirement to use the adopted NCPDP SCRIPT standard.[25] SCRIPT is a computer data-transaction standard that allows data to be used interchangeability across electronic healthcare records systems. CMS had previously adopted certain such "foundation standards" for electronic transactions with healthcare records, including for electronic prescribing. Computer-generated faxed scripts had previously been exempt from the requirement to use the SCRIPT foundation standard required for other modes of e-prescribing.

If CMS finalizes this rule, providers will be required to obtain or upgrade to SCRIPT-compliant software to electronically transmit prescriptions. CMS plans to make this requirement effective one year from the effective date of the final rule on the 2008 Physician Fee Schedule. Even those providers who have access to SCRIPT-compliant software have only minimally adopted it (15%) for electronic prescription transactions. This very low percentage of users would suggest that there are significant real and/or perceived barriers to using SCRIPT-compliant software for prescribing. Conversely, this means that 85% of those already having compliant software will be adversely affected by eliminating the exemption and will have to alter their prescribing patterns. As CMS points out:

> "(s)ureScripts, which operates the Pharmacy Health Information Exchange, the largest network to link electronic communications between pharmacies and physicians, serving more than 95 percent of all pharmacies and all major physician technology vendors in the United States, it estimates that of the 150,000 prescribers now using software that is capable of generating SCRIPT transactions, only 15 percent are doing so. The remaining 85 percent are still generating paper faxes."[26]

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[24] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 31894:
"We propose to revise § 423.160(a)(3)(i) to eliminate the computer-generated facsimiles (faxes) exemption to the NCPDP SCRIPT Standard for the communication of prescription or certain prescription-related information between prescribers and dispensers for the transactions listed at § 423.160(b)(1)(i) through (xii)."

[25] *Ibid.,* CMS Proposed Rule [CMS–1385–P], at 31895:

"The November 7, 2005 final rule included an exemption for entities that transmit prescriptions or prescription related information by means of computer-generated facsimile (faxes) from the requirement to use the adopted NCPDP SCRIPT standard. ''Electronic media'' was already defined by the HIPAA, so e-prescribing utilized the same definition. As a result, faxes that were generated by a prescriber's/ dispenser's computer and sent to a provider's/dispenser's fax machine which prints out a hard copy of the original computer-generated fax (that is, ''computer-generated'' faxes) fell within the definition of ''electronic media'' for e-prescribing. Absent an exemption, entities transmitting computer generated faxes would be required to comply with the adopted foundation standards."

[26] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38195.

APA members tend to be low on the scale of technology adopters with many not using complex computerized functions. For those who now use non-SCRIPT compliant computer programs to efficiently fax prescriptions, eliminating this exemption would require them to purchase new software or upgrades in order to be SCRIPT-compliant. The added expense is more likely to make those physicians revert to using paper for prescriptions, rather than to continue using technology for this.

In addition, "SureScripts reports that all chain drug stores and 20 percent of independent pharmacies are capable of sending and receiving SCRIPT transactions."[27] That leaves 80% of independent pharmacies unable to receive SCRIPT transactions, regardless whether a physician can generate a SCRIPT prescription. For physicians who routinely prescribe for patients who use independent pharmacies, such as those in more rural areas, this proposed rule would have no actual effect.

We appreciate the goal of CMS and other programs to eventually encourage widespread adoption of electronic prescribing and other health information technology solutions. However, adoption of technology should not be rushed, as physicians need time to become used to the changes in their practices at a reasonable pace. Pressuring them unduly to use specific types of SCRIPT-compliant software or services may have the effect of discouraging their participation in federal programs. We agree with AMA's stance on this issue:

> 'We believe, however, that removing this exemption will inhibit physician adoption of e-prescribing. Specifically, it will cause many prescribers who currently elect to use electronic technology to forgo utilizing it in order to avoid costly upgrades in existing products/programs. Prescribers will instead use paper. This will slow down the adoption of health information technology in general and e-prescribing in particular. In addition, mandating that all e-prescribers use this standard is premature given that all the e-prescribing standards have not been adopted.'[28]

TRHCA—SECTION 101(b): Physician Quality Reporting Initiative (PQRI) 38196

We do not agree with CMS's interpretation of Section 1848(k)(2)(B)(i) of the Act that covers quality measures for reporting in 2008.

> "(F)or purposes of reporting data on quality measures for covered professional services furnished during 2008, the quality measures specified under this paragraph for covered professional services shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that include

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[27] *Ibid.*, CMS Proposed Rule [CMS–1385–P], at 38195.

[28] Paraphrased from the American Medical Association (AMA) draft comments of August 31, 2007, to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 22. (AMA's final comments were unavailable by the filing date of these comments.)

> measures that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures. Such measures shall include structural measures, such as the use of EHRs and electronic prescribing technology."[29]

CMS says that, "we do not interpret the provision requiring inclusion of measures submitted by a specialty to apply to each measure." CMS appears to be saying that specialty quality measures submitted by a specialty physician or organization are not each required to undergo the same procedures as any other quality measure, just that "a consensus organization must include in its consideration process at least some measures submitted by one physician or organization representing a particular specialty."

In order to effectuate CMS' stated goal of enhanced quality of patient outcomes through quality reporting programs, it makes sense to have every quality measure, whether of a general or specialty nature, be subject to the same statutory requirements. In fact, the language of Section 1848(k)(2)(B)(i) does not single out specialty measures for different treatment. The provision uses the general term "quality measures" to cover all measures used for reporting data. The pertinent part of the provision is: "for purposes of reporting data on quality measures. . . the quality measures specified under this paragraph . . . shall be measures that have been adopted or endorsed by a consensus organization. . . that include measures that have been submitted by a physician specialty. . ." The clause "that include measures that have been submitted by a physician specialty" clearly means to clarify that specialty measures are just a subcategory of quality measures, all of which are to be subject to the designated procedural requirements. We agree with AMA's statement:

> 'We wish to reinforce, however, that the statute also requires that 2008 measures are those that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures. Congress' intent with this provision was to ensure that physician-level quality measures are developed by physicians through the physician medical specialties as well as a consensus-based process.'[30]

We also note that Table 21 "OTHER NQF-ENDORSED MEASURES" of the proposed rule lists quality measures that are being considered for PQRI in 2008 but does not include any of the twelve mental health measures endorsed by the National Quality Forum (NQF) in December 2006 that

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[29] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38196-38197.

[30] Paraphrased from the American Medical Association (AMA) draft comments of August 31, 2007, to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 10. (AMA's final comments were unavailable by the filing date of these comments.)

were also not included from the 2007 PQRI measures.[31], [32] *(See Appendix 3: NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR AMBULATORY CARE JULY 2007)* These omissions raise concerns that PQRI currently has a relatively small role for the participation of mental health professionals. We ask that CMS reconsider its approach to the inclusion of quality measures related to mental health for the 2008 PQRI program.

Submission of Data on Quality Measures via a Medical Registry or Electronic Health Record

Due to Section 1848(k)(4) of the Act, CMS intends to allow physicians to report quality measures through clinical database registries or electronic health records and to test this mechanism with the 2008 PQRI.[33] Physicians could conceivably authorize the registries to report to PQRI or similar programs on their behalf. This would render the registry a "data submission vendor." While efficiency and relieving the administrative burden are potentially positive results of this approach, it is essential to ensure that all available privacy protections are in place to avoid sensitive patient information from being accessed and disseminated. For instance, use of data encryption technology, opt-outs for patients and other techniques should be considered and used, wherever appropriate, to afford the highest possible level of privacy protection. Optimally, physicians would retain control over the information and access to it and there would be transparency so that patients would understand where their information was going. APA has expressed its concerns as to patient privacy and electronic health records in prior comments:

> APA Comments Filed April 5, 2005 ("B. IMPACT ANALYSIS: Privacy Concerns," pages 18-19) to CMS Proposed Rule "Medicare Program; E-Prescribing and the Prescription Drug Program," CMS-0011-P; APA Comments Filed January 23, 2006 ("B. Privacy and Electronic Records," pages 4-5) to CMS Proposed Rule: HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments; CMS-0050-P; and APA Comments Filed December 18, 2006 ("Physicians' Judgment, Patients' Privacy and Commercial Exploitation," pages 14-15) to CMS Proposed Rule: "Medicare Program; Medicare Part D Data;" CMS–4119–P RIN # 0938–AO58

TRHCA Section 101(d)—Physician Assistance and Quality Initiative (PAQI) Fund

While TRHCA Section 101(d) does not actually require a binary choice, CMS states that it must either use the Physician Assistance and Quality Initiative (PAQI) fund

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[31] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38202.

[32] APPENDIX 1: "NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR AMBULATORY CARE, JULY 2007;" at 7-8

[33] *Ibid.*, CMS Proposed Rule [CMS–1385–P], at 38202-38204.

to reduce the negative update by approximately 2% or for 2008 PQRI bonuses.[34] CMS decided that, "we are proposing to use the PAQI Fund for the 2008 PQRI program, we also propose that the bonus payments to individual physicians be subject to an aggregate cap of $1.35 billion."[35] We agree with AMA that the $1.35 billion PAQI fund should be used to reduce the estimated 9.9% reduction in the 2008 update.[36] CMS estimates that this would effectuate an offset of about 2%, which would make the 2008 reduction around 8%.[37] This would be sound policy, as this approach would benefit more physicians than just PQRI participants and would so without imposing an extra requirement beyond providing patient services.

Physician Scarcity Area (PSA) Bonus

Section 413(a) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) added a new Section 1833(u) to the Social Security Act that authorized a physician scarcity area (PSA) 5% bonus payment to physicians furnishing services in those designated scarcity areas. Non-primary care physicians, such as psychiatrists, have been able to receive the bonus in a specialist-care scarcity area. The statutory authority for this bonus will expire on January 1, 2008, thus, will not apply to physicians' services furnished after that date.[38] If it is possible for CMS to create or work with Congress to create a replacement bonus payment of this type, it would produce an incentive for services to be provided to underserved areas.

Preventive Psychiatric Screening, per Section 411.15

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[34] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38205-38206:
"Section 1848(1) of the Act, as added by section 101(d) of the MIEA–TRHCA requires the Secretary to establish a Physician Assistance and Quality Initiative Fund (PAQI) which shall be available for physician payment and quality improvement initiatives, which may include application of an adjustment to the update of the PFS CF."

"this Fund can be used to either buy down the negative update to the fee schedule or for quality improvement initiatives."

[35] *Ibid.,* CMS Proposed Rule [CMS–1385–P], at 38206.

[36] From the American Medical Association (AMA) draft comments of August 31, 2007, to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 4. (AMA's final comments were unavailable by the filing date of these comments.)

[37] *Ibid.,* CMS Proposed Rule [CMS–1385–P]. at 38206.

[38] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38171.

As we stated in our comments of October 10, 2006, to the PPS 2007, "CMS should include psychiatric screening examinations in the list of preventive health screenings and examinations exceptions from services that are excluded from Medicare coverage, under proposed Sec. 411.15. Especially with the high prevalence of psychiatric disorders within the Medicare population, it is essential that these beneficiaries receive psychiatric screening examinations. Psychiatrists will be motivated to encourage such examinations if they can obtain Medicare reimbursement for them. Early identification of psychiatric disorders can often lead to better patient outcomes and decreased services utilization, as is true of other preventive health services that this section is designed to cover. Clearly, these advantages are among the reasons for having Medicare coverage of these preventive health services in the first place. It is grossly disparate to expect Medicare beneficiaries to pay for their own psychiatric screening examinations, while other, similar preventive health services are covered by Medicare."[39]

CMS' proposed Section 411.15 for 2008 "Particular services excluded from Coverage" still does not allow coverage for psychiatric screening examinations and we urge CMS to revise this regulation for that coverage purpose.

Physicians Need Reimbursement for Federal Programs' Administrative Demands

Medicare needs to reimburse psychiatrists and other physicians for the substantial time that they will continue to expend to deal with a panoply of demands imposed by federal programs, including Medicare Part D. This is especially important, considering the projections for ensuing years of net diminution in physician reimbursements under Medicare. We are concerned that inequitable reimbursements will create a disincentive to continue treating patients under federal programs. We continue to encourage CMS to work toward inclusion of this time outlay in reimbursement schemes. Results of a national study by the American Psychiatric Institute for Research and Education (APIRE) on the Medicare Part D program's effects on patients and psychiatrists were recently published. Part of the findings concerned administrative requirements of the Part D program for psychiatrists and their staff. This provides a snapshot of just one element of one federal program that has substantially increased the level of uncompensated administrative time for psychiatrists:

> "Psychiatrists reported that they or their staff spent on average 45.6 minutes on administrative issues related to prescription drug plan coverage (including filling out paperwork and Internet, telephone, or other time with patients, prescription drug plans, pharmacies, or the Centers for Medicare and Medicaid Services) for every hour of direct patient care provided since Jan. 1, 2006."[40]

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[39] APA comments of October 10, 2006 (at 1-2) to Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B;" [CMS–1321–P] RIN 0938–AO24 [Federal Register: August 22, 2006 (Vol. 71, No. 162)].

[40] West, Joyce C.; Wilk, Joshua E.; Muszynski, Irvin L.; *et al*; "Medication Access and Continuity: The Experiences of Dual-Eligible Psychiatric Patients During the First 4 Months of the Medicare Prescription Drug Benefit," *Am J Psychiatry 2007; 164:789–796,* at 792-793:
"Prescription Drug Plan Administration Issues

Computer Equipment Should be Included in Office Expenses, under Practice Expense (PE) RVUs

It is certainly commendable that CMS has proposed to adopt all of the American Medical Association's (AMA) Specialty Society Relative Value Update Committee (RUC) recommendations submitted in 2007, which reflect updated direct practice expense data.[41] Of the direct and indirect cost categories for calculating practice expense (PE) relative value units (RVUs), none comprises commonly used office equipment, apart from the telephone, which is included within the indirect cost category of "office expenses."[42] The proposed rule for CY 2008 still does not include computers or other electronic communications equipment under practice expenses because these are omitted in the AMA Socioeconomic Monitoring Survey (SMS) PE data, the most recent of which are adjusted to a common year, 2005.[43] Since most psychiatrists do not use medical equipment in their practices, as other physicians do, the type of office equipment they require for their practices may be only non-medical equipment.

For psychiatrists, especially those in solo or small group practices, common office equipment, such as computers, printers, scanners, shredders, answering machines, copy machines and fax machines, constitutes a substantial financial outlay which is not reimbursed through the current definitions for PE RVU categories. Typical office equipment expenses should be included in PE RVU calculations. This is especially so, since CMS is encouraging physicians to adopt or expand existing electronic communication infrastructures for prescribing and general medical records.

Malpractice: Professional Liability Insurance (PLI) Relative Value Units

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Psychiatrists reported that they or their staff spent on average 45.6 minutes on administrative issues related to prescription drug plan coverage (including filling out paperwork and Internet, telephone, or other time with patients, prescription drug plans, pharmacies, or the Centers for Medicare and Medicaid Services) for every hour of direct patient care provided since Jan. 1, 2006. Patients with medication access problems required a little less than two times as much administrative time per hour of direct patient care (56 minutes versus 30 minutes) (p=0.0005). As indicated in Table 4, many of the prescription drug plan features studied were associated with significantly greater administrative time. For 29.7% of patients, the psychiatrist reported the patient having problems with prescription drug plan enrollment or changing to a desired plan. In addition, 27.4% of the patients had exceptions requests or appeals initiated on their behalf, whereas 19.3% of the psychiatrists reported changing or discontinuing clinically indicated medications rather than pursuing appeals or exceptions processes."

[41] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38127-38128.

[42] *Ibid.*, CMS Proposed Rule [CMS–1385–P], at 38127:
"The SMS data provide the following six categories of PE costs: . . . Office expenses, which include expenses for rent, mortgage interest, depreciation on medical buildings, utilities and telephones." at 38127.

[43] *Ibid.*, CMS Proposed Rule [CMS–1385–P], at 38127.

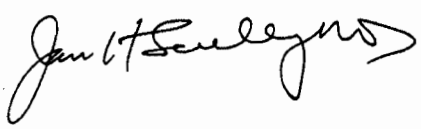
CMS is mandated to conduct five-year reviews of the professional liability insurance (PLI) RVUs to reflect marketplace changes in the physician community's ability to acquire PLI. CMS notes that, "some technical services which have assigned MP RVU values that have never been part of the review process. Consequently, the MP RVU values assigned to these technical services have not been revised since their initial assignment. The reason these services have never been reviewed is directly related to a lack of suitable data on the cost of PLI for technical staff or imaging centers. . ."[44]

The AMA's RUC PLI Workgroup was convened to respond to CMS' request for information and concluded that there are not separately identifiable costs for professional liability for technical professionals. As CMS points out, "(t)he RUC's PLI Workgroup brought to our attention the fact that there are approximately 600 services that have a technical component MP RVU that is greater than the professional component MP RVU. The RUC has asked CMS to change the technical component MP RVU values, stating that, as physicians have to pay the larger PLI premiums, there should be higher RVUs associated with the professional portions of these services." We agree with the RUC's position. According to AMA, the RUC will discuss this issue in September and review a recommendation to reduce the PLI technical component to zero. We urge CMS to consider the RUC's recommendations and ensure that PLI relative values are based on the most current possible data and are resource-based.

CONCLUSION

APA urges CMS to consider these concerns and thanks CMS for the opportunity to communicate them.

Sincerely,



James H. Scully Jr., M.D.
Medical Director and C.E.O., American Psychiatric Association

APA Contact: Angela Foehl, J.D., M.P.H., Deputy Director, Regulatory Affairs

[44] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule. . . CY 2008;" [CMS–1385–P] RIN 0938–AO65; (Federal Register / Vol. 72, No. 133 / July 12, 2007), at 38142-38143.

Phone: 703.907.7842 *Email: afoehl@psych.org*

Submitter : **Dr. Shale Imeson** **Date: 08/31/2007**

Organization : **Stockton Anesthesia Medical Group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely yours,

Shale Imeson, M.D.

Submitter : **Dr. Elizabeth Bauer-Marsh** **Date: 08/31/2007**

Organization : **Peoria-Tazewell Pathology Group**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Thank you for the opportunity to submit comments on the Physician Self Referral Provisions of CMS-1385-P. I am a board-certified pathologist and a member of the College of American Pathologists. I practice in Peoria, IL as part of a twelve member pathology group. We practice in several hospitals in our region.

I applaud CMS for undertaking this important initiative to end self-referral abuses in the billing and payment of pathology services. I am aware of arrangements in my practice area that give physician groups a share of the revenues from pathology services ordered and performed for the group's patients. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close loopholes that allow physicians to profit from pathology services.

An analogy to this abhorent practice is if a family practice physician sent his patient to a surgeon for an appendectomy, the surgeon billed the family practice doctor for the surgery, and then the family practice doctor turned around and billed the patient (a higher fee) as if he (the family practice doctor)performed the surgery himself!

Specifically, I support the expansion of the anti-markup rule to purchased pathology interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. I believe that physicians should not profit from the provision of pathology services unless the physician personally performs or supervises the service.

The proposed changes do not impact the availablity or delivery of pathology services and are designed only to remove the financial conflict of interest that compromises the integrity of the Medicare program.

Sincerely,

Elizabeth A. Bauer-Marsh, M.D.

Submitter : **Conney Willis** **Date: 08/31/2007**

Organization : **Conney Willis**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter

Sincerely,

Conney Willis.

Submitter : Mr. Matt Adams **Date:** 08/31/2007

Organization : ligaliga

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Why does medicare keep cutting rates. the quality of service provided is going down and almost pushing us towards bankruptcy?
Please email me at ligaligacfo@yahoo.com

Submitter : Mr. Michael Switlik **Date:** 08/31/2007

Organization : University of Arkansas at Little Rock

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am the Head Athletic Trainer for the University of Arkansas at Little Rock. I coordinate the healthcare for 16 NCAA Division I sports and about 200 student athletes. I have been a BOC Certified Athletic Trainer for 11 years as well as Licensed in the State of Arkansas for 11 years. I have a B.S. in Education from the University of Arkansas and a M.S. in Physical Education from Springfield College.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Michael Switlik, MS, ATC
Head Athletic Trainer
UALR Athletics

15227

AMS
Solutions for Life

10700 Bren Road West
Minnetonka, MN 55343 USA

Phone: 952-933-4666
Fax: 952-930-6157

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: CMS-1385-P - Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Deputy Administrator Kuhn:

American Medical Systems ("AMS") welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008.

AMS is a leader in medical devices and procedures to treat urological and gynecological disorders such as erectile dysfunction ("ED"), incontinence, prostate disorders, and menorrhagia. Although not life-threatening, these disorders can greatly affect one's quality of life and social relationships.

AMS is also a member of the Pelvic Health Coalition (PHC) and the Coalition for the Advancement of Prosthetic Urology (CAPU). The PHC is a broad-based coalition dedicated to raising awareness, particularly among elected Federal healthcare policy makers, of the critical importance of pelvic health issues. By dispelling myths and misunderstandings, the PHC is committed to improving the quality of life for women with pelvic health disorders.

CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology and the nation's leading manufacturers and developers of innovative prosthetic urology devices. As the leading representative of the prosthetic urology community, CAPU's mission is to ensure that the issues affecting this community are given appropriate consideration in the formation of federal health care and reimbursement policy.

AMS joins with both CAPU and PHC in sharing with CMS the following comments on the Proposed Medicare Physician Fee Schedule for CY 2008:

I. **"Resource-based Practice Expense (PE) RVUs"**

A. "Bottom-Up" Practice Expense Methodology

AMS continues to be concerned regarding the impact of the "bottom-up" approach to calculating the direct practice expense (PE) costs per codes where the procedure involves the use of an expense – i.e. greater than $200 - supply/disposable. With 2008 being the half way point in the four (4) year transition to PE inputs being calculated completing under the bottom-up methodology, **we urge CMS to consider that for those procedures with high cost supplies or disposables CMS would agree to not move them forward into the second year of the PE methodology transition prior to the AMA completing the new Socioeconomic Monitoring Survey (SMS) that is currently under way and will be completed if mid-2008.**

The use of an average PE percentage is inherently unfair to those procedures within a specialty that have a high cost disposable or higher than average equipment costs. The use of an average PE percentage weights the split between direct and indirect costs towards office visit practice expenses, because these would be the majority, by volume of type of code billed, for any specialty. For example, a TUMT procedure to treat BPH or an Endometrial Cryoablation procedure to treat abnormal bleeding have significantly higher supply costs then many other office-based procedures thus a 33% direct costs versus 67% indirect, where it is more heavily weighted towards indirect costs, leaves inadequate dollars in the direct cost pool to cover these costs, forcing a budget neutrality adjustment of higher than necessary portions to those procedure costs with high cost disposables.

Given the bottom-up nature of PE methodology, starting with a sum of the costs of each direct input followed by a budget neutrality adjustment to the direct inputs of greater than 30%, is in effect is causing physicians to assume a 30% discount off the cost of the disposables, costs physicians have already incurred prior to performing the procedure. In the previous "top-down" methodology, there were only a few specialties that did not have a supply scaling factor of close to or greater than one. Thus the cost of the supplies to the physician was included in the PE calculation. Under the new methodology, physicians are forced to "pay" CMS a discount.

Physicians will not be able to absorb the discounts assumed in the budget neutrality formula and subsequent adjustment on top of significant other reductions, such as the budget neutrality adjustments on work RVUs due to increase in anesthesia work RVUs and the 10% reduction in the conversion factor that they are facing. Many procedures that are now safely and effectively being provided in a physician's office will likely migrate back to hospital outpatient departments, a potentially more costly setting.

Therefore, we again urge CMS to review those procedures with high cost supplies/disposables and not transition them into year two of the PE methodology until the new AMA SMS survey is completed and we have been able to re-address the direct versus indirect PE split and the issues of budget neutrality in the bottom-up PE methodology.

B. Equipment Use Rate

AMS agrees with CMS that the 50 percent utilization rate for medical equipment is appropriate for equipment used as part of office-based surgical procedures. For surgical specialties, such as urology and gynecology, procedure specific equipment such as the console or laser used for ablation of an enlarged prostate or the cryoablation console used for endometrial ablation is used approximately one – two days a week, depending on the service mix of a specific office.

In general for surgical specialties, surgeons spend two days at the hospital performing inpatient and outpatient surgical procedures. Surgeons then usually spend another two days performing office-visits to follow-up on patients that have already received surgery and to conduct visits to prepare a patient for surgery.

Most surgeons perform office-based or minimally invasive surgical procedures that use procedure specific equipment usually one-day a week or approximately 20% of their practice time.

AMS is aware that ACOG has conducted a survey of a group of its members regarding their use of ultrasound equipment, a fairly common piece of equipment in an ob/gyn's office. AMS believes that these types of specialty specific surveys are important and the type of data that CMS should be considering when making code specific decisions. **AMS urges CMS to not assume that higher utilization found by MedPAC for some types of imaging equipment is automatically similar for all types of imaging equipment – i.e. ultrasound - or for other types of equipment. Instead, CMS needs to use specialty and code specific data to answer these types of questions in the future.**

C. Changes to PE Inputs in Ob/Gyn Codes

AMS commends CMS for making changes to the content and price of the pelvic exam pack by adding in a sterile drape and its cost. Also, AMS thanks CMS for standardizing the equipment used in post-operative follow-up visits to include both a power-table and a fiber-optic lamp.

Given the clinical nature of these procedures and the configuration of the female anatomy, it is important that ob/gyn's being able to account for the costs that using a power table with stirrups and a fiber-optic lamp to assess healing of the pelvic area as they seek to cover the costs of replacing standard exam room equipment.

II. "Coding – Additional Codes From Five-Year Review"

A. Use of a Work Adjustor for Budget Neutrality

AMS is concerned regarding the continued impact of the last five-year review on the pool/distribution of work RVUs per specialty, and then per code. The impact of the proposed 32% increase in work RVUs for anesthesia codes would again, by law, require CMS implement a proposed budget-neutrality adjustor of approximately 11.8%.

Applying the budget-neutrality adjuster to the work RVUs is contrary to long-held CMS policy. In the past, when CMS applied a budget neutrality adjuster to the work RVUs, it caused considerable confusion among many non-Medicare payers, as well as physician practices, that adopt the resource-based relative value scale (RBRVS). CMS later acknowledged the confusion and ineffectiveness of applying the budget neutrality adjuster to the work RVUs. However, many non-Medicare payers have now figured out how to apply the budget neutrality adjustment to the work RVUs proposed in Addendum B and thus they too are taking these reductions, even though they are not subjected to any budget neutrality laws.

Furthermore, constant fluctuations in the work RVUs due to budget neutrality adjustments impede the process of establishing work RVUs for new and revised services. In recognition of these difficulties, CMS has been applying budget neutrality adjustments, due to changes in the work RVUs, to the physician fee schedule conversion factor since 1998 and needs to revert back to this practice for 2008.

AMS urges CMS to re-consider this proposal and instead apply the budget neutrality adjuster to the physician fee schedule conversion factor.

III. "TRHCA – Section 101(b) – PQRI"

AMS joins with CMS in support of quality health care for Medicare beneficiaries. AMS has watched the evolution of the quality reporting programs and has been educating its customers regarding those quality measures that relate both male and female urologic care.

AMS would like to encourage CMS to work with both the National Quality Forum (NQF) and the Ambulatory Quality Alliance (AQA) with regard to each being considered consensus organizations that would adopt or endorse measures that CMS would them work to implement. Given the level of enthusiasm for working in the area of quality measurement, it is unclear to AMS that it would not be of benefit to have two avenues where organizations could go to have their measures approved. This would also allow for more organizations to be personally involved in these quality efforts.

Also, AMS would like CMS to consider a role for industry in the development and implementation of quality measures. AMS has much expertise in the care and treatment for urinary incontinence and would be willing to serve as a resource to CMS and others, such as the AMA Physician Consortium, AQA, or NQF during the measure development, endorsement, and implementation process of measures in this area. At present, it is difficult due to a lack of transparency and specifically defined steps in the process for industry to find its exact role. Greater direction in response to the comments regarding the 2008 PQRI program would be extremely helpful.

And, AMS would hope that CMS would continue to have each measure as part of its program for at least three consecutive years, allowing for offices to make a commitment and to allow for a level of data that is appropriate to make some decisions with regarding patterns of care.

Finally, AMS would encourage CMS to consider as one of its structural measures for 2008 the participation in a clinical outcomes registry. AMS is working with various medical societies and organizations regarding the registry concept and how these types of data can lead to knowledge regarding outcomes and thus influence the care received by Medicare patients. In some respects, participation in a registry could be determined to be "super" structural measure and thus qualify an office as having participated in the PQRI program fully for 2008.

Again, AMS thanks CMS for the opportunity to provide comments on the 2008 Proposed Rule on the Medicare Physician Fee Schedule. If you have any questions regarding these comments or if you would like additional information, please contact Gary Goetzke at 952-930-6000.

Sincerely,

Gary Goetzke
Senior Director
Health Care Affairs

Suzy Geroux
Federal Government Programs Manager
Health Care Affairs

Submitter : **Dr. Richard Whitten** **Date: 08/31/2007**

Organization : **Noridian Administrative Services**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Colleagues: On page 38179 of the July 12, 2007 Proposed Rule, is the discussion of your concern about allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic testing services and to then realize a profit when billing Medicare which may lead to abusive overutilization of services. This is a serious, very real and rapidly growing concern. We have attached one brochure that was distributed by a firm at a physician conference within the past several weeks. We have seen similar incentives lead to contracting for and then captive billing of pathology services by urologic offices. Typically the captive pathologist is hired by the practice on a salaried or other basis, and then the practice bills for both the surgical and all pathology services (which we have noted are often in considerably greater quantity than comparable other offices). There is clearly a moral hazard here fostering inappropriate overutilization (as the attachment makes pretty clear). These incentivised arrangements suggest that there need to be additional limitations on this induced self-referral. Thank you for considering! Richard W. Whitten, MD, MBA, FACP; Contractor Medical Director, Medicare B for AK, HI & WA

CMS-1385-P-15228-Attach-1.DOC

15228

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : Dr. philip glengary **Date:** 08/31/2007

Organization : long lake anesthesia consultants

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15229-Attach-1.DOC

15229

Philip J Glengary, MD
72 Estate River #16
Kingshill, USVI 00850
August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations. For instance, in Michigan where I practice primarily, the senior citizens are often sent to institutions which do not offer the highest quality care. This shunting or shuffling occurs in the ER's and primary care physician offices. A second effect seen here in Michigan is the poor recruiting that we encounter to meet our future manpower needs to serve all of the citizens here. Why become an anesthesiologist, a profession known to be extremely high stress when a less stressful medical specialty beckons at often a higher reimbursement.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Philip J Glengary, MD

Submitter : **Mr. Matthew O'Brien** **Date: 08/31/2007**

Organization : **Oklahoma State University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Matthew O'Brien and I am a assistant professor in the Athletic Training Education Program and practicing clincian at Oklahoma State University. While teaching future allied healthcare clincians I also serve as the certfied Athletic Trainer (ATC) for the wheelchair basketball team providing for the healthcare for 10 individuals with a variety of musculoskeletal and neurological conditions.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Matthew S. O'Brien, PhD, LAT, ATC
Assistant Professor
Oklahoma State University

Submitter : **Tim Palesano** **Date: 08/31/2007**

Organization : **Tim Palesano**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Tim Palesano

Submitter : **Mr. Robert Roche** **Date: 08/31/2007**

Organization : **Minnesota Vikings**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Robert Roche and I am a certified Athletic Trainer working as an assistant athletic trainer with the Minnesota Vikings.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Sincerely,

Robert Roche MS, ATC

Submitter : Dr. M. Nasar Qureshi **Date:** 08/31/2007

Organization : QDx PathAlliance

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15233-Attach-1.RTF

15233

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Allen Gersh **Date:** 08/31/2007

Organization : Hattiesburg Clinic, P.A.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-1385-P-15234-Attach-1.PDF

15231

HATTIESBURG CLINIC

Sanjay Derhgawen, M.D.
John M. Fitzpatrick, M.D.
H. Allen Gersh, M.D.
Jon D. Thornton, M.D.
Daniel M. Habeeb, M.D.
Brian Rifkin, M.D.

DEPARTMENT OF NEPHROLOGY

August 24, 2007

MEMORANDUM

Re: Proposed Stark Regulations Involving Dialysis Provider Arrangements for Hospital-based Dialysis.

Dear Sir:

I believe it will be counterproductive in many areas of the country to prohibit under-arrangement dialysis contracts between physician owned facilities and hospitals. It is important in many rural areas that dialysis providers be allowed to contract for hospital-based dialysis even though the individuals involved admit to that hospital. In rural areas, especially with smaller hospitals, the hospitals do not have the technical or financial ability to provide dialysis services especially if the need for dialysis is only intermittent or involves a small number of patients. It would be very difficult for these hospitals, which are not economically strong and carry low censuses, to keep the technology and staff available for dialytic therapy. These hospitals, however, are the major health care provider in the area and may need to have dialysis services available for inpatients. I believe that there is no need to further regulate this relationship since hospitals in fact do not want to encourage the admission of ESRD patients to their hospital since by and large they lose money on these DRGs. The hospitals would not maintain a dialysis relationship to encourage admissions of patients with end-stage renal failure.

I also believe that it is difficult to over utilize this treatment modality since the need for dialysis is very well defined and much less subjective than patient care in other areas. In summary, to prohibit dialysis providers from assisting hospitals with inpatient dialysis would only serve to reduce expertise and availability of these services and curtail the ability to provide these services with a rapid response time. Furthermore, there is very little risk of abuse in this area. Thank you.

Sincerely,

Allen Gersh, MD
Medical Director, Hattiesburg Clinic
/cc

415 South 28th Avenue • Hattiesburg, Mississippi 39401-7283 • (601) 264-6000

Submitter : **Mr. Robby Vought** **Date: 08/31/2007**

Organization : **Army Athletic Association**

Category : **Other Practitioner**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Robby Vought. I am a certified athletic trainer at the United States Military Academy at West Point, New York. I have been a certified athletic trainer for 14 years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Robby M. Vought, MS, ATC

Submitter : **Nesa Palesano** **Date: 08/31/2007**

Organization : **Nesa Palesano**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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In an cffort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undcrvaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Nesa Palesano

Submitter : **Mr. Anton Martinez** **Date: 08/31/2007**

Organization : **Free Lance**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I have been an athletic trainer for over 30 years. After I graduated from UNO, I was the athletic trainer for Westside High School. In 1996, I decided to take my career another path. I accepted a job at Rotella s Bakery and did whatever I could in the athletic training field during my free time (i.e. Athletic trainer for events such as The NCAA College World Series and Nebraska High School state games, Red Cross trainer, etc.)

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day to day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Tony Martinez, Certified Athletic Trainer

Submitter : **Mr. Douglas Ashton** **Date: 08/31/2007**

Organization : **Freemqn Health System**

Category : **Other Practitioner**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Dear Sir or Madam,

My name is Douglas Ashton and I currcntly serve as thc Outreach Coordinator at Freeman Health System in Joplin, MO. For the past 11 years I have had the privilege of serving the needs of the community in both clinical and leadcrship roles. I find myself continually frustratcd with thc lack of respect that certain health care providers receive. I am writing today to voice my opposition to the therapy standards and requirements regarding the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

My concern regards the ommitance of certified athletic trainers from the provisions set forth in the proposed standards. Through the years I have bcen fortunate to work with a diverse and committed group of professionals consisting of physical therapists, occupational thcrapists, speech therapists, and certified athletic trainers. I've found through years of experience and education that certified athletic trainers have thc knowledge and educational background necessary to treat the physically active. It's interesting that the world's elite and professional athlete s primary health care providers are athletic trainers yct the general population is sometimes restrictcd from receiving treatment from these qualified professionals due to bureaucratic regulations.

While I am concernrd that these proposed changes to the hospital Conditions of Participation havc not received the propcr and usual vetting, I am more concerned that these proposed rules will creatc additional lack of accrss to quality health care throughout the nation. With the Baby Boomer generation coming of age, it will be more difficult to provide quality health care to an active population.

Athletic Trainers are qualified to perform physical medicine and rehabilitation services. Athletic Trainers education, clinical experience, and national certification exam ensure that patients receive quality health care. State law, leading medical professionals and the American Medical Association (AMA) have deemed athletic trainers qualificd to perform these services. The proposed changes in 1385-P attempts to circumvent those standards.

There is a therapy workforce shortage and a lack of access to qualified rehabilitative services throughout the country. The ability to provide flexible staffing in hospitals and other rehabilitation facilities are needed to ensure that patients receive the best, most cost-effective treatment available.

I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility. I strongly support legislation and regulation that permits our country's physically active the ability to receive treatment from Certified Athletic Trainers.

Sincerely,

Douglas Ashton MS, LAT
Freeman Sports Medicine

1239

Gail Daubert
CAPU Executive Administrator
Reed Smith LLP
(202) 414-9241
http://www.capu.us

CAPU

Coalition for the Advancement of Prosthetic Urology

August 31, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8010
Baltimore, MD 21244-8010

Delivered via http://www.cms.hhs.gov/eRulemaking/01_Overview.asp

RE: CMS-1385-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2008 and Other Changes to Payment

Dear Mr. Kuhn:

On behalf of the Coalition for the Advancement of Prosthetic Urology (CAPU), we are pleased to submit comments in response to Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2008 and other Changes to Payment under Part B. CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology and the nation's leading manufacturers and developers of innovative prosthetic urology devices. As the leading representative of the prosthetic urology community, CAPU's mission is to ensure that the issues affecting this community are given appropriate consideration in the formation of federal health care and reimbursement policy.

Over the past few years, CAPU has been concerned regarding the Relative Value Units (RVUs) assigned to prosthetic urology procedures. We are concerned that for CY 2008 the specialty of prosthetic urology, due to the conversion factor and the budget neutrality adjustor for work RVUs, could be facing a reduction that is close to 15 percent. This is simply not sustainable. For many urologic surgeons, their patient mix tends to be higher with regard to Medicare beneficiaries, due the nature of the diseases and conditions we treat. Unfortunately, we can't sustain reductions of this magnitude and access for Medicare beneficiaries may be jeopardized. We are extremely concerned that 2008 will be the year that this happens.

The one bright spot is the increases due to the changes in the practice expense methodology; however, there is still more that can be done to ensure future access for Medicare beneficiaries to prosthetic urology procedures. Therefore, as explained in greater detail below, CAPU has the following recommendations:

I. "Resource-based Practice Expense (PE) RVUs"

A. "Bottom-up" Practice Expense Methodology

CAPU strongly supported switching to a "bottom-up" methodology for

calculating PE RVUs and we continue to believe that it meets CMS's stated goals of using the most appropriate data, simplifying the practice expense methodology and increasing the stability of the practice expense payments. CAPU supported CMS' proposal to move to a "bottom-up" methodology where the real numbers of direct costs including clinical staff minutes, supplies, and equipment, are accounted for. It is imperative that the PE-RVU levels for prosthetic urology procedures take the larger than average post-service requirements into account. CAPU has been concerned for the last six years that many of the urologists specializing in prosthetic urology procedures would not be able to continue to offer these procedures due to the heavy financial burden and lack of appropriate payment rates. Therefore, CAPU urges CMS to move forward and complete the transition in 2008 to PE-RVUs for prosthetic urology procedures such that 100 percent of the PE RVUS are based on the "bottom-up" methodology, accounting for all the direct costs from either actual survey data or from the inputs in the CMS Practice Expense Inputs Data Base.

II. "Coding – Additional Codes From Five-Year Review"

A. Use of a Work Adjustor for Budget Neutrality

CAPU is concerned regarding the continued impact of the last five-year review on the pool/ distribution of work RVUs per specialty, and then per code. The impact of the proposed 32% increase in work RVUs for anesthesia codes would again, by law, require CMS implement a proposed budget-neutrality adjustor of approximately 11.8 percent.

Applying the budget-neutrality adjuster to the work RVUs is contrary to long-held CMS policy. In the past, when CMS applied a budget neutrality adjuster to the work RVUs, it caused considerable confusion among many non-Medicare payers, as well as physician practices, that adopt the resource-based relative value scale (RBRVS). CMS later acknowledged the confusion and ineffectiveness of applying the budget neutrality adjustor to the work RVUs. However, many non-Medicare payers have now figured out how to apply the budget neutrality adjustment to the work RVUs proposed in Addendum B and thus they too are taking these reductions, even though they are not subjected to any budget neutrality laws.

Furthermore, constant fluctuations in the work RVUs due to budget neutrality adjustments impede the process of establishing work RVUs for new and revised services. In recognition of these difficulties, CMS has been applying budget neutrality adjustments to the physician fee schedule conversion factor, when needed, since 1998 and needs to revert back to this practice for 2008.

CAPU urges CMS to re-consider this proposal and instead apply the budget neutrality adjustor to the physician fee schedule conversion factor.

III. Medicare Physician Payment Rate for 2008

In 2008, physicians and other health care practitioners whose payment rates are tied to the physician fee schedule face a 10% payment rate cut. CAPU urges CMS to work with Congress to avert this cut and ensure that physician payment updates for 2008 and subsequent years accurately reflect increases in medical practice costs.

Payments to physicians today in 2007 are essentially the same as they were six years ago in 2001. Due to

the SGR, physicians now face drastic Medicare payment cuts totaling almost 40% over the next eight years. Yet, during this same time period, the Medicare Economic Index (MEI), which measures increases in medical practice costs, is expected to increase by about 20%. Physicians cannot absorb these draconian cuts.

Only physicians and other health professionals face steep cuts under this flawed payment formula. Other providers, such as nursing homes and hospitals have payment updates that reflect the cost of inflation. Further, the 10% cut in payment rates facing physicians is in stark contrast to Medicare Advantage (MA) plans, which are paid on average 112% above the cost of traditional Medicare, with a significant number of MA plans paid from 120% to more than 150% of traditional Medicare. These overpayments are shortening the life of the Medicare trust fund.

***

Sincerely,

John J. Mulcahy, MD

John J. Mulcahy, M.D., Ph.D., F.A.C.S.
Chair

cc: Dr. Jim Regan, Chairman of Health Policy Council, AUA
Robin Hudson, AUA
CAPU Board Members (via email only)

Submitter : **Mr. Ryan Chamberlin** **Date: 08/31/2007**

Organization : **South Eastern Regional Medical Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Ryan M. Chamberlin and I am an NATA certified and Ohio licensed Athletic Trainer working at Southeastern Ohio Regional Medical Center in Cambridge Ohio. As an Athletic Trainer here I provide assistance to the Physical Therapists and I also provide Medical coverage to Meadowbrook High School.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

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Sincerely,

Ryan M. Chamberlin, ATC/L

Submitter : Mr. Donald Rohde **Date:** 08/31/2007

Organization : Mr. Donald Rohde

Category : Other Health Care Professional

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Dear Sir or Madam:

My name is Donald Rohde, I'm a student Athletic Trainer at Hardin-Simmons University. This year will be my second year in the program and I am still undecided on what setting I would like to pursue after I receive my diploma and pass my certification exam, which is why I am worried about the proposed revisions.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Sincerely,

Donald Rohde

Submitter : **Mr. Bob Hamre** **Date: 08/31/2007**

Organization : **Kent Physical Therapy**

Category : **Health Care Industry**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

see attached

CMS-1385-P-15242-Attach-1.DOC

1652-P-242

Aug 27 2007

Dear Sir or Madam:

My name is Bob Hamre. I own and operate a physical therapy and sports performance business in the Seattle, WA area. I have been working as a Certified Athletic Trainer for ten years, in hospitals, private clinics, and professional sports teams.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Sincerely,

Bob Hamre, ATC, CSCS
Kent Physical Therapy and Sports Performance Center

Submitter : **Miss. Lydia Vanderford** **Date: 08/31/2007**

Organization : **CSU - SmartBodies & New Directions Fitness Therapy**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a certified athletic trainer employed at Clayton State University as a fitness instructor and rehabilitation coordinator. In our facility, we service students, student athletes, employees, and members of the community. I graduated from Valdosta State University with a degree in Sports Medicine (Athletic Training) and Eduction May 1994 and received my certification through the National Athletic Trainers' Association Board of Certification June 1994. I also received my Master of Science in Exercise Physiology from Montana State University in 1997. I am currently licensed to practice as an athletic trainer in the state of Georgia.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposcd in 1385-P.

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Sincerely,

Lydia Vanderford, MS, LAT, ATC

Submitter : **Dr. Nathan Nachlas** **Date: 08/31/2007**

Organization : **Boca Clinic**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See attachment

15214

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Plea.. note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : Dr. Terry DeWitt **Date:** 08/31/2007

Organization : Ouachita Baptist University

Category : Academic

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am an Athletic Training educator. We have an Athletic Training major at the university I work at. My whole professional career stems from teaching allied health care education to up and coming professionals.

The purpose of this letter to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P. While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health eare. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Terry DeWitt, PhD, ATC
Associate Professor, Director
Athletic Training Education Program

Cf: Congressman Mike Ross
Congressman Vic Snyder
Congressman John Boozman
Congressman Marian Berry
Senator Blanch Lincoln
Senator Mark Pryor

Submitter : **Dr. Robert Dove** **Date: 08/31/2007**

Organization : **Dr. Robert Dove**

Category : **Physician**

Issue Areas/Comments

Background

Background

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to inerease anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Robert M Dove III MD

Submitter : **Mrs. Dana Benson** **Date: 08/31/2007**

Organization : **AANA**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES

Dear Administrator:

As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

This increase in Medicare payment is important for several reasons.

? First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
? Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
? Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.

Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).

America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.

Sincerely,

_Dana L. Benson, CRNA
Name & Credential
195 Muscovy Trail
Address
_Livingston, Texas 77351

Submitter : **Dr. Carol Parrot** **Date: 08/31/2007**

Organization : **Northwest Anesthesiologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Carol A. Parrot, MD
19431 46th Ave NE
Lake Forest Park, WA 98155

Submitter : **Date: 08/31/2007**

Organization : **Olympic Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

BRIEF INTRO ABOUT SELF ie. Where you work, what you do, education, certification, etc.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Taro Iwamoto,MS, ATC,CSCS

Submitter : **Dr. Charles Huang** **Date: 08/31/2007**

Organization : **Dr. Charles Huang**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (the Proposed Rule) published in the Federal Register on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.
There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the all physicians crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as interventional pain physicians for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to all physicians for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology.

Submitter : **Miss. Jeanie Burch** **Date: 08/31/2007**

Organization : **Greenwood Leflore Hospital**

Category : **Hospital**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer at Greenwood Leflore Hospital. I work closely with physicians, nurses, and PTs on a daily basis, not to mention high school coaches, parents and children at local high schools. I am board certified and required to obtain continuing eduction units in order to remain so. I am sure that if you have ever had a child assisted by a certified athletic trainer, you know the importance of our profession and its impact on many lives.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Jeanie Burch, ATC, MEd

15252

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Richard Whitten **Date:** 08/31/2007

Organization : Noridian Administrative Services

Category : Physician

Issue Areas/Comments

Malpractice

Malpractice

Colleagues: In the July 12, NPRM at page 38142 et seq. and 38138 et seq. and 38368, you describe CMS s approach to updating the practice liability GPCIs for 2008 and 2009. In answer to part of your question on page 38143, the practice liability purchased either directly by a physician or by the physician s employing entity on behalf of the physician will also provide liability coverage for technicians being supervised by the physician. Your statement that it would not be consistent with a resource-based fee schedule methodology to make changes in the professional RVUs that are not supported by actual data seems completely logical and appropriate. By the same logic, it does NOT appear consistent with the methodology to make changes to a state s PL GPCI where such a change is NOT supported by data. The proposed changes for the State of Washington seem unsupportable when actual statewide and national data are reviewed and compared. In the first place, it is proposed to divide the WA PL GPCI into the two areas: King County and Rest of Washington in spite of the fact that NO practice liability insurance appears to be sold with this artificial division in the state and the vast majority is sold with single STATEWIDE premium rates. Next, after confirming that CMS used base years of 2001-3 data, Washington data have been compared with national norms and variances for both primary care and specialty practices, suggesting that WA as a whole (and it should be treated as a whole) is slightly below a 1.00 midpoint, but no where near as low as even the current statewide level of 0.805 and it appears looking at data to 1996 that a reduction from this level is unsupportable. It is recommended that CMS continue the single statewide PL GPCI of 0.805 until CMS has more carefully reviewed data for Washington and other states. Source of data, who may with her staff help CMS staff to further confirm and assess include: Mary-Lou A. Misrahy, ARM; President and Chief Executive Officer; Physicians Insurance - A Mutual Company; Seattle, WA; (206) 343-7300. Thank you for considering. Richard W. Whitten, MD, MBA, FACP; Contractor Medical Director, Medicare B for AK, HI & WA

Submitter : **Mr. Benjamin Williams** **Date: 08/31/2007**

Organization : **Greensboro Orthopaedics**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dcar Sir or Madam:

I am an athletic trainer who currently works in the clinical outreach setting.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Benjamin James Williams, MEd LAT, ATC

Submitter : **Dr. Edward Jones** **Date: 08/31/2007**

Organization : **Kidney Care Partners**

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15255-Attach-1.PDF

1525

KIDNEY CARE
PARTNERS

August 31, 2007

Mr. Herb Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS 1385-P: Proposed Rule for Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008

Dear Administrator Kuhn,

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year (CY) 2008 (Proposed Rule).[1] KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care for individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[2] We appreciate the initiatives CMS has undertaken to ensure that ESRD patients have access to appropriate and high quality treatment services and would like to offer the following recommendations as additional steps in this effort.

I. ESRD PROVISIONS: CMS should adopt an accurate proxy to estimate the update to the drug add-on adjustment for CY 2008 and allow for forecast error adjustments to ensure that the estimates are correct.

While KCP does support the use of an index to establish the annual update amount to the drug add-on adjustment, we remain concerned that the methodology included in the Proposed Rule fails to provide for an accurate estimate of changes in price and utilization of ESRD

[1] 72 Fed. Reg. 38122 (July 12, 2007).
[2] A roster of members of Kidney Care Partners is included as Attachment A.

separately billable drugs. Given the potential shortcomings of the proposed methodology, KCP encourages CMS to adopt a proxy index for price and utilization and to establish a mechanism to permit forecast error adjustments. KCP also urges CMS to work transparently with the kidney care community as it considers a CY 2010 transition to trend analysis using ASP-based historical expenditure data.

A. CMS' selection of the Producer Price Index may not result in an accurate assessment of prices for ESRD-related pharmaceuticals.

KCP acknowledges that the Producer Price Index (PPI) selected by CMS may have some value as a measure of a price estimate but we believe that there are other available indices that would provide more accurate data on ESRD-related drugs. However, should CMS choose to move forward with continued use of the PPI, we urge the Agency to carefully assess the correct PPI percentage in the Final Rule to ensure that its estimate reflects the most current data available.

B. KCP urges CMS to reevaluate the data and methodology it uses to estimate utilization changes.

KCP is concerned that CMS continues to rely on incomplete and stale data to conclude that the utilization of separately billable drugs remains flat. Using the same methodology it introduced in last year's Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule,[3] CMS employs the change in drug expenditures from CY2005 and CY2006 as a baseline for estimating trends in drug utilization. KCP continues to encourage CMS to clarify how it develops these estimates. Additionally, KCP is concerned that the CY2005 and CY2006 data is not the most recent data for separately billable drugs. Finally, we also believe that CMS' decision to employ utilization figures that are limited to independent dialysis facilities and exclude hospital-based data may significantly skew the accuracy of the utilization growth data.

KCP believes that the data flaws outlined above may result in a utilization estimate that does not accurately reflect reality, and we strongly encourage CMS to reevaluate its proposal to continue the use of the same methodology it relied upon last year.

C. Given the potential for inaccuracy posed by the proposed methodology to calculate the update to the drug add-on adjustment, KCP urges CMS to adopt a stable index for both price and utilization and to establish a mechanism to permit forecast error adjustments.

KCP encourages CMS to acknowledge the data and methodological problems associated with the Proposed Rule and use a more stable and consistent proxy to estimate price and utilization for the purposes of calculating the update to the drug add-on adjustment for CY2008. By adopting an alternative index, such as the National Health Expenditure (NHE) index, KCP believes that CMS can avoid the problems identified in the proposed methodology. As we noted in our comments submitted on the CY2007 Proposed Rule, use of the NHE index may be

[3] 71 Fed. Reg. 48982 (August 22, 2006).

beneficial because it provides a comprehensive index measurement of both price and utilization changes and would be a preferred alternative until CMS has credible data that allows it to estimate price and utilization more accurately.

Regardless of how CMS addresses the proxy issue in the short-term, KCP continues to recommend that CMS establish a forecast error mechanism that will allow it to audit its own projections for accuracy on a prospective basis until it has stable data with which to estimate the utilization change. KCP appreciates CMS' position that it meets its statutory obligations absent a forecast error mechanism but we continue to believe that both CMS and KCP should be committed to calculating the update in as accurate a manner as possible.

D. KCP urges CMS to work with the kidney care community as it considers a CY 2010 transition to trend analysis using ASP-based historical expenditure data.

CMS proposes to use current methods of estimating the drug add-on update until it has at least three years worth of ASP-based historical drug expenditure data that can be used to conduct a trend analysis to estimate growth in drug expenditures. CMS suggests that the requisite data will be available by CY 2010 and that it will reevaluate its methodology at that time. In light of the significant impact such a transition will have on the kidney care community, KCP encourages CMS to provide greater clarification as to its intentions and planning on the subject. Specifically, we are concerned about the impact of the recent shift to blended reimbursement of Epogen and Procrit and the impact of this blending on the accuracy of the product ASP for specific purchases. We urge CMS to further examine its intent in light of this change to ensure that the data accurately reflects the sales price and provider cost for Epogen. KCP further urges CMS to work with the kidney care community in the early stages of the process to address this transition.

II. ESRD PROVISIONS: KCP requests that CMS further clarify the budget neutrality calculation used for the geographic wage index by explaining the methodology used by the Agency in its assessment.

KCP remains concerned that the calculation of the budget neutrality factor for the geographic wage index is not transparent in the Proposed Rule. The modifications to the geographic wage index have significant consequences for small providers, for whom minor differences in the index amount to a large impact on their payments and financial sustainability. These providers need to be assured that the budget neutrality factor is being calculated correctly. Accordingly, KCP urges CMS to provide the data and methodology that are used to calculate the budget neutrality factor in the Proposed Rule so as to enable the community to assess the impact of the proposed changes.

III. ANEMIA QUALITY INDICATORS: CMS should maintain use of the ESA claims monitoring policy for beneficiaries with End Stage Renal Disease (ESRD) treated in renal dialysis facilities.

KCP supports CMS' use of the "Claims Monitoring Policy: Erthropoietin/darbepoetin alfa Usage for Beneficiaries with End Stage Renal Disease" (EPO Monitoring Policy) to monitor the use of anemia treatment drugs for ESRD patients receiving dialysis. We strongly believe that the EPO Monitoring Policy strikes the appropriate balance between promoting the efficient use of Erthropoietin (Epotin) and darbepoietin alfa (Aranesp) and ensuring that patients continue to have access to critically important anemia treatment.

CMS recently announced changes to the current EPO monitoring policy, and we look forward to working with the Agency to develop a solution that effectively manages the use of ESAs without creating obstacles to access for these treatments. We would, however, like to emphasize that the review of EPO Monitoring Policy must recognize that existing policy does not constitute a treatment guideline but is instead a reimbursement-auditing tool. Under the current policy, if a patient's hemoglobin reaches 13 g/dL and the dose is not reduced, then CMS will reduce the payment by 25 percent. Current policy does not call for, nor recommend, that patients' hemoglobin levels be maintained above 12 g/dL. Instead, CMS has appropriately and responsibly set a reimbursement auditing trigger at a level which takes into account individual and temporal variability in how hemoglobin levels respond to anemia management drugs, and we hope to see continuation of this approach in the revised policy.

With respect to anemia quality indicators, KCP believes that the current monitoring program through Clinical Performance Measures (CPMs) provides an effective assessment of patients' clinical and treatment status, including dialysis adequacy, anemia management, and vascular access management. However, KCP also supports the implementation of a comprehensive quality initiative incorporating, among other elements, an expanded set of CPMs. KCP remains committed to the Kidney Care Quality Initiative (KCQI) and is willing to work actively with CMS to put such a program in place.

IV. PHYSICIAN QUALITY REPORTING: KCP encourages CMS to include CKD and ESRD-related quality measures in its physician reporting intiative.

KCP is pleased to see that the Proposed Rule includes CMS implementation of quality measures for physicians related to treatment of ESRD and chronic kidney disease (CKD). KCP shares CMS' commitment to quality, and in 2005, KCP launched the Kidney Care Quality Alliance (KCQA) to bring together members of the kidney care community to collaborate on building a foundation for improving the quality of care for services provided to patients with ESRD and CKD. Specifically, the KCQA's goal is to involve patients and their advocates, care professionals, providers, suppliers and purchasers in the development of performance measures at the facility and physician levels to evaluate and improve the quality of care for patients with chronic kidney disease. The group also focuses on developing data collection and aggregation strategies and promoting transparency through the reporting of performance measures to consumers, patients, care professionals, dialysis facilities and others in the kidney care community to inform choice and improve outcomes.

We believe that inclusion of ESRD and CKD-related measures in the Physician Quality Reporting Initiative (PQRI) is an important step in enhancing the quality of services furnished to Medicare beneficiaries. KCP supports the development of both facility and physician level

measures that enhance quality in connection with an added payment incentive. Specifically, KCP champions the reporting of valid and meaningful process and outcomes measures to ensure transparency and promote quality of care within the Medicare program. We also appreciate CMS' efforts to work with groups outside the KCQA who are active in the development of quality measures, and we encourage CMS to continue to collaborate with interested parties to develop and implement measures that will enhance and strengthen the quality of care furnished to ESRD patients.

V. CONCLUSION

On behalf of KCP, I would like to express my gratitude for the Agency's willingness to consider our comments on the Proposed Rule. As I mentioned, we look forward to continuing to work with you to resolve these issues and ensure patient access to ESRD treatment and quality of care for Medicare beneficiaries. If you have any questions or would like additional information, please do not hesitate to contact Piper Nieters Su at 202-457-6159.

Sincerely,

Edward R. Jones, MD
Chairman
Kidney Care Partners

Attachment A

Abbott Laboratories
AMAG Pharmaceuticals
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners Nursing and Technicians
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
DSI
Fresenius Medical Care North America
Fresenius Medical Care Products and Hospital Group
Genzyme
National Association of Nephrology Technicians and Technologists
National Kidney Foundation
National Renal Administrators Association
National Renal Alliance, LLC
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
Roche
Satellite Healthcare
U.S. Renal Care
Watson Pharma, Inc.

Submitter : **Mr. Jeremy Geus** **Date: 08/31/2007**

Organization : **Champion Sports Medicine**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a Licensed, Certified Athletic Trainer in an outpatient rehabilitation center. I aid one of the leading physical therapists in the field of sports medicine; as well as outreach to secondary schools. I have a Bachelor s degree and graduated with honors from an NATA approved curriculum program. I have credentials from the National Strength and Conditioning Association as a Certified Strength and Conditioning Specialist.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jeremy J Geus, ATC, CSCS

Submitter : **Mr. Patrick Hughes** **Date: 08/31/2007**

Organization : **Orthopedic Surgeons and Sports Medicine**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am the Head Athletic Trainer at Montana State University-Billings, but I am employed through a private practice physician's office.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Patrick Hughes, MS, ATC
Head Certified Athletic Trainer
Montana State University-Billings

Submitter : **Mr. Philip Leone** **Date: 08/31/2007**

Organization : **CardioNet**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15258-Attach-1.PDF

August 31, 2007

HAND DELIVERED

Herb Kuhn
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Kuhn:

CardioNet thanks you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007.[1] As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

CardioNet ("Cardionet") is a provider of remote, real-time cardiac monitoring through wireless communications, and computerized arrhythmia detection technology called mobile cardiac outpatient telemetry ("MCOT"), an important breakthrough technology which is significantly improving physicians' ability to diagnose cardiac arrhythmias. MCOT is a technology that diagnoses clinically significant cardiac arrhythmias by monitoring, recording, and real-time wireless transmission of every heart beat while patients are at home, at work, traveling, or otherwise conducting their normal activities. MCOT is the first mobile outpatient telemetry system to provide real-time ECG monitoring, 24/7/365 analysis and immediate communication of life threatening symptomatic and asymptomatic arrhythmias to treating physicians via the CardioNet monitoring station.

IDTF Issues

We wish to comment on the CMS proposal in the Proposed Rule for the CY 2008 Medicare Physician Fee Schedule to prohibit IDTF's from "sharing space, equipment, or staff or sublease its operations to another individual or organization."

[1] 72 *Fed. Reg.* 38120 (July 12, 2007).

down suspect arrangements, the CMS proposal would also prohibit wholly owned corporate subsidiaries and affiliates under common control from sharing staff, space and equipment so that can efficiently share resources and reduce the costs of remote cardiac monitoring services. The type of sharing we proposed to undertake has nothing to do with creating incentives or opportunities for physicians to profit from their own referrals and thereby promote over-utilization of services. CardioNet and PDSHeart rely on practicing physicians (including internists, family practitioners, and cardiologists), none of whom have an ownership or investment interest in either entity, to refer patients for our services. Further, neither CardioNet or PDSHeart are able to refer patients to themselves or to each other

Should CMS implement its proposed sharing and subleasing prohibition, we strongly recommend that CMS specifically exempt IDTFs that have common ownership and common control from the definition of "individual or organization" in the proposed regulatory language §410.33(g)(15) so that we, and other companies, have the flexibility necessary to structure our businesses and operations in a manner that results in the efficient use of resources to obtain overall cost savings.

Both CardioNet and PDSHeart have distinct monitoring stations that are separately enrolled as IDTFS in Pennsylvania, Georgia, Florida and Minnesota. Each of the stations is enrolled as separate IDTFs and provides distinct cardiac monitoring services. We have maintained separate corporate structures for financial accounting and business purposes. The separate corporate structures allow us to more easily maintain separate cost accounting records to track the costs associated with the delivery of each type of cardiac monitoring service. Because we have recently purchased PDSHeart, we are still gathering critical financial and operational information necessary to improve our operations. By maintaining separate corporate structures and accounting records, we are able closely monitor the expenses associated with each remote monitoring service so that we can determine where we can appropriately increase efficiencies and reduce costs while maintaining high quality monitoring services for our patients.

If CardioNet and PDSHeart use co-located monitoring stations, they can share staff, space and equipment. For example, administrative staff can be shared in a manner that allows for coordinated scheduling and staffing levels needed to meet patient demand. The same billing staff can handle claims submission for both IDTFs and the same customer service representatives can handle patient questions. Further, the IDTFs could share information storage systems and other information technology. On the other hand, MCOT equipment needs to be handled, stored, and inspected separately from event and Holter monitoring equipment and the technicians who inspect and repair event and Holter monitors may not be able to inspect and repair MCOT monitors.

Should the sharing prohibition go into effect, CardioNet and PDSHeart each would be forced to hire separate administrative staff and would be unable to share information systems and space which would substantially increase our staffing, leasing, and overhead costs. Outside of technicians our greatest expense is in information technology and if we are not granted an exception CardioNet and PDSHeart would have to purchase duplicate information systems each of which would have excess capacity.

We request that CMS revise its proposed regulatory language prohibiting sharing of space and equipment as follows:

Revise proposed §410.33(g)(15) to read as follows:

"Does not share space, equipment, or staff or sublease its operations to another individual or organization, except for a subsidiary or affiliated IDTF that is wholly owned by, and under the complete control of, the IDTF."

Without this exception, CDI and PDSHeart would be forced to purchase/lease separate office space, purchase duplicate diagnostic equipment, information technology, office equipment and maintain duplicate staff. This would significantly reduce our efficient use of resources and increase costs.

* * *

Thank you for your consideration of these comments. If you have any questions, please do not hesitate to contact Paul Rudolf, MD, JD at 202-775-5731.

Respectfully submitted,

Philip Leone

Philip Leone
Vice President, Payer Relations
CardioNet, Inc.

Submitter : **Dr. Johannes Peters** **Date: 08/31/2007**

Organization : **Dr. Johannes Peters**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Johannes Peters M.D.

Submitter : **Date: 08/31/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15262-Attach-1.DOC

August 31, 2007

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Recommended changes to CMS Proposed Rule, Federal Register, Vol. 72, No. 133

Revisions to Personnel Qualification Standards for Therapy Services

- This rule should only apply to internationally educated occupational therapists, not occupational therapy assistants. There are no internationally educated occupational therapy assistants, thus, language proposing to adopt similar standards for OTAs should be stricken from the proposed rules. Specific references are found on page 38192, 2nd column, 2nd paragraph and page 38193, 1st column, 1st paragraph.

- Individuals trained by the United States military are required to complete occupational therapy programs accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE). These individuals are not required to complete occupational therapy programs accredited by the World Federation of Occupational Therapists (WFOT) as the proposed rules indicate. The references in the proposed rules should be amended accordingly.
  Specific references are found on page 38192, 2nd column, 2nd paragraph (general language linking therapists who obtain occupational therapy education outside the Unites States and therapists who obtain their education through a U.S. military program), page 38192, 3rd column, 4th paragraph and page 38230, 2nd column, (B) ii.

- Concerning internationally educated occupational therapists, we support implementing standards which are comparable to that of an occupational therapist educated in the United States. As the proposed rules indicate on page 38192, 2nd column, 2nd paragraph, the NBCOT has and continues to conduct this eligibility determination review process. As indicated before, individuals educated through U.S. military occupational therapy education programs are not required to complete the eligibility comparability determination review process because these programs are accredited by the Accreditation Council for Occupational Therapy Education, ACOTE.

- On page 38193, 1st column, 1st paragraph of the proposed rules, we recommend that eligibility criteria number three (3) for the internationally educated occupational therapist be amended as follows: 'have successfully completed the certification examination for Occupational Therapist Registered' as opposed to the current language which reads as 'Registered Occupational Therapist.'

- We support the position of CMS to stipulate and require that the personnel qualifications for occupational therapists and occupational therapy assistants be applicable to and consistent throughout all treatment settings. This proposed requirement is sited on page 38193, 2nd column, 2nd paragraph.

- Regarding the grandfathering and personnel qualifications provisions relating to qualifications of occupational therapists and occupational therapy assistants, we recommend that draft language setting forth individuals who began work in the field prior to 1977, those who worked in the field between 1977 and January 1, 2008 and those who will begin work after January 1, 2008 be stricken from this rule. References to such date frames are found on page 38192, 1st and 2nd columns and page 38230, 2nd and 3rd columns. Instead, we recommend the following qualifications language:

  Occupational therapist means an individual who meets all practice requirements as set forth by the State in which occupational therapy services are provided and who is certified and in good standing with the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

  Occupational therapy assistant means an individual who meets all practice requirements as set forth by the State in which occupational therapy services are provided and who is certified and in good standing with the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

  As a point of clarification: eligibility requirements for an occupational therapist or occupational therapy assistant have changed over time and the entities involved in accreditation or certification, by national examination, have changed over time as well. Rather than complicating the qualifications outlined in the rules, we are suggesting that one set of qualifications be applied to all sections of the rules, no matter when the individual entered into professional practice, as long as an occupational therapist or occupational therapy assistant meets all practice requirements set forth by the state in which occupational therapy services are furnished and that the occupational therapist or occupational therapy assistant

comply with and meet national certification requirements established by NBCOT.

- With regards to physical therapists and physical therapist assistants, we recommend adopting the same position for the qualifications of physical therapists and physical therapist assistants and that the draft language setting forth individuals who began work in the field prior to 1977, those who worked in the field between 1977 and January 1, 2008 and those who will begin work after January 1, 2008 be stricken from this rule. Instead, we recommend adopting the following qualifications language:

  'Physical therapist means an individual who meets all practice requirements as set forth by the State in which physical therapy services are provided and who is licensed as a physical therapist.'

  'Physical therapist assistant: means an individual who meets all all practice requirements as set forth by the State in which physical therapy services are provided and who is certified as a physical therapist assistant'.

PART 409—Hospital Insurance Benefits
Subpart B—Inpatient Hospital Services and Inpatient Critical Access Hospital

- **§ 409.17(b) Establishment of the plan**

  - We recommend the following language be incorporated in § 409.17(b).

    (1) The plan must be established before treatment begins.
    (2) The plan must be developed by one of the following:
    (i) A physician who is furnishing care to the patient.
    (ii) A nurse practitioner, a clinical nurse specialist or a physician assistant furnishing care to the patient.
    (iii) The physical therapist furnishing the physical therapy services.
    (iv) A speech-language pathologist furnishing the speech-language pathology services
    (v) An occupational therapist furnishing the occupational therapy services.
    (2) Prior to implementation of the plan of care the physician responsible for the patient's care must review it in order to assure that the plan is consistent with the patient's medical status and that the patient is likely to benefit from the plan.
    (3) The plan of care must be implemented in accordance with the orders of the physician responsible for the patient's care.

- **§ 409.17(d) Changes to the plan**

    - We recommend the language in (d) be stricken from this rule and amend language to read: '**Changes to the plan of care cannot be made without an order by the physician responsible for the patient's care.**'

- **§ 409.17(e) Review of the plan**

    - We recommend redesignating the current proposed 'e' to 'f' and adding a new 'e' with the following language: 'Prior to initial implementation of the plan of care, or of changes to an existing plan of care, the physician responsible for the patient's care must review the plan of care or changes, as applicable, to assure that the plan is consistent with the patient's medical status and is likely to benefit from the proposed plan of care'.

§ 410.105 Requirements for coverage of CORF Services

- § 410.105(b)(3)(i) clarifies the issue of whether therapy services may be provided in the patient's home (in addition to the single home evaluation visit). We recommend that this same language be written into § 485.58(e)(2). § 485.58(e)(2) should read: 'Physical therapy, occupational therapy, and speech-language pathology services may be furnished away from the premises of the CORF, including the individual's home, when payment is not otherwise made under Title XVIII of the Act.' **The condition for coverage and the condition of participation need to be consistent.** (page 38223)

Part 485—Conditions of Participation for Hospitals
Subpart D—Optional Hospital Services

- **§ 482.56 Condition of participation: Rehabilitation Services**

    - The hospital CoPs require that patient care is the responsibility of the physician responsible for the care of the patient. Other practitioners cannot have equal authority to order rehabilitation services or revise the plan of care. The responsible physician must develop the plan of care and must order rehabilitation

services or write orders implementing the plan of care if the plan of care is developed by other practitioners. All changes in the plan of care must be ordered by the physician responsible for care of the patient and can only be implemented in accordance with the order of that physician. If the plan of care is developed and/or implemented without coordination and outside the direction of the responsible physician, the patient's health and safety is likely to be placed in jeopardy.

The plain language of the proposed regulation would authorize the implementation of rehabilitation services outside the responsibility and direction of the physician responsible for the care of the patient. The preamble did discuss that this is "implied". However, the plain language of the regulation always supersedes any language in the preamble.

Therefore, we recommend a change to the language of **§ 482.56(a)(2)** to read as follows:

'(a)(2) Rehabilitation services must be provided in accordance with the orders of the physician responsible for the patient's care'.

- As in other sections, we recommend that current timeframe language for therapy practitioners be stricken from this rule. Therefore, we recommend **§ 482.56(b)(ii)** to read as follows:

- **'(b)(2)** By qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists who have been licensed, certified, registered, or otherwise recognized by the State in which they are practicing.'

- As stated above, the physician who is responsible for care of the patient must approve a modified plan of care. Therefore,

  § 482.56(b)(3) should read as follows:

  '(b)(3) Changes in the plan of care must be made in writing, signed by the physician responsible for the care of that patient ,and implemented in a timely manner.

- **§ 482.56(b)(3)** *Plan of treatment requirements*—(i) *Establishment of the plan.* We recommend the language in this citation be revised and renumbered to be consistent with § 409.17(b) and should read as follows:

'(A) The plan must be developed by one of the following:
(1) A physician who is furnishing care to the patient.
(2) A nurse practitioner, a clinical nurse specialist or a physician assistant who is furnishing care to the patient.
(3) The physical therapist furnishing the physical therapy services.
(4) A speech-language pathologist furnishing the speech-language pathology services
(5) An occupational therapist furnishing the occupational therapy services.
(B) The plan must be established before treatment begins.'

- **§ 482.56(b)(iii)** *Changes in the plan.*
    - We recommend the current language in this citation be stricken from this rule and amended to read:

      '(iii) Changes to the plan of care cannot be made without an order by the physician responsible for the patient's care.'

- **§ 482.56(b)(iv)** *Review of the plan*
    - We recommend the current language be deleted and replaced with the following language:

      '(iv) Prior to initial implementation of the plan of care, or of changes to an existing plan of care, the physician responsible for the patient's care must review the plan of care or changes, as applicable, to assure that the plan is consistent with the patient's medical status and is likely to benefit from the proposed plan of care.'

Other recommendations:

- We recommend inserting an 'or' at the end of (e)(1) page 38232, 1st column to clarify your intent that providers must meet one of two conditions.
- Using the same rationale, we recommend inserting an 'or' at the end of § 491.9(c)4)(A) on page 38232, 2nd column.
- For Subpart H, §485.705 Personnel Qualifications (page 38232) 1st column, we recommend an 'or' after (a)(3)(i). Furthermore, we also

recommend striking all language relating to timeframes under § 485. 705(a)(3)(ii) and placing a period after '.....therapy assistants by the State in which practicing.'

Part 485—Conditions of Participation: Specialized Providers

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

- **§ 485.70 Personnel Qualifications**
    - We recommend inserting an 'or' between § 485.70(c)(1) (page 38231) and (c)(2) (page 38232).
    - We recommend inserting an 'or' between § 485.70(e)(1) (page 38232 and § 485.70(e)(2). (page 38232)

Subpart H—Conditions of Participation and Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

- **§ 485.705 Personnel Qualifications**
    - We recommend inserting an 'or' between § 485.705(a)(3)(i) and § 485.705(a)(3)(ii). (page 38232)
    - We recommend deleting the current language in § 485.705(a)(3)(ii) regarding timeframes for personnel qualifications and to amend the section to read:

'**(a)(3)(i)** Physical Therapy, occupational therapy or speech-language pathology services may be furnished by qualified physical therapists, physical therapist assistants, occupational therapists, or occupational therapy assistants who have been licensed, certified, registered or otherwise recognized as physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants by the State in which the services are provided.' (page 38232)

§ 491.9 Provision of Services

- We recommend inserting an 'or' between §491.9(c)(4)(i)(A) and § 491.9(c)(4)(i)(B). (page38232)

Submitter : **Mr. Dana Putnam** **Date: 08/31/2007**

Organization : **Army Athletic Association**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Dana Putnam and I work as a Certified Athletic Trainer at the United States Military Academy.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Dana Putnam, ATC, MEd

Submitter : Mr. Gary Minnella **Date:** 08/31/2007

Organization : Mercy Hospital Port Huron

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Dear Sir or Madam:

My name is Gary Minnella, a certified athletic trainer in Michigan. I have a Maters degree in athletic training from Western Michigan University. I hold certifications in athletic training, strength and conditioning, and teaching (health education). I have been involved with high school athletics for 25 years and currently work in a hospital base clinic for which I have been employed for 18 years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Gary Minnella, ATC, CSCS

1526(5)

Dear Sir or Madam:

I am currently a senior at a private college studying Athletic Training. My plans after college are to take my board of certification exam for athletic training and pursue a job in a clinic.

I am writing you today to voice my position on the therapy standards and requirements in regards to staffing athletic trainers in hospitals and facilities proposed in 1385-P.

I am concerned that with these new proposed rules it will shrink my chances of getting a job and long-term goal of working in a rehabilitation clinic. I feel I have just spent my $32,000 dollars a year on tuition cost for nothing because if this were to be passed I would be unable to pursue my love.

As an athletic training student I am qualified to perform physical medicine and rehabilitation services, which is not the same as physical therapy. My class work, clinical experience, and soon to be national certification exam ensure that I am qualified to provide adequate health care.

Since CMS seems to have come up with these proposed changes without justification I strongly encourage CMS to consider the recommendations of those professionals that are overseeing the day-to-day operations. I respectfully request that you withdraw your proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Meghan Devlin, ATS

Submitter : **Dr. Nathan Nachlas** **Date: 08/31/2007**

Organization : **Boca Clinic**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

see attachment

CMS-1385-P-15266-Attach-1.DOC

We are a group of 12 physician practices, with 81 physicians, that are commenting on CMS –1385-P, the proposed changes to the physician fee schedule for CY2008. In reliance on the existing regulations, our physician practices have invested over 8 million dollars in imaging and diagnostic equipment that we share among ourselves in the medical office building where we regularly practice. We are very concerned with the proposed changes to the physician self-referral provision, specifically the proposed changes to the anti-markup provision, the in- office ancillary services exception, and the unit of service payment in space and equipment leases.

We would like CMS to confirm that nothing in the proposed changes will affect the provision of in office ancillary services through facilities that are owned and shared by separate medical groups that practice in the same medical office building. The Stark II regulations specifically permitted such arrangements, which are both cost-effective and convenient for patients. Medical groups like us have relied on the current regulations in making substantial investments of time and money.

Our arrangement is a *bona fide* shared facility. In our MOB situation, the physicians have built and own an 8 million dollar state of the art imaging center. The group tenants in the building each pay a fixed fee each month for lease of the imaging center, in addition to a per click fee for each service utilized. The base fee covers the common expenses of the center and the variable expenses are divided through the "per click" methodology. The entire arrangement including the division of expenses through base leases and the "per click" were reviewed and approved by a reputable national health care law firm. A radiologist who is full time in the building and has part time contracts with each of the tenant groups reads the images. He is compensated directly by each practice for his services performed.

This type of arrangement was specifically approved by CMS in the 2001 Physician Self referral Phase I rulemaking (856 Fed. Reg. 856, 892-94) (January 4, 2001). In response to multiple commenters seeking a separate exception for shared facilities, CMS stated:

> Response: In the August 1995 final rule and the preamble to the January 1998 proposed regulation, we observed that the in-office ancillary services exception would allow certain shared facility arrangements among solo practitioners who do not wish to become a group practice. For example, we noted that two solo practitioners who share an office and jointly own a laboratory can continue to refer to that laboratory, as long as each physician (1) furnishes physician services unrelated to the furnishing of DHS in the office (that is, the arrangement meets the "same building" requirements), (2) directly supervises the laboratory services for his or her own Medicare or Medicaid patients while they are being furnished, and (3) bills for the services. We further noted that if only one of the solo practitioners owns the laboratory in a shared office, the nonowning physician can refer to the laboratory as long as he or she is not receiving compensation from the owner in exchange for referrals. We solicited comments on the effects of section 1877 of the Act on other shared facility arrangements.

After careful review of the public comments, we are persuaded that our original approach in the January 1998 proposed regulations is most consistent with the purposes of section 1877 of the Act. Under that approach, shared facilities are permitted if they comply with the supervision, location, and billing requirements of the in-office ancillary services exception. With respect to the location of the shared facility, Phase I of this rulemaking permits shared facilities that meet the "same building" requirements. (However, shared facilities do not qualify under the "centralized building" standard because they will not meet the exclusively used requirement). Thus, as noted above, two solo practitioners who share an office and jointly own a laboratory can continue to refer to that laboratory, as long as each physician furnishes substantial physician services unrelated to the furnishing of DHS in the building where the laboratory is located, provides (directly or through an independent contractor if permitted under applicable payment and coverage rules) the appropriate level of supervision for DHS for his or her own Medicare or Medicaid patients, and bills for the services. We believe the relaxation of the direct supervision requirement under these regulations will enable additional shared facilities to come within the exception.

Additionally, if only one of the solo practitioners owns the laboratory in a shared facility arrangement, the nonowning physician can refer to the laboratory as long as he or she is not compensated by the owner in exchange for referrals.

We are not persuaded, however, that a separate exception for shared facilities is warranted. The BBA 1997 language that several commenters proffered would apply to services that are furnished-

- Personally by the referring physician who is a shared facility physician or personally by an individual directly employed or under the general supervision of such a physician;
- By a shared facility in a building in which the referring physician furnishes substantially all of the services of the physician that are unrelated to the furnishing of shared facility services;
- To a patient of a shared facility physician; and
- That are billed by the referring physician or a group practice of which the physician is a member.

Given that we are revising the supervision standards under the in-office ancillary services exception, we believe that the in-office ancillary services exception will cover most, if not all, of the nonabusive shared facility arrangements that would have been protected by this commenter's proposed additional exception.

Comment: A commenter questioned the application of the proposed regulations if physicians who share a building, but for legal or personal reasons are not formally organized into a professional structure (that is, a "single legal entity"), form a joint venture to establish a clinical laboratory or other ancillary service provider.

Response: As explained above, solo practitioners may own and operate shared DHS facilities so long as they fit in the in-office ancillary services exception. If the practitioners form a separate joint venture to provide the services, they may run into problems complying with the billing requirements of the in-office ancillary services exception, if the joint venture does the billing (that is, the joint venture will not qualify as a wholly owned entity and, therefore, will not fit into any of the in-office ancillary billing requirements under section 1877(b)(2)(B) of the Act or 411.355(b)).

Nothing has changed to justify prohibiting these shared arrangements, especially given the justifiable and substantial reliance by medical groups. More importantly, the elimination of these arrangements would adversely affect patient care and increase patient inconvenience.

We are also concerned with the proposed anti-markup provision with respect to professional services. Our groups provide overhead, administrative, billing, and other services with respect the radiology services and each group has a bona fide employment relationship with the radiologist. These arrangements were negotiated at arms length and are common in group practices that frequently employ specialists on a part time basis. CMS should not be taking sides in what is a medical specialty turf war.

Please ensure that any CMS regulations allow for legitimate sharing of ancillary services as described above.

Thank you for your consideration.

Submitter : Mr. Gadi Weinreich **Date:** 08/31/2007

Organization : Sonnenschein Nath & Rosenthal LLP

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15267-Attach-1.RTF

15267

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : **Mr. Eric Lehnert** **Date: 08/31/2007**

Organization : **Stony Brook University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Eric Lehnert. I am an Assistant Athletic Trainer at Stony Brook University, on Long Island New York. I have received my BS in Biology from Stony Brook University and my MS in Athletic Training and Sports Sciences from Long Island University-Brooklyn. I am also a certified EMT-Critical Care, an ALS provider.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Eric Lehnert, MS, ATC, EMT-CC
Assistant Athletic Trainer
Stony Brook University
Insurance Coordinator

Submitter : **Mr. Gary Peters** **Date: 08/31/2007**

Organization : **Northeast Louisiana Ambulance**

Category : **Individual**

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

P O Box 27
233 Taylor Street Phone: 318-435-8351
Winnsboro, LA 71295 Fax: 318-435-0406

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Re: CMS-1385-P: Geographical Price Cost Indices

Dear Mr. Kuhn:

This letter serves as our comments on the Geographical Price Cost Indices section of the Proposed Rule (CMS-1385-P). Our organization strongly opposes any reductions in Medicare reimbursement for ambulance service providers which would have an adverse impact on patient access to vital emergency and non-emergency ambulance care. The Proposed Rule would unfortunately cause that exact effect in areas where providers would receive lower reimbursement as a result of the updated Geographical Price Cost Index (GPC) figures.

While we recognize the statutory requirement for CMS to update the GPCI, any reductions in reimbursement would be in direct contradiction to the findings of the May 2007 Government Accountability Office (GAO) report entitled Ambulance Providers: Costs and Expected Medicare Margins Vary Greatly (GAO-07-383) which determined that Medicare reimburses ambulance service providers on average 6% below their costs of providing services and 17% for providers in super rural areas. For those ambulance service providers who would receive lower reimbursement as a result of the changes to the GPCI, the Proposed Rule will further exacerbate the problems already caused by below-cost Medicare reimbursement.

The GAO recommended that CMS monitor the utilization of ambulance transports to ensure that negative Medicare reimbursement does not impact beneficiary access to ambulance services particularly in super rural areas. We believe that the Proposed Rule would have a considerable impact on beneficiary access in all areas adversely affected by the changes in the GPCI. We implore CMS to take this into consideration as it finalizes the Proposed Rule and alleviate any harmful impact these changes in the GPCI will have on providers while ensuring that those providers who would benefit from the changes receive the proposed increases which are desperately needed.

Thank you for your consideration of these comments.

Sincerely,

Gary Peters, NREMT-P
Northeast Louisiana Ambulance
Vice-President

Submitter : **Ms. Sara Nickoles** **Date: 08/31/2007**

Organization : **George Mason University**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer at George Mason University in Fairfax, Virginia. I am currently the ATC for the Men s Soccer Team and am currently enrolled in the Graduate Program at GMU. I have obtained my certification as well as an undergraduate degree in Athletic Training from the Athletic Training Education Program at Salisbury University. Both George Mason as well as Salisbury have CAAHEP accredited programs.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Sara Nickoles, VATL, ATC

Submitter : **Miss. Helen Malone** **Date: 08/31/2007**

Organization : **Mansfield High School**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am the head athletic trainer for a division 1 high school. At the high school level I care for 23 athletic teams and over 650 athletes. I received a 4 year degree from Bridgewater State College and continued on to receive a Master of Edcuation. It is my position the a change is due, but the change you are proposing does not do justice to the needs of my or any community. The follwoing reasons should be taken with the seriousness deemed necessary for the best care that can be provided to the public.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Helen Malone M.Ed, ATC, CSCS
Mansfield High School
250 East Street
Mansfield, MA 02760
508-261-7540 ext1460
helen.malone@mansfieldschools.com

Submitter : Dr. JAMES SCULLY, JR. **Date:** 08/31/2007

Organization : AMERICAN PSYCHIATRIC ASSN.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

PLEASE SEE ATTACHMENTS IN THIS MS WORD FILE & ASSOCIATE THEM WITH THE BODY OF COMMENTS SUBMITTED VIA THIS SITE A FEW MINUTES AGO. DUE TO ITS SIZE, I HAD TO BREAK THE FILE INTO TWO PARTS IN ORDER TO TRANSMIT. THANK YOU. A.F.

Submitter : Dr. Jeffrey Stone **Date:** 08/31/2007

Organization : Dr. Jeffrey Stone

Category : Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To whom it may concern:
With regard to potentially excluding Therapy Services from the In Office ancillary exemption, I would respond that physician oversight is absolutely necessary as therapists often do not understand nor do they have the background to comprehend many of the complex issues involving the care of our patients. Furthermore corporate oversight of therapy services can potentially further cloud and complicate the direct lines of communication between physician and therapist. Moreover the lack of intimate awareness of patient and physician positions inherent to corporate oversight would likely increase overall costs and negatively effect individual care and outcomes. The close contact allowed by physician owned PT allows for efficient communication and oversight, leading to better overall patient outcomes, better patient satisfaction, and more efficient health care delivery.

Submitter : **Lori Patterson** **Date: 08/31/2007**

Organization : **Lori Patterson**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
__Lori Patterson CRNA_____
Name & Credential
____315 Bloomfield Dr ___
address
___Keller, TX 76248_____
City, State ZIP

Submitter : **Dr. Scott Pace** **Date: 08/31/2007**

Organization : **Arkansas Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

See Attached Comments

CMS-1385-P-15275-Attach-1.PDF

1527S

Arkansas Pharmacists Association

417 South Victory • Little Rock, Arkansas 72201 • (501) 372-5250 • Fax (501) 372-0546

August 31, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed Elimination of Exemption for Computer-Generated Facsimiles

Dear Ms. Norwalk,

Thank you for the opportunity to comment on the proposed elimination of the exemption for computer-generated facsimiles. While the Arkansas Pharmacists Association supports the ultimate adoption of e-prescribing, we think it could be harmful to providers and patients alike to eliminate this exemption on computer-generate facsimiles at this time.

It is important to consider the original intent of the exemption, which was to continue to foster the use of electronic programs to write and transmit prescriptions from prescriber to pharmacist. While the current intent is to force the utilization of the NCPDP SCRIPT standard for the transmission of e-prescriptions, the effect of the removal of the exemption is likely to have the opposite result, as was originally contemplated when the exemption was issued, by decreasing the use of existing technology and reverting back to hand-written prescriptions. In addition, removal of the exemption could create an undue economic burden for many providers.

Pharmacy has always been on the front-edge of technology in the healthcare community, and we continue to support such a movement towards the use of the e-prescribing standard. However, we ask CMS to consider the following issues when contemplating removing this exemption:

- Removing the exemption would increase the number of handwritten prescriptions and increase the opportunity for medication errors;
- While significant investment has been made in this technology, there are many pharmacies and prescribers, particularly in rural areas that will be subjected to a significant financial investment to comply;
- There is a per prescription, transaction fee that the pharmacies will have to pay, which does not exist in any significant manner with receiving a faxed prescription;
- The Drug Enforcement Administration (DEA) does not currently recognize an electronic signature for any controlled substance; and

- Additional unintended consequences, such an overall reduction in the use of some technology may occur.

We respectfully submit to CMS several recommendations as to how to handle the removal of this exemption:

- Create a reasonable, incremental timeline in the implementation;
- Mandate to state Medicaid programs and Medicare Part D providers that they provide a reasonable incentive to pharmacies and prescribers for utilizing the NCPDP SCRIPT standard when transmitting and receiving prescriptions;
- Consider maintaining the exemption for certain patient groups, such as Long Term Care patients or for providers where compliance would create an undue economic hardship.

In summary, while we support the concept and intent of e-prescribing, we would be remiss if we did not voice our significant concern that a swift removal of the computer-generated facsimile exemption could create significant detriment to both patients and providers, and as such we respectfully ask that the exemption remain as is, with the establishment of a reasonable timeline for providers to comply with the e-prescribing standard.

Respectfully,

Scott Pace

Scott Pace, Pharm.D.
Associate Executive Vice President

Submitter : **Ginger Fenter** **Date: 08/31/2007**

Organization : **Ginger Fenter**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I would like comment on the issue surrounding physician self-referral and the in-office ancillary services exception. I believe this is the July 12 proposed 2008 physician fee schedule rule. My purpose is to draw your attention to an abusive situation continuously occurring within our region because of physician-owned physical therapy services and the current exception.

I am a physical therapist in private practice in Arkansas providing care since 1989. My partners and I have successfully provided physical therapy services in hospitals as well as home health services in four different rural areas. We have a reputation for providing exceptional patient care as evidenced by the retention of contracts for over 15 years and the success of an additional free-standing out-patient clinic. The drive from any of our hospital serviced areas to the nearest large city is approximately an hour.

I submit this information because I feel a blatant abuse of the in-office ancillary services exception occurs in this city. Two large multi-specialty and family practice physician owned groups exist in this city. Both of these groups have physical therapy clinics in the same building. The common practice of the larger group is to strongly recommend that patients drive three times week to their office for physical therapy. The other group more frequently refers their rural patients back to their home town clinic.

Consider: A patient is seen by a physician in the larger group. They are immediately sent to the physical therapy department for a physical therapy evaluation and treatment at which time they are strongly encouraged to continue treatment at the physician-owned facility. We are told by the patient that they are not offered any other option.

Occasionally, we will be contacted requesting services but the patient has not been seen by a physician. We explain the Medicare requirement of physician referral and the patient chooses to see one of these physicians. When we follow up on the patient, we are told that they would rather come to us but have to go to the larger city to see their doctor s physical therapist.

I must disclose that if the patient adamantly refuses to return after their evaluation and treatment, they are then given our facility information with instructions to contact us for an appointment. The patient is usually told at that time that we provide a good service. Once we finally receive the referral, we have a good working relationship with the physicians of both groups. Please note, an unnecessary duplication of the evaluation charge must occur when the patient changes physical therapy providers after one visit.

A problem exists when a patient simply wants to do what they feel their doctor wants them to do. That should be a positive. But, when the financial interests of a group dictate that a patient, especially an elderly patient, drive more than an hour one way, three times a week, it obviously is not a positive. Most of these patients either do not know they have an option or are too afraid to say they would rather see a local therapist. Many of the ones that finally reach our clinic out of exasperation are tearful and apprehensive because they fear repercussion from not attending their doctor s therapy service. They explain to us that they simply cannot afford the drive, have no one to take them that far consistently or are hurting worse from the drive than if they didn t attend at all.

I have attempted to state the facts and remove any emotional component from this submission. However, after hearing this from patient after patient and realizing that the vast majority of Medicare recipients in our area find themselves in this difficult position, not being incensed at this occurrence would indicate apathy.

Submitter : **Dr. Pam and Bob Ardis** **Date: 08/31/2007**

Organization : **Dr. Pam and Bob Ardis**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation, a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Pam and Bob Ardis

Submitter : Mr. George Miller **Date:** 08/31/2007

Organization : National Rural Health Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1385-P-15278-Attach-1.DOC

Administrative Office
521 E 63rd Street
Kansas City, Missouri 64110-3329
Telephone: [816] 756.3140
FAX: [816] 756.3144

NATIONAL RURAL HEALTH ASSOCIATION

15278

Government Affairs Office
1600 Prince Street, Suite 100
Alexandria, Virginia 22314-2836
Telephone: [703] 519.7910
FAX: [703] 519.3865

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Delivered Via On-Line Form: *http://www.cms.hhs.gov/eRulemaking*

Subject: CMS-1385-P – Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Polices for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

Dear Deputy Administrator Kuhn:

The National Rural Health Association (NRHA) appreciates the opportunity to comment on the impact of the Centers for Medicare and Medicaid Services' above referenced proposed rule on the nation's physicians and the Medicare program. We look forward to working with you on our mutual goals of improving access and quality of health care for all rural Americans, while making sure that the proposed rule does not have a negative impact on the unique circumstances of rural physicians and other health care providers.

The NRHA is a national nonprofit membership organization with more than 15,000 members that provides leadership on rural health issues. The Association's mission is to improve the health of rural Americans and to provide leadership on rural health issues through advocacy, communications, education and research. The NRHA membership consists of a diverse collection of individuals and organizations, all of whom share the common bond of an interest in rural health.

Please find some general comments below on the topic of the Medicare Physician Payment Rate for 2008, followed by specific comments organized by topic in the order each appeared in the proposed rule.

General Comments on the Medicare Physician Payment Rate for 2008

In 2008, physicians and other health care practitioners whose payment rates are tied to the physician fee schedule face a 10 percent payment rate cut. The NRHA urges CMS to work with Congress to avert this cut without harming any other rural providers such as rural hospitals and ensure that physician payment updates for 2008 and subsequent years accurately reflect increases in medical practice costs.

Payment rates for physician services in 2007 are essentially the same as they were six years ago in 2001. Due to the Sustainable Growth Rate (SGR) formula, physicians now face drastic Medicare payment cuts totaling about 40 percent over the next nine years. Yet, during this same time period, the Medicare Economic Index (MEI), which CMS relies on to measure increases in medical practice costs, is expected to increase by 20 percent. Physicians cannot absorb these imbalances. In a 2007 American Medical Association survey, 60 percent of physicians predicted that they would be forced to limit the number of new Medicare patients they can accept if the 10 percent cut goes into effect January 1, 2008.

A stable payment environment for physician services, especially in rural areas, is critical. Many of our rural communities have already been designated as Health Professional Shortage Areas (HPSAs) or Medically Underserved Areas (MUAs). These areas will also see further decline in payments due to this proposed rule and the expiration of rural add-on payments and a Work Geographic Practice Cost Index floor as detailed below. Rural physicians, critical to safety net care in many rural communities, are in jeopardy and time is running out. CMS must work with Congress to avert Medicare fee-for-service physician pay cuts by enacting positive physician payment updates that reflect increases in medical practice costs, as indicated by the MEI. There are a number of options for CMS to consider in lessening the blow. Some of these options are detailed below; please take this opportunity to address these concerns and work with Congress to avoid such negative cuts without harming any other rural provider.

Summary: A ten percent cut in physician payments will be detrimental to the ability of Medicare beneficiaries to access quality care in rural settings. CMS and Congress must work together to avert this cut and ensure that physician payment updates for 2008 and subsequent years maintain the rural safety net.

Geographic Practice Cost Indices (GPCIs)

As CMS noted in the proposed rule, the 1.000 floor for the work component of the GPCI as required under the Tax Relief and Health Care Act of 2006, Division B, Medicare Improvements and Extension Act of 2006 (hereafter referred to as MIEA-TRHCA as written in the proposed rule) expires as of January 1, 2008. However, the rationale for such a floor has not changed. We urge CMS to use its regulatory authority to continue the 1.000 floor for the work component of the GPCI.

Rural areas tend to receive a lower payment rate under this component of the GPCI. Yet, physicians are able to chose to practice in any part of the country they so desire. The recruitment of physicians is at least a state-wide market and more accurately a national market, and should be paid as such. Rural communities are asked to compete nationally to recruit a health workforce,

but are paid through Medicare as if it is a local market. This leads to a situation where many rural communities are considered HPSAs or MUAs.

Further, many rural communities that have a low rate for their work component of the GPCI are near urban areas with much higher rates. Even if a physician desires to live in a rural community, they may be able to practice in an urban area and therefore be paid a much higher rate, leaving that rural community with no primary care services. Taken together, the work component of the GPCI has a negative impact on the ability of our vulnerable rural communities to access care in this country.

Summary: CMS should use its regulatory authority to continue the 1.000 floor for the work component of the GPCI.

Medicare Telehealth Services

We are pleased that CMS is proposing to add the neurobehavioral status exam to the list of Medicare-covered telehealth services. As stated in the review of the impact of this proposed rule, past telehealth services have not led to significantly higher costs to the Medicare system. However, these services can, and in the future will, have an impact on the ability of rural beneficiaries to access care not offered locally. This can have a very beneficial impact on rural beneficiaries that would otherwise have to travel long distances for care.

CMS declined at this time to add neuropsychological testing and subsequent hospital care to Medicare-covered telehealth Services, and asked for further information on both of these for further consideration. The NRHA hopes that such information is provided and that CMS will reconsider adding these to the list of approved Medicare telehealth services. Such expansions will provide better access to care for our rural seniors.

Summary: The NRHA is pleased that CMS is proposing to expand the list of Medicare-covered telehealth services and hopes that further expansions will happen where appropriate to provide higher level of quality care to rural seniors.

ASP Issues

Medicare Part B covers a limited number of prescription drugs and biologicals (hereafter both referred to as drugs) that are physician administered. In 2005, Medicare began paying for Part B drugs using the average sale price (ASP). According to CMS, the vast majority of Medicare Part B drugs that are not paid on a cost or prospective payment basis are paid under ASP. The ASP is currently calculated based on data reported quarterly to the agency by manufacturers. The payment rate is 106 percent of ASP. CMS has proposed changes related to the determination of the payment amounts for covered Part B drugs as well as the manner in which manufacturers calculate and report ASP data to the agency.

The NRHA's overriding concern is that the ASP payments for covered Part B drugs are not sufficient to cover the actual cost of covered drugs to physicians, especially for small, rural providers. MedPAC reports that in the first quarter of 2005 the new payment system produced

dramatic decreases for many products, and in 2006 payment rates were beginning to stabilize. However, according to MedPAC, "most physicians" reported that they cannot purchase some drugs at the ASP payment rate. If this situation is not remedied, access will continue to diminish.

The NRHA believes that since the ASP is calculated in a manner that includes discounts, including those for bulk purchases, which most small, rural physician practices are unable to receive, these providers are finding it increasingly difficult to continue providing physician-administered drugs. This is particularly true where these and other discounts are not passed along to the physician, but may be provided by the manufacturer to a wholesaler or some other "middle man." MedPAC noted that "larger practices were better able to negotiate lower drug prices" and "achieve economies of scale in their practices" relative to small practices. This means that smaller practices, including most rural practices, over time will be pushed out of the market.

We urge CMS to exercise its discretion to ensure that the ASP does not systematically short change small, rural physician practices. CMS has proposed a method to allocate bundled discounts in order to more closely approximate actual prices. However, this is not sufficient to address the serious consequences of the existing ASP policy.

Summary: While CMS has made a step in the right direction by proposing a method to allocate bundled discounts, small, rural physician practices are still at a disadvantage under the ASP as they are unable to purchase drugs at the same rate as larger facilities. Such disparities should be eliminated.

ESRD Provisions

In the proposed rule, CMS proposes a way to compute the wage index values for areas with no hospital data. Two of the areas where this proposed rule applies are in rural Massachusetts and in rural Puerto Rico. CMS proposes to compute the wage index values in a way similar to the CY 2007 Home Health PPS and the CY 2008 Hospice PPS. We were supportive of such an approach in the latter of the two rules.

However, we ask that CMS not simply take this formula and use it across the nation without further review if needed in further situations. CMS has shown good sense in looking at the cases of rural Massachusetts, rural Puerto Rico and urban Georgia differently. Similarly, the formula that seems to make a lot of sense in Massachusetts, looking at adjacent counties, may not work in others. The NRHA is not sure whether similar tweaks may be necessary if other situations present themselves. It is our belief, however, that they should be evaluated if needed.

Summary: The flexibility of computing the wage index for ESRD differently in three separate situations should be continued if CMS needs to calculate wage index values for areas without hospitals in the future.

Physician Scarcity Areas

As CMS noted in the proposed rule, Section 413(a) of the Medicare Modernization Act of 2003 (hereafter referred to as the MMA), which provided a five percent incentive payment to physicians furnishing services in Physician Scarcity Areas (PSAs) expires as of January 1, 2008. However, the rationale for such a payment has not expired. We urge CMS to use its regulatory authority to continue the five percent incentive payment to physicians furnishing services in PSAs.

As stated previously, for a variety of reasons, rural physicians tend to be paid lower rates than urban providers. Due to this, rural communities have a more difficult time recruiting physicians in the national market for health care providers. While one-fifth of the U.S. population and over a quarter of Medicare beneficiaries lives in rural America, only ten percent of physicians practice in these communities. This disparity leads to difficulty in accessing care for rural seniors. This is not something that should be accepted.

In addition, rural physicians practicing in PSAs will also face the across the board ten percent cut in physician payments. Taken together, the rural health physicians furnishing services in PSAs will face a large reduction in payments next year, making it more likely that they will chose to practice elsewhere or reducing the likelihood that a rural community could recruit a physician to address this scarcity. This will only continue the imbalance in practice areas in the country.

Summary: CMS should use its regulatory authority to continue the five percent incentive payment to physicians furnishing services in PSAs.

Beneficiary Signature

The NRHA commends CMS for recognizing that providers and suppliers of emergency ambulance transportation face significant hardships in seeking to comply with the beneficiary signature requirements of 42 C.F.R. §424.36. Ambulance services are atypical among Medicare covered services to the extent that, for a large percentage of encounters, the beneficiary is not in a condition to sign a claims authorization during the entire time the supplier is treating and/or transporting the beneficiary. The very reason they need ambulance transportation often contraindicates the appropriateness of attempting to obtain a signature from the beneficiary.

However, the relief being proposed by CMS would have the unintended effect of increasing the administrative and compliance burden on ambulance services and on the hospitals. Accordingly, we urge CMS to abandon this approach, and to instead eliminate the beneficiary signature requirement for ambulance services entirely.

While the intent of the proposed exception is to give ambulance providers explicit relief from the beneficiary signature requirements where certain conditions are met, we note that the proposed exception does not grant ambulance providers any greater flexibility than is currently offered by existing regulations. When the beneficiary is physically or mentally incapable of signing, the industry has been following the requirements listed in the CMS Internet Only Manual, Pub. 100-02, Chapter 10, Section 20.1.2 and Pub. 100-04, Chapter 1, Section 50.1.6(A)(3)(c). These

sections require the ambulance provider or supplier to document that the beneficiary was unable to sign, the reason for the inability, and that no one could sign for the beneficiary.

The proposed rule would add a requirement that an employee of the facility, i.e. hospital, sign a form at the time of transport, documenting the name of the patient and the time and date the patient was received by the facility. The NRHA does not believe this new requirement is appropriate as this would place new administrative burdens on both the ambulance providers and the hospital, without providing any new information for CMS to review the claim. In addition, by requiring the receiving facility, usually a hospital, to sign for the patient at the time of transport, CMS is requiring both the ambulance service and the hospital to concentrate on paperwork more than the care of the patient. This is especially egregious in the case of ambulance services, where most of the care provided will be of medical emergencies, especially when a person is unable to sign their own form.

Summary: The NRHA is pleased that CMS has recognized the difficulties in requiring beneficiary signatures for transport services but believes that the proposed remedy should be withdrawn as it adds more burden without providing better quality of care.

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Section 101 of the MMA mandates the use of uniform e-prescribing standards for prescribers who voluntarily elect to electronically transmit prescriptions for drugs covered by the Medicare prescription drug benefit (Part D). Use of these standards became effective January 1, 2006. However, the November 2005 final rule also created an exception to this requirement that allowed electronic prescribers to continue using computer-generated facsimiles in lieu of e-prescribing consistent with the SCRIPT standard. CMS has proposed removing the "facsimile" exemption.

The NRHA supports the use of electronic prescribing as it reduces prescription errors. We believe, however, that removing this exemption will inhibit physician adoption of e-prescribing, especially among small, rural physician practices. Specifically, it will cause many prescribers who currently elect to use electronic technology to forgo utilizing it to avoid costly upgrades in existing products/programs. Prescribers will instead use paper. This will slow down the adoption of health information technology in general and e-prescribing in particular. In addition, mandating that all e-prescribers use this standard is premature given that all the e-prescribing standards have not been adopted.

In the proposed rule CMS cites SureScripts data and states that "of the 150,000 prescribers now using software that is capable of generating SCRIPT transactions, only 15 percent are doing so." While the number of physicians utilizing e-prescribing is certainly increasing, there are over one million physician prescribers in the United States. Therefore, the vast majority of prescribers are not using e-prescribing at all; or, alternatively, are using e-prescribing via fax functionality without software that supports the SCRIPT standards. This underscores that there are large numbers of prescribers who would be adversely affected by the elimination of the facsimile exemption, and who would be required to undertake costly upgrades or revert to paper transactions to avoid this requirement.

In a recent article published in the April 2007 edition of *Health Affairs,* researchers at the Center for Studying Health System Change reported the results of a study that analyzed physicians' experiences with commercial electronic prescribing systems. Numerous barriers to adoption of electronic prescribing were reported. Furthermore, the smallest practices surveyed were 5 practitioners or more and were "likely among the earliest adopters of e-prescribing in their local markets...." In stark contrast, approximately 50 percent of physician practices have fewer than 5 physicians yet account for 80 percent of outpatient visits. (The foregoing numbers do not include solo practitioners.) This highlights the concern that the smallest rural practices will be unable to comply with this proposed rule.

The NRHA continues to believe that CMS's original conclusion that prescribers and dispensers who already make use of electronic prescribing would in all likelihood revert back to paper prescriptions without the ability to fax is still correct. CMS acknowledges in the proposed rule that the majority of costs will be shouldered by physicians who do not currently possess the ability to send using the SCRIPT standards. Unfortunately these facilities are also the most likely to be having trouble with health information technology in general. It will be a further case of small, rural providers paying for a system that only has financial benefit for the payers. In addition, patients should be able to choose where to receive their prescriptions. If the ability to fax is removed for e-prescribers this will put physicians in the untenable position of determining which pharmacy the patient can use to fill the prescription. This is neither desired nor good policy.

While CMS views the rate of e-prescriber adoption to be moving at a slower rate than anticipated, the creation of incentives by the commercial payers and others in the private sector have aided physician adoption of e-prescribing. This has created a positive momentum that could be jeopardized should CMS remove the fax exemption. Should CMS move ahead with removing the fax exemption to the use of the SCRIPT standard for e-prescribing, it could very well have the unintended consequence of significantly hampering the nascent adoption of health IT.

Summary: The NRHA urges CMS to withdraw the proposal to eliminate the exemption for computer-generated facsimile transmissions.

TRHCA-Section 104 Physician Pathology Services

As CMS noted in the proposed rule, Section 104 of the MIE-TRHCA provided an additional year extension to allow carriers to continue to pay independent laboratories under the PFS for the technical component (TC) portion of physician pathology services furnished to patients of a covered hospital. This extension expires as of December 31, 2007. However, the rationale for such a payment has not expired. We urge CMS to use its regulatory authority to continue to pay both the TC and professional component (PC) under one global bill.

The NRHA believes that the TC grandfather should be made permanent. Under this provision, hospitals are "grandfathered" and direct payment made to the laboratory if the hospital had been utilizing the services of an independent laboratory as of July 22, 1999. We believe this change is

necessary to ensure that hospitals can continue to rely on independent laboratories for critical pathology services without incurring increased costs and administrative burdens. Without a "grandfather," administrative burdens would be costly, especially for rural hospitals, including critical access hospitals. Under direct billing, laboratories submit a single bill to Medicare for both the TCs and the PCs. Without direct billing, laboratories will have to issue two bills — one to Medicare for the PC and another to the hospitals for the TCs, doubling billing costs. New billing systems and administrative overhead requirements will have to be created that are costly and unnecessary.

CMS has voiced concern that the TC costs are already included in the DRG. However, in 1983, when DRGs were developed, hospitals were instructed not to include TC costs in their base cost report if they were utilizing independent laboratories. In 1992 when the Medicare physician fee schedule was begun, the agency reiterated that independent laboratories should bill Medicare directly for both the PC and TC of physician pathology services furnished to hospital inpatients and outpatients.

For outpatients, if Medicare continued to allow independent laboratories to bill Medicare directly for hospital outpatient pathology TC payments, hospitals would not simply bill the program for these services and would receive no payment since under outpatient PPS, the hospital bills Medicare a procedure code for each of the services the outpatient receives — e.g. office visit, radiology, surgery, pathology etc. Medicare converts each code to an Ambulatory Procedure Code (APC) that has a determined rate and pays the hospital multiple APCs for each outpatient. In other words, if the laboratory billed for the TC service, the hospital would not. Hence, there is no issue of this resulting in CMS "paying twice."

In addition, we believe that language in the proposed rule to terminate this current "grandfather" is misleading and, if finalized, it is in need of clarification. Specifically, the proposed rule states the following: "For services furnished after December 31, 2007, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient." We believe that if this provision is implemented, it should read: "For services furnished after December 31, 2007, an independent laboratory may not bill the carrier for the technical component of physician pathology services furnished to a hospital inpatient or outpatient." This modification would clarify CMS' intent should the agency finalize this proposal.

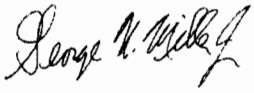
Summary: CMS should use its regulatory authority to continue to allow "grandfathered" relationships to pay for the TC and PC of pathology services under a global bill.

Ambulance Services

The NRHA has no objection to CMS' proposal to eliminate the requirement that annual updates to the Ambulance Inflation Factor be published in the Federal Register, and to thereafter provide for the release of the Ambulance Inflation Factor via CMS instruction and the CMS website. We applaud the efforts of CMS to make this process faster and more transparent.

Thank you for your consideration of these comments. We look forward to continuing our work together to mutual goals of improving access and quality of health care for all rural Americans. If you would like additional information, please contact Maggie Elehwany, Vice President of Government Affairs and Policy at 703-519-7910.

Sincerely,



George Miller
President

Submitter : Crystal Kennon **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15279-Attach-1.DOC

ADVANCED PAIN MANAGEMENT

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August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Crystal Kennon
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : C Specos **Date:** 08/31/2007

Organization : The Lawrenceville School

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a High School Certified Strength and Conditioning Specialist/ Coach and also a Certified Athletic Trainer. I work in central NJ and practice as a strength and conditioning professional at a prep boarding school called the Lawrenceville School, just outside of Princeton Univeristy. I received my bachelors in Athletic Training from West Chester University of PA and my Masters in Exercise Science and Health Promotion from California University of Pennysylvania. Although I am not currently working full time as an Athletic Trainer, I am still certified and writing because I am concerned about my profession.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinieal experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Christina Specos, MS, ATC, CSCS, PES

Submitter : Mr. Stephen Northrup **Date:** 08/31/2007

Organization : WellPoint, Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15281-Attach-1.DOC

WELLPOINT

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stephen.northrup@wellpoint.com

Stephen J. Northrup
Vice President
Federal Affairs

August 31, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1385-P (Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.)

Dear Mr. Kuhn:

On behalf of WellPoint, Inc., thank you for the opportunity to comment on proposed rule CMS-1385-P (Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions) published in the *Federal Register* on July 12, 2007.

WellPoint's mission is to improve the lives of the people it serves and the health of its communities. WellPoint, Inc. is the largest health benefits company in terms of commercial membership in the United States with medical enrollment of 34.9 million members. Through its nationwide networks, the company delivers a number of leading health benefit solutions through a broad portfolio of integrated health care plans and related services, along with a wide range of specialty products such as life and disability insurance benefits, pharmacy benefit management, dental, vision, behavioral health benefit services, as well as long term care insurance and flexible spending accounts.

PHYSICIAN SELF-REFERRAL PROVISIONS

Services Furnished "Under Arrangements"

WellPoint strongly supports the proposed modification to the Stark Law regulations to address and correct abuses of the increasingly prevalent "under arrangements," whereby a hospital contracts with a

third party to provide medical services to patients. Historically, these services were furnished "under arrangements" as a means to access necessary services without having multiple parties acquire and operate the same specialized services and technology. However, as CMS correctly notes, the increasing frequency of "under arrangements" contracts, coupled with greater Medicare payment to the contracting hospitals, provides what may be an irresistible financial incentive for medical providers and hospitals to refer patients to the contracted third party.

The CMS proposal would revise the definition of "entity" under the Stark Law regulations, such that a designed health services (DHS) entity would include not only the person or entity performing the DHS, but also the person or entity that submits claims or causes claims to be submitted to CMS for the DHS. This proposal would result in requiring the contracted third party to bill Medicare directly for designated health services rendered.

WellPoint shares CMS' concern about the high risk of overutilization and increased Medicare program costs due to "under arrangements," based upon its experience in its commercial markets. Because hospitals use the same billing system and methodology for both Medicare and private payers, in its commercial markets WellPoint has frequently reimbursed hospitals in situations where services were actually performed by entities under contract with the hospital to provide services, such as ambulatory surgery centers (ASCs). Since WellPoint's contractual reimbursement rate is higher for hospitals than for ASCs, in an "under arrangement" situation WellPoint inadvertently provides excessive reimbursement for the actual cost of care rendered, further inflating the cost of medical care. These additional costs are not insignificant; one hospital in one state was excessively reimbursed $4 million over a two-year period. Moreover, it is difficult to discern these arrangements, which are typically found only after an audit, and it is administratively costly to adjust the erroneous reimbursements, adding to the cost of health insurance premiums.

CMS specifically solicits comments on whether it should implement the MedPAC recommendation, or whether to follow its proposed approach of allowing the arrangements, but requiring an entity to bill CMS directly for DHS rendered. As a method of controlling "under arrangements," MedPAC, in its March 2005 Report to Congress, recommended that the Secretary expand the Stark Law definition of "physician ownership" to include interests in an entity deriving a "substantial proportion" of its revenue from a provider of designated health services. Essentially, the MedPAC approach would prohibit "under arrangements." WellPoint supports the CMS approach and believes that it is sufficient to control abusive "under arrangements." In WellPoint's view, the CMS approach fairly balances the interests of medical providers and the Medicare program.

PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

WellPoint appreciates the opportunity to comment on the Proposed Elimination of Exemption for Computer-Generated Facsimiles. The CMS proposal would do away with the current exemption for computer-generated faxes and would require entities to comply with the SCRIPT e-prescribing standard when transmitting prescriptions electronically for Part D enrollees.

WellPoint strongly supports the adoption and appropriate use of e-prescribing technology to enhance patient safety, quality of care and health care affordability. E-prescribing can eliminate the need for handwritten prescriptions and the serious errors in doses and drug combinations that they sometimes cause. In order to encourage the widespread use of e-prescribing, WellPoint has launched, or is participating in, a number of initiatives to incentivize adoption.

In January of this year, WellPoint, through its Anthem Blue Cross and Blue Shield subsidiary, announced a pilot project to help Ohio physicians purchase e-prescribing hardware and software. WellPoint is also taking part in the National E-Prescribing Safety Initiative (NEPSI), a multi-payer initiative to make e-prescribing software available for free to any physician for 5 years. Through this initiative, WellPoint hopes to make it possible for all physicians, even those in underserved areas or with very small practices, to e-prescribe. Finally, WellPoint is participating in a New Hampshire initiative that calls for all health care clinicians in New Hampshire to have the ability to e-prescribe by October 2008. As part of its involvement in the program, WellPoint has made financial support available for e-prescribing, has leveraged its relationship with telecom companies to offer e-prescribing hardware free to physicians, has lent health informatics expertise for a metrics study, and has leveraged provider network and communication staff.

As CMS notes in the proposed rule, an estimated 127,500 prescribers are not e-prescribing in accordance with the SCRIPT standards despite the fact that they have software capable of such transactions. Greater penetration of SCRIPT-compliant e-prescribing among this group would be a significant advance in the drive toward widespread e-prescribing.

WellPoint supports CMS' efforts to further encourage the adoption and appropriate use of e-prescribing technology. While we believe that computer-generated faxes do likely have a cost and safety advantage over paper faxes, we agree that the provision of a long-term exception for this technology may result in slower adoption of e-prescribing.

WellPoint would like to take this opportunity to make several comments regarding the manner in which CMS proposes to implement this change.

First, while it is potentially feasible for some providers, pharmacies, and health plans to meet an implementation deadline one year after the effective date of the proposed rule, WellPoint suggests linking the effective date to that of the initial standards identified and tested last year for support of electronic prescribing that must be effective no later than April 1, 2009. These standards include Medication History and Fill Status Notification, both of which are segments of the SCRIPT standard used to transmit electronic prescriptions. Requiring a single effective date for both the elimination of the computer-generated fax exemption and the use of initial SCRIPT standards like Medication History and Fill Status Notification would minimize confusion among plans and providers; would allow greater operational efficiency for plans, providers, and technology vendors; and would likely delay the elimination of the computer-generated fax exemption by no more than six months.

Additionally, as CMS notes in the proposed rule, only an estimated 20 percent of independent pharmacies are capable of supporting SCRIPT-compliant transactions. For low-volume independent

pharmacies, it may not be cost-effective to implement SCRIPT-compliant e-prescribing technology. Eliminating the facsimile exemption would therefore likely result in prescribers currently using computer-generated faxes to revert to paper prescriptions instead when dealing with independent pharmacies. This would be a step backward for these prescribers. Although computer-generated faxes certainly do not provide cost and quality benefits on par with SCRIPT-compliant e-prescribing, they nevertheless facilitate the electronic transmission and storage of information. Extending the effective date of the elimination of the exemption to coincide with that of the initial standards would give low-volume pharmacies a longer time period in which to come into compliance.

WellPoint also supports allowing computer-generated facsimiles as a back-up or fail-safe in cases where technological problems or emergency situations prevent SCRIPT-compliant transactions. Many e-prescribing systems currently have this functionality and it allows physicians to continue to electronically submit prescriptions and maintain prescription data. It also prevents physicians and patients from being forced to switch from electronic to paper transactions in these situations.

In summary, WellPoint supports CMS' effort to spur more widespread e-prescribing. We suggest that CMS consider the following recommendations:

- CMS should set a single effective date for both the elimination of the computer-generated fax exemption as well the implementation of the "initial standards" identified to support ePrescribing. This will minimize confusion among plans, providers, and pharmacists; allow greater operational efficiency for plans, providers, and technology vendors; and likely allow additional time for low-volume pharmacies to comply.

- CMS should allow the use of computer-generated facsimiles when technological difficulties or emergency situations prevent the use of SCRIPT-compliant e-prescribing.

We look forward to continuing to work with you and your staff on the finalization and implementation of this rule. If you have any questions, please do not hesitate to contact me at 202-628-7840.

Sincerely,

Stephen J. Northrup
Vice President, Federal Affairs

Submitter : **Marjorie Rodd** **Date: 08/31/2007**

Organization : **Spine**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Submitter:

Organization:

Category:

Issue Areas/Responses

Physician Self-Referral Provisions - Physician Self-Referral Provisions

I urge you to close the Stark Referral for Profit loophole. I acknowledge the concern for the inherent possibility of fraud and abuse and am aware of studies where the utilization of services has been documented. However, my primary concern and the area where I have direct and personal experience are in regard to the QUALITY of services. Healthy and fair competition encourages us to be and do our best; that competition is destroyed when a therapist is employed by a Physician owned practice. The patients are guarantied. An extremely important aspect of this is that the great majority of patients do not realize they have a choice of where to have their therapy when their Physician gives them their prescription; I have been told this repeatedly. I have had numerous patients who wanted to come back to us and even took the time to come by or call and tell us so. One individual was in tears and when advised that she could go anywhere she felt best, she responded that she 'did not want the physician to get mad at her.' I believe this is a far more common occurrence than is realized and the most important reason to remove Physical Therapy from the self-referral loophole. A physical therapist owned clinic has one 'boss', and that is the patient. Patients in this setting know instinctively that if they are unhappy with any aspect of their eare they can easily communicate this to their physician without any discomfort. As the owner of my own clinic I realize I also need to keep my employees and physicians happy, but if my patients are not extremely satisfied, there is no clinic. When a patient says something like 'I have heard so many good things about you', I respond with, 'thank you, but that was yesterday, now I have to prove my self today'. That is the simple truth of a physical therapy owned clinic that does not exist in a Physician owned clinic. If there is a concern over medical care and safety I believe it is an unrealistic one. The patient comes to us with a diagnosis of 'neck pain', 'back pain' or 'shoulder pain' which may indeed be a symptom they present with, but does little to address the diagnosis. A qualified Physical Therapist is able to perform the appropriate evaluation and establish the treatment plan thus saving unnecessary time spent by the physician which would add unnecessarily to medical costs. If the therapist has a concern the Physician is notified and appropriate action taken. I admittedly have a personal interest in this referral conflict. I decided to be a Physical Therapist when I was 10 years old. I opened my own practice 12 years ago and grew from one therapist to six. Over the last 3 years my referrals have dropped by 2/3; at this same time the Physician owned clinics significantly increased- there is only one Orthopedist in Vero Beach that is not involved with a physical therapy clinic. My clinic is very special and we deliver exceptional therapy with respect, integrity and sincere caring. I ask that I be allowed to practice my chosen profession. Most Sincerely, Marjorie R. Rodd P.T., Cert MDT

CMS-1385-P-15282-Attach-1.RTF

Submitter: Marjorie Rodd

Organization: Spine

Category: Physical Therapist

Issue Areas/Responses

Physician Self-Referral Provisions - Physician Self-Referral Provisions

I urge you to close the Stark Referral for Profit loophole. I acknowledge the concern for the inherent possibility of fraud and abuse and am aware of studies where the utilization of services has been documented. However, my primary concern and the area where I have direct and personal experience are in regard to the QUALITY of services. Healthy and fair competition encourages us to be and do our best; that competition is destroyed when a therapist is employed by a Physician owned practice. The patients are guarantied. An extremely important aspect of this is that the great majority of patients do not realize they have a choice of where to have their therapy when their Physician gives them their prescription; I have been told this repeatedly. I have had numerous patients who wanted to come back to us and even took the time to come by or call and tell us so. One individual was in tears and when advised that she could go anywhere she felt best, she responded that she "did not want the physician to get mad at her." I believe this is a far more common occurrence than is realized and the most important reason to remove Physical Therapy from the self-referral loophole. A physical therapist owned clinic has one "boss", and that is the patient. Patients in this setting know instinctively that if they are unhappy with any aspect of their care they can easily communicate this to their physician without any discomfort. As the owner of my own clinic I realize I also need to keep my employees and physicians happy, but if my patients are not extremely satisfied, there is no clinic. When a patient says something like "I have heard so many good things about you", I respond with, "thank you, but that was yesterday, now I have to prove my self today". That is the simple truth of a physical therapy owned clinic that does not exist in a Physician owned clinic. If there is a concern over medical care and safety I believe it is an unrealistic one. The patient comes to us with a diagnosis of "neck pain", "back pain" or "shoulder pain" which may indeed be a symptom they present with, but does little to address the diagnosis. A qualified Physical Therapist is able to perform the appropriate evaluation and establish the treatment plan thus saving unnecessary time spent by the physician which would add unnecessarily to medical costs. If the therapist has a concern the Physician is notified and appropriate action taken. I admittedly have a personal interest in this referral conflict. I decided to be a Physical Therapist when I was 10 years old. I opened my own practice 12 years ago and grew from one therapist to six. Over the last 3 years my referrals have dropped by 2/3; at this same time the Physician owned clinics significantly increased- there is only one Orthopedist in Vero Beach that is not involved with a physical therapy clinic. My clinic is very special and we deliver exceptional therapy with respect, integrity and sincere caring. I ask that I be allowed to practice my chosen profession. Most Sincerely, Marjorie R. Rodd P.T., Cert MDT

Submitter : **Mr. Michael Moll** **Date: 08/31/2007**

Organization : **Wisconsin Athletic Trainers' Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I work as a licensed athletic trainer in the collegiate setting at the University of Wisconsin Madison, providing and coordinating medical care to our student athletes. I also serve as an officer for the Wisconsin Athletic Trainers' Association which serves approximatly 1000 licensed health care professionals in Wisconsin. Although I do not work in a setting were Medicare coverage would affect my practice, it certainly reflects on my competency as a health care provider and who physicians would be able to refer patients to.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, elinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Michael Moll, M.Ed., ATC

Submitter : Dr. Jim Billys **Date:** 08/31/2007

Organization : Jim Billys

Category : Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

In my practice we have in house PT and OT. I find having them on site is very beneficial to my patients as I am able to directly interact with the physical therapist or hand therapist regarding my patients care initially and during their treatment. Often times the therapist will escort the patient to clinic leading to better care. I feel this greatly improves patient outcomes, rather than sending them to someone I do not know. I feel I am better informed of patient progress or lack thereof and can act accordingly for the benefit of the patient. This enhanced communication I find leads to better overall patient outcomes and patient satisfaction, and I would believe this helps to lower overall medical costs.

Submitter : **Miss. Melanie McGee** **Date: 08/31/2007**

Organization : **National Athletic Trainers Association**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Melanie McGee and I am a student athletic trainer at an accredited university in Texas. I am also a licensed athletic trainer, and have worked in this profession as a high school student, college student, professional athletic trainer at the high school level, and an currently enrolled as a graduate student working toward a Masters in Athletic Training.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Melanie McGee, LAT

Submitter : Mrs. Judy Bogard **Date:** 08/31/2007

Organization : Fairbanks Memorial Hospital

Category : Physical Therapist

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam,

Thank you for the opportunity to comment on the proposed changes to the therapy standards and requirements for staffing in hospitals and rehabilitation facilities identified in 1385-P. I am concerned that the thought given to these changes has been short sighted and will create difficulty for the beneficiaries to obtain necessary and appropriate services in the field of rehabilitation. Hospitals and rehabilitation facilities must have the ability to incorporate into the therapy process the services provided by exercise physiologists, massage therapist and certified athletic trainers. Under the direction of a Physical or Occupational therapist these degreed professionals contribute extraordinarily to the provision of rehabilitation services in the therapy setting. Each of these professionals has in their training, specific and detailed education and experience in the provision of rehab treatment techniques. Their contributions to the overall rehabilitation process are valuable and beneficial to the individuals receiving service.

As the director of a rehabilitation department located at an acute care hospital which also services outpatients, I receive requests directly from physicians requesting that a certified athletic trainer or a degreed exercise physiologist participates in the provision of the rehabilitation service because of the specialty training these professionals have. If they are not allowed to work in the rehabilitation clinics then the CMS beneficiaries and other patients will not have the opportunity to receive the benefit of their skill and training. Nationally there are not sufficient numbers of physical and occupational therapsits to meet the needs of the population requiring services. If these professionals who have been working with therapists in the clinic are no longer allowed to provide services then the shortage of rehabilitation personnel will escalate even further having a negative impact on the individuals requiring therapy. So not only will the specific and special services these professionals can contribute to the therapy process be lost, but the ability to obtain service will be hindered as accessibility will be further compromised.

I strongly urge and request that CMS does not make the proposed changes in the rehabilitation staffing requirements. These changes will only be a disservice to the beneficiaries and further hinder the accessibility to rehabilitation therapy services overall.

Respectfully,
Judy Bogard PT, MPA
Director Rehabilitation Services

Submitter : **Dr. Amanda Allen** **Date: 08/31/2007**

Organization : **California University of PA**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

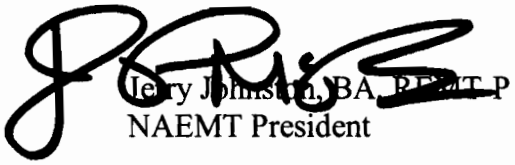
Dear Sir or Madame;

My name is Dr. Amanda Allen, and I am currently a faculty member and athletic trainer at California University of Pennsylvania.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Dr. Amanda M. Allen, ATC

Sincerely,



Jerry Johnston, BA, [redacted]-P
NAEMT President

Submitter : **Mr. James Drake** **Date: 08/31/2007**

Organization : **Charleston Southern University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Brad Drake. I am Certified Athletic Trainer at Charleston Southern University. I hold a Bachelor of Science degree in Biology from Presbyterian College as well as a Masters Degree in Health and Exercise Science from Furman University.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

James Bradley Drake MA,ATC
Associate Athletic Trainer
Charleston Southern University

Submitter : **Mr. Toby Harkins** **Date: 08/31/2007**

Organization : **Charleston Southern University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am the Head Athletic Trainer and Assistant Director of Athletics at Charleston Southern University. I received my Bachelor of Seience degree from Erskine College and my Masters of Health and Exercise Science from Furman University. I have been a Certified Athletic Trainer for almost ten years, and have served here in the state of South Carolina for each of those years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certifieation exam ensure that my patients receive quality health eare. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Toby W. Harkins, ATC
Head Athletic Trainer & Assistant Director of Athletics
Charleston Southern University
Charleston, SC 29423

Submitter : Vishal Lal **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15291-Attach-1.DOC

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

ADVANCED PAIN MANAGEMENT

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Vishal Lal
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Mr. Darrell McKigney **Date:** 08/31/2007

Organization : Long Term Care Pharmacy Alliance

Category : Health Care Professional or Association

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Since the notice was posted regarding the proposed elimination of the exemption for computer generated faxes, the Long Term Care Pharmacy Alliance has received a high volume of inquiries from concerned long term care pharmacies and nursing homes about this proposed rule. As CMS is aware, long term care pharmacies (LTCPs) receive large numbers of prescription drug orders from nursing homes in form of a fax transmission. Because of this, it is not surprising that many nursing homes and LTCPs were greatly concerned when they heard that there would be a new rule impacting fax transmissions. We have communicated those concerns to CMS staff, who have assured us that the proposed new rule will not apply to or impact the fax transmission of orders from nursing homes to LTCPs. While we appreciate that verbal clarification, we believe CMS in finalizing this rule should specifically make that clarification clear in the rule itself in order to prevent any further concern or confusion on the part of nursing homes, assisted living facilities, other institutions and long term care pharmacies.

Submitter : Mr. Shawn Sparks **Date:** 08/31/2007

Organization : Sports Medicine Specialists of Mississippi

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Shawn P. Sparks and I live and work on the Gulf Coast of Mississippi. For 12 years now, I have worked as a Certified Athletic Trainer in various settings including a junior college, a high school, a DME company, and currently a private rehabilitation company that, among other things, contracts rehabilitation services to our local, county-owned hospital system. The hospital system's ability to contract these services reduces the amount of time and money it has to dedicate to hiring and maintaining personnel on its own, and thus allows it to invest more time, money, and effort on improvement and expansion (i.e., offering more services to more people in more places) without compromising the quality of its rehabilitation services.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Shawn P. Sparks, ATC/L
Ocean Springs, Mississippi

Submitter : **Ms. Tuesday Patterson** **Date: 08/31/2007**

Organization : **Charleston Southern University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I an a graduate ahthletic trainer at Charleston Southern University. I went to Erskine College where I recieved a Bachelors degree in Athletic Training. I am attending CSU as a graduate student in Business and also working as a full time Certified Athletic Trainer.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health eare for my patients.

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Sincerely,

Tuesday L. Patterson, ATC

Submitter : **Mr. David Matyas** **Date: 08/31/2007**

Organization : **Epstein Becker**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Comments Submitted by Epstein Becker & Green on behalf of clients

CMS-1385-P-15295-Attach-1.PDF

CMS-1385-P-15295-Attach-2.PDF

1295

EPSTEIN BECKER & GREEN, P.C.

ATTORNEYS AT LAW

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August 31, 2007

VIA ELECTRONIC SUBMISSION
AND HAND DELIVERY

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Rm 309-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code CMS – 1385-P
Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008

Comments Concerning Proposed Physician Self-Referral Provisions

Dear Centers for Medicare and Medicaid Services:

This letter is submitted in response to the Proposed Rule published by the Centers for Medicare and Medicaid Services (referred to herein as "CMS") in the July 12, 2007 Federal Register (referred to herein as the "Proposed Regulations") regarding physicians' referrals to health care entities with which they have financial relationships under the Medicare and Medicaid programs (referred to herein as the "Stark Law").

We are submitting these comments on behalf of several of our clients including not only physicians and physician groups but also other stakeholders, such as hospitals and health systems, physician-owned non-designated health service suppliers and other health care entities furnishing designated health services.

The overarching comment we have is our surprise and dismay that CMS is taking a piecemeal and hurried approach to issuing regulations under the Stark Law, which is a highly complex area

of the law. The Proposed Regulations, which suggest significant and sweeping changes to a number of provisions set forth in the final Stark II Phase II Regulations, are buried within a 273-page issuance largely focused on physician fee schedule issues. This is in contrast to the traditional promulgation of Stark regulations as a separate rulemaking devoted exclusively to the self-referral law which puts all stakeholders on notice of new rules, not just physicians. This is especially important because the entity subject to penalties for Stark Law violations is the DHS entity, not typically the physicians.

In addition, the Proposed Regulations provide the public with less than 60 days to submit comments. This is in contrast to the expectation of a meaningful comment period for Proposed Regulations of this significant nature. We are especially dismayed by the fact that CMS has used the Proposed Regulations to reopen long settled areas of interpretation, like the scope of the in-office ancillary services exception, as well as the definition of what constitutes a DHS, now 3 years after the publication of final Phase II regulations.

CMS issued the final Stark II regulations three years ago with a great deal of fanfare touting that it had resolved all significant areas of overreaching that were reflected in the prior versions of the regulations. In referring repeatedly in these Proposed Regulations to its positions in the 1998 proposed regulation, CMS appears to have completely forgotten the controversial nature of that earlier proposal and the substantial efforts undertaken by the health care community to convince CMS that it would be prudent to scale back its overly expansive interpretation of the Stark law. Yet, just three years after issuance of the Phase II Stark II final regulations which definitively resolved these controversies, and based only on "anecdotal reports" of abuse, this new proposal now contemplates a return to decade-old interpretations that would involve massive restructuring in the health care community. In addition, if the Proposed Regulations, along with the issues in which CMS seeks public comment, were to be finalized, then it could result in wholesale elimination of the delivery of services that have been furnished in group practice settings for many years.

We fail to understand (or be able to explain to our clients that seek to comply with these requirements) why CMS is not addressing all of the issues relating to the Stark Law in a consolidated process of rulemaking, by publishing a single comprehensive set of proposed regulations that are easily identified to all relevant stakeholders, and which allow a time period that is long enough for meaningful comments to be crafted and submitted. This is further evidenced by the fact that CMS is scheduled to issue in next week's Federal Register the Stark II Phase III Final Regulations, which are being issued without a comment period and which will become effective 90 days after publication in the Federal Register.

Various areas addressed in the Proposed Regulations are merely broad "solicitations" for comments based only on anecdotal evidence, *e.g.*, the discussion of various in-office ancillary services exception issues involving pathology, clinical laboratory, occupational and physical therapy services and referrals among specialists; also the discussion of the period of disallowance for noncompliance financial relationships. These areas cannot be considered as true "proposed" regulations that give the public a meaningful opportunity to comment on an articulated CMS proposal. As such, these areas require issuance of a true proposed regulation

with proposed language for the public to react to and comment on. This is particularly important when comments on this proposed rule are due before the final Stark II Phase III regulations have even been officially published in the Federal Register, meaning that the public has not had an opportunity to assess the implications of the final regulation on these proposals. A further complicating factor is that the final Stark II Phase III regulations are alluded to throughout the Proposed Regulations yet not addressed directly.

We are also dismayed by the fact that so many concepts and positions originally proposed by CMS in the 1998 Stark II proposed regulations, which were ultimately modified in Phases I and II in 2001 and 2004, have been reincorporated into this set of Proposed Regulations. Specifically, in the preamble to the Phase I and Phase II regulations, CMS acknowledged that there are good reasons for maintaining flexibility in the Stark regulations. The Stark law is black and white, so that any overly restrictive Stark law interpretations mean that services cannot be furnished to Medicare patients, even if the patients want those services in that setting or from that physician. Moreover, any abuse that arises from any particular physician financial relationship can always be prosecuted as an anti-kickback violation, or a breach of the various Medicare payment and coverage rules. Similarly, abuses perceived in site of service, quality, or reimbursement can be remedied through modifications to those underlying Medicare rules, not the Stark Law. However, in these Proposed Regulations, CMS is proposing to eliminate some of this flexibility based upon perceived abuses.

For these reasons, we urge CMS to abandon the notion of issuing the Final Medicare Physician Fee Schedule with the Stark Law sections included in the Final Rule, but instead postpone publication of these aspects of the Proposed Regulations until such time as it publishes a consolidated proposed rule on the physician self-referral law (*i.e.*, "Phase IV Regulations").

As we have done in the past, we welcome the opportunity to meet with you to discuss these issues in greater detail and/or provide some supplemental information related to the topics addressed below.

Services Furnished Under Arrangements

In an attempt to address what it considers a problem of potential over-utilization of services by physicians who have an ownership interest in an entity that performs tests or procedures pursuant to an "under arrangements" relationship with a hospital, CMS proposes to expand the current definition of "entity" (to which a physician is prohibited from making a referral if he or she has a financial relationship with the entity), from only that entity which bills for the designated health service ("DHS") to now include the entity that actually provides the DHS in an "under arrangements" relationship.

This proposed interpretation of the Stark Law contradicts the position taken by CMS in the Stark II Phase I Final Regulations in 2001, where CMS stated that it "would treat 'under arrangements' financial arrangements between hospitals and physician-owned entities as compensation and not ownership relationships." At that time, comments were made by individuals concerned that the definition of inpatient and outpatient hospital services would impact hospitals that purchase

services "under arrangements" from entities owned in whole or in part by referring physicians. In 2001, CMS stated that it would not interpret the statute to consider "under arrangements" to be "ownership interests" because to do so, given the high volume of these arrangements, would "disrupt patient care" and that "*bona fide* "under arrangement" relationships could easily be structured to comply with the personal services arrangement exception, or, in some cases, the fair market value exception" and that there was precedent in the statute for treating them as compensation. *See* 66 Fed. Reg. at 942.

In proposing this change, CMS treats as one and the same services furnished "under arrangements" that are themselves on the list of DHS with services that are not DHS. An "under arrangements" contract should not convert a service that is not a DHS to a DHS simply because there is a contract with a hospital and the service appears on the hospital bill. The law and Stark regulations already constrain physicians from owning entities that furnish DHS (*e.g.*, lab, therapy, radiology, etc.) absent a relevant exception. Treating the entity that furnishes a service that has not been designated by Congress as a DHS as if it is a DHS entity merely because that the entity has a contractual arrangement with a hospital that bills it as an inpatient or outpatient hospital service is an unwarranted expansion of the Stark Law.

Despite CMS's receipt of "anecdotal reports" of hospital/physician joint ventures that now provide services formerly provided by the hospital itself, there remain many legitimate reasons for a hospital contracting with an entity to provide services on an "under arrangements" basis. Specifically, we have been informed by health care entities that many of these services can often be provided on a more efficient, clinically appropriate basis by an entity that specializes in the provision of a particular type of services. For example, a free-standing ambulatory surgery center ("ASC") focuses only on the provision of outpatient surgeries and procedures. Because the ASC does not have the multiple departments with their conflicting interests and demands, it can often provide surgical services more effectively and efficiently than can a general acute care hospital. This leads to greater patient satisfaction because of less rescheduling and delays of surgery due to emergency/unscheduled surgeries. This is very important since most patients are transported to and from the ASC by family or friends who must take off work to perform this task. Cancellations and delays only lead to more days off of work for these transporters with a resulting negative effect on the economy and employers. In addition, ASCs allow for block scheduling which inpatient facilities are less able to do. This allows surgeons a greater efficiency which assists them in accepting low-paying Medicare patients, thus giving these patients access to a wider and more readily available group of specialists.

Hospitals that enter into "under arrangements" relationships are relieved of the burden of maintaining or expanding a particular service line, while still being able to provide much needed services to the members of its community. This frees up hospital capital to be spent on other much needed services and space and other resources within the hospital to be used for other services. It has been our experience that hospitals have found themselves unable to keep up with the demand for outpatient surgery capacity and have found that investing in ASCs to be a better use of their resources as compared to building and staffing larger outpatient surgery areas within

the hospitals. In addition, the partnered ASCs are not taxable entities providing tax revenues that would not be forthcoming from a nonprofit inpatient hospital.

Another advantage of having outpatient surgeries performed in the ASC setting is that in a hospital surgical patients are exposed to other patients with chronic illnesses or infectious diseases, making the post-operative patient susceptible to nosocomial infections. Microorganisms and pathogens can thrive in a hospital setting and can be transmitted by food and water, transfused blood and intravenous fluids, medications, air, direct human contact, linens and other carriers. ASCs pose less risk of infection because patients spend relatively little time in these facilities and have only minimal exposure to other patients and staff. In fact, the Institute for Healthcare Improvement has estimated the inpatient rate of surgical site infections to be between two and five percent (2-5%) for patients undergoing clean extra-abdominal operations and up to 20% in patients undergoing intra-abdominal procedures. This is compared to a post-surgical infection rate of 0.18% for ASCs (data taken from the Outcomes Monitoring Project Report, 1st quarter 2007).

From CMS's comments, it appears that it believes that entities only provide services "under arrangements" that are "medically less intensive." However, this is not accurate. Many ASCs provide a full range of surgical services, including complicated surgeries and procedures, that are comparable to hospital outpatient surgery units. We believe that CMS should research and compare the types of surgeries and procedures performed in hospital outpatient surgery units and those being performed at ASCs before concluding that ASCs are performing medically less intensive services than hospital outpatient surgery units.

CMS's concerns about the potential for over-utilization are already addressed, at least in part, by the "under arrangements" regulations that require that the provider of the services ensure that the procedures being performed are medically necessary. These requirements are summarized in CMS's General Information Eligibility and Entitlement Manual which states that "the provider (other than a SNF) must ensure that the medical necessity of such services is reviewed on a sample basis by the utilization review (UR) committee if one is in place, the facility's health professional staff, or an outside UR group. (CMS Pub. 100-1 Chapter 5) § 10.3. CMS may be in a better position to end abuses without negatively affecting legitimate providers of services under arrangement by enforcing the "under arrangements" requirements such as this one.

Instead of reversing Congress' and its own prior stance on this matter and trying to "fix" under arrangement violations by casting a wide net through the use of the Stark Law, CMS should instead focus its efforts on revising the "under arrangements" regulations to put a halt to the abusive arrangements. By doing so, CMS is much more likely to stop the abuses while allowing legitimate, non-abusive "under arrangements" relationships to continue.

Stand in the Shoes

In the Proposed Regulations, CMS suggests amending §411.354(c) to provide that, where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS

In addition, medical equipment in general is very expensive and becoming more and more specialized. It may not be possible or desirable for a hospital or other entity to use precious capital on specialized equipment. The same is true for some entities when it comes to finding space for the variety of services it provides. It may be much more cost effective for the hospital or other entity to lease equipment/space from a physician lessor who also has a need for the equipment or space, or to lease equipment or space to a physician who needs are sporadic in nature. This is especially true for equipment purchases. For example, a specialize surgeon may purchase a piece of equipment that she uses several times a month primarily during outpatient surgeries. A hospital to which the physician refers patients may have an occasional need for this equipment for use on inpatients or for use by another surgeon performing the same or similar procedures at the hospital on a sporadic basis. It would make no sense for the hospital to spend scarce resources on a piece of expensive equipment it has a need for only occasionally. It makes much more sense to rent the equipment on a per-use basis from the physician owning the equipment. This is also true for arrangements in which the equipment is leased to the physician for occasional use.

CMS is trying to make it more difficult, if not impossible, for legitimate business arrangements for expensive space and equipment rentals between physicians and hospitals to exist. Prohibiting these types of arrangements will make expensive equipment less available to those health care entities and providers already struggling for their financial lives. It can be argued, of course, that these types of arrangement may still be permissible, but that a hospital would need to pay the physician leasing the equipment to or from the entity a set fee or in some other manner for the use of the equipment on his/her referred patients. Once again, CMS is putting an unnecessary administrative burden on health care providers to categorize use of the equipment based on the referring physician.

Set in Advance and Percentage Based Compensation Arrangements

In the Phase I Final Regulations promulgated in 2001, CMS took the position that percentage based arrangements did not satisfy the "set in advance" standard, which is a requirement of many of the exceptions applicable to compensation arrangements. However, given the prevalence of percentage-based compensation and the outcry by various segments of the industry, CMS subsequently postponed the adoption of this provision in the Phase I Final regulations. Finally, in the Phase II Interim Final Regulations promulgated in 2004, CMS reversed its stated position stating that it was "persuaded that our original position was overly restrictive" 69 Fed. Reg. at 16068. CMS then proceeded to modify the set in advance definition to allow percentage arrangements, provided that the percentage compensation is established with specificity prospectively, is objectively verifiable and is not be changed over the course of the agreement between the parties based on the volume or value of referrals or other business generated by the referring physician.

In the Proposed Regulations, CMS has once again reversed its current position on percentage arrangements by now proposing that percentage based compensation can apply only to pay

physicians for personally performed physician services. This is a surprising reversal given the attention that was previously given to percentage compensation arrangements in the Phase II regulations, as described above. Further, this proposed position makes meaningless the existing statutory exception for "physician services" (42 U.S.C. §1395nn(b)(1) and corresponding regulations (at 42 C.F. R. § 411.355(a)).

Under the Stark Law, it is only necessary to determine whether compensation is "set in advance" for referrals by a physician who has a compensation arrangement with an entity that needs to qualify under a Stark law exception that includes the "set in advance" requirement. However, CMS has defined the term "referral" to exclude any DHS "personally performed or provided by the referring physician." See 42 C.F.R. §411.351. As a consequence, any financial relationship that is related to services that the physician personally performs would not be subject to the Stark Law in the first place, since the provision of those services by the physician would not constitute a "referral" by definition. Thus, by limiting the definition of "set in advance" to allow only percentage compensation arrangements in connection with the services "personally performed" by the physician, CMS will be adopting a superfluous provision. It would never be necessary for a physician who receives compensation related to services that he/she is personally performing to even need to take advantage of an exception that includes a set in advance requirement.

We also believe that CMS's proposal creates an unwarranted restriction on compensation that rewards the achievement of certain milestones not directly related to physician services in a hospital. This proposal would seemingly overturn favorable advisory opinions issued by OIG in this area as well as other initiatives underway by Congress and CMS to reward physicians based on departmental quality and cost savings.

For these reasons, we do not believe that in 2004 CMS intended for the definition of "set in advance" to only permit percentage arrangements for services personally performed by a physician. We request that CMS withdraw its proposal to prohibit percentage based compensation arrangements to such services. We believe that the current standard for set in advance adequately protects CMS's interests because it requires percentage arrangements to be reflected formally in agreements, set the furnishing of the items or services and be stated in sufficient detail so that it can be objectively verified.

Burden of Proof

In the Proposed Regulations, CMS clarifies that in any appeal of a denial of payment for a DHS that was made pursuant to a prohibited referral, the burden is on the entity submitting the claim for payment to establish that the services was not furnished pursuant to a prohibited referral. CMS explains that this burden of proof posture is consistent with its policy governing claims denials. This provision on burden of proof for claims involving Stark covered services should not affect the burden of proof otherwise applicable in connection with other governmental sanction and enforcement provisions, such as civil monetary penalties, exclusions and other possible civil penalties.

In-Office Ancillary Services Exception

Although CMS declines to issue a specific proposal for amending the in-office ancillary services exception in the Proposed Regulations, it asks for comments as to whether changes are necessary and also asks for comments to four specific questions relating to (1) whether services not furnished on an incident to basis should be protected, and whether services not needed at the time of an office visit to assist the physician in diagnosis or plan of treatment should be protected, (2) whether changes to the definitions of "same building" and "centralized building" should be made, (3) whether nonspecialist physicians should be able to use the exception to refer specialized services to refer patients for specialized services involving use of equipment owned by the nonspecialists, and (4) whether other restrictions on the ownership or investment in services would curtail program or patient abuse.

In response, CMS should consider that the Stark Law was not intended to address physician scope of practice. We read CMS's discussion in the Proposed Regulations about pathologists, specialists, and physical therapy and occupational therapy services being furnished under the in-office ancillary services exception to reflect CMS's interjecting itself into "turf battles" between specialists, which is an area outside of the Stark Law. If CMS has a concern based on quality of care that a specialized service needs to be performed by a particular kind of physician, then CMS should address the issue in the coverage guidelines, not in self-referral regulations.

CMS also suggests amending the in-office ancillary services exception to limit the exception to services needed at the time to assist the physician in diagnosis or treatment. We believe that it is beyond CMS's statutory authority to promulgate a temporal restriction on the scope of the in-office ancillary services exception, and that such a provision would pose an unwarranted restriction on the scope of the in-office ancillary services exception. The in-office ancillary services exception was plainly intended to confirm the broad authority of physicians to practice medicine in a group practice setting where services can be performed on a cost-effective and patient-convenient basis. It is unclear why CMS would want Medicare and Medicaid patients to have to endure multiple appointments in disparate locations instead of obtaining one-stop shopping in a physician office setting. It also is unclear what precisely is the "cut-off" of services anticipated by the "needed at the time" restriction. Does this mean that services not essential to that particular physician office visit would no longer qualify for protection? What does this mean for courses of treatment now carried out more conveniently and cost-efficiently in a physician's office, such as chemotherapy? Are patients to be sent back to the more costly treatment venue of the hospital for such services?

With respect to adopting a limitation applying the exception to incident-to services only, it is clear that the statute does not limit the exception to only incident to services. Indeed, the term "incident to" is never mentioned in the statute, and the statute calls for "direct supervision" rather than the more stringent "direct personal supervision" of the incident-to standard. Moreover, this is resurrecting an issue that was put to rest long ago in the previous final Stark regulations. In the 2004 final regulations, CMS confirmed and restated definitively its position from the 2001 final regulation that the Stark law supervision standard is merely "the level necessary to meet the Medicare program payment and coverage rules applicable to the particular designated health

service." Thus, the Stark law supervision standard is "incident to" when Medicare requires it for coverage purposes, but a less stringent standard when Medicare coverage provisions allow general physician supervision for the service. This standard has been clear since 2001, and any modification absent clear and convincing evidence of abuse (not just "anecdotal reports") is plainly unwarranted.

Obstetrical Malpractice Insurance Subsidies

We applaud CMS's moving away from strict safe harbor compliance as the measure of Stark compliance. However, we believe that the exception should not be limited geographically to medically underserved areas or HPSAs. The problem that CMS described in the preamble for obstetrical malpractice insurance subsidies is not limited to HPSAs or MUAs. This issue over access to care can appear in any geographic area where there is unmet need for obstetrical services. We believe that there should be no requirements in the Stark Law exception relating to location of the entity or medical practice.

Period of Disallowance for Noncompliance Financial Relationships and Alternative Criteria for Satisfying Certain Exceptions

We support that CMS is contemplating setting limits on the period of disallowance for Stark law noncompliance as well as allowing "alternative" criteria for satisfying exceptions. This is especially important given the onerous Stark Law penalties involved, even in the event of inadvertent Stark law violations.

Indeed we believe that some circumstances warrant no "period of disallowance" at all. Specifically, if the parties to an arrangement did not realize that they were in violation, they ought to be able to reconcile the arrangement to be in compliance with the exception without any period of disallowance at any time before they are alerted by the government that there is a possible violation. Physicians frequently are not aware of the far reaching implications of the Stark law on their long-standing arrangements until they engage a compliance review which points out certain discrepancies in their longstanding practices. This may occur, for instance, in group practice compensation formulas. In such circumstances, the parties should be able to determine what permissible compensation should have been, alter the methodology on a going forward basis, and make an internal payment reconciliation with the affected physicians to achieve compliance, without violating the Stark law for any period of time whatsoever. Such a provision would encourage health care entities to conduct frequent compliance assessments and remedy any shortfalls in compliance, without being subject to the potentially onerous and far reaching Stark law penalties.

There also should not be any continuing disqualification from using an exception, also in light of the onerous Stark law penalties. In CMS's example, a mere $600 fair market value discrepancy would cause a hospital to be out millions of dollars in revenue from services referred by the physician, in addition to possible fines and penalties. Under such circumstances, CMS should not lengthen the period of time or make it more difficult to qualify for an exception.

We also question why the alternative means of satisfying exceptions for "violations" that are inadvertent and innocent is only upon self-disclosure. In light of the tremendous penalties involved and black and white nature of the prohibitions, there ought to be a means specified in the regulations for the parties to "fix" inadvertent "violations" internally or among themselves, and for CMS or any reviewing agency to exercise discretion upon later review without the need to go through the burden and expense of a self-disclosure.

The proposed regulations also contemplates that the "violations" are "self-disclosed to us." The question raised under this language is to what agency the disclosure must be made. Is it to CMS? Would a formal voluntary disclosure through the OIG self-disclosure protocol be required? Could a provider with a Corporate Integrity Agreement self-disclose to its CIA monitor? Would disclosure to the carrier or fiscal intermediary or program safeguard contractor suffice?

In sum, we fail to understand why there is no mechanism for simply fixing inadvertent violations without the burden and expensive of voluntary disclosure. We would recommend that the self-disclosure prerequisite be eliminated. If not, we believe that any reasonable disclosure to any governmental agency or agent should be acceptable.

* * *

We appreciate the opportunity to comment on these proposed regulations, and we look forward to further clarification of these issues. In the meantime, please feel free to contact us if you have any questions or require further information in this regard.

Sincerely,

Marci Handler

David E. Matias

Carrie Valiant

Submitter : Linda Culver **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15296-Attach-1.DOC

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Linda Culver
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Dr. JAMES SCULLY, JR. **Date:** 08/31/2007

Organization : AMERICAN PSYCHIATRIC ASSN.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

PLEASE SEE ATTACHMENTS IN THIS MS WORD FILE & ASSOCIATE THEM WITH THE BODY OF COMMENTS SUBMITTED VIA THIS SITE A FEW MINUTES AGO. DUE TO ITS SIZE, I HAD TO BREAK THE FILE INTO TWO PARTS IN ORDER TO TRANSMIT. THANK YOU. A.F.

Submitter : **Mr. zach evans** **Date: 08/31/2007**

Organization : **national association of portable x ray providers**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Coding--Reduction In TC For Imaging Services

Coding--Reduction In TC For Imaging Services

Over the past several years, the portable x-ray provider community has taken a significant hit on reimbursement. There are multiple examples that can be provided, however we will focus our attention on one in particular - the Q code. Since 1991, there has been no update on the Q Code. Part of the reasons was that there was no RVU associated with the Q code. However, CMS created a formula/methodology in order to establish and RVU. So, finally in 2006 there was an update on the code, but the update is being phased in over 4 years. Over the 4 years there was to be an 8% increase in the RVU but then the physician fee schedule included a 10% decrease in the technical component which we completely oppose. As such, instead of obtaining an 8 % increase (which we believe should be effective immediately and not phased in over time), we essentially received a 2% decrease. This taken with all the Medicaid cuts, deficit reduction act cuts and other glitches in the system which have caused cash flow problems is creating financial hardships for NAPXP members. We request that CMS examine all the cumulative changes to this provider type and make some adjustments.

Recommendation: CMS reexamine the q code and implement the full update immediately. NAPXP would also like to better understand the methodology that took place in establishing the RVU. NAPXP would also like to urge CMS not to decrease the technical component for imaging services.

IDTF Issues

IDTF Issues

August 30, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore Maryland 21244-1850

RE: CMS-1385-P Proposed Physician Fee Schedule fro CY 2008

Dear Acting Administrator Norwalk:

The National Association of Portable X-ray Providers (NAPXP) is submitting our comments on the proposed physician fee schedule for Calendar year 2008 (72 FR 38121).
NAPXP is a national non profit association representing portable/mobile x-ray providers. The members of the NAPXP are largely small and micro businesses whose companies provide services to the elderly in a safe, convenient fashion, as they, literally, provide care at patients bedsides. Portable x-ray providers allow for the Medicare and Medieaid programs to obtain cost savings (estimated at $2 billion annually) as well as patient convenience (patients do not need to leave the nursing home or their own home in order to obtain the necessary services). They are the specialty 63 providers who, in order to provide other modalities (such as ultrasound), are forced to become Independent Diagnostic Testing Facilities (IDTF). As such, many NAPXP members are IDTFs and are impacted by the proposed rule and specifically the IDTF standards.

We have divided our comments into three parts. First, our general comments. Second, our comments regarding the clarification of certain IDTF standards. Finally, our comments addressing the new standards identified in the proposed rule.

I. General Comments

Over the past several years, the portable x-ray provider community has taken a significant hit on reimbursement. There are multiple examples that can be provided, however we will focus our attention on one in particular - the Q code. Since 1991, there was no update on the Q Code which provides payment for the set-up of x-ray proceedures. Part of the reason for the lack of an upate was that no RVU is associated with the Q code. However, CMS created a formula/methodology in order to establish an RVU. So, finally in 2006 there was an update on the code, but the update is being phased in over 4 years. Over the 4 years there was to be an 8% increase in the RVU but then the physician fee schedule included a 10% decrease in the technical component which we completely oppose. As such, instead of obtaining an 8 % increase (which we believe should be effective immediately and not phased in over time), providers essentially received a 2% decrease. This taken with all the Medicaid cuts, Deficit Reduction Act cuts and other glitches in the system which have caused eash flow problems is creating financial hardships for NAPXP members. We request that CMS examine all the cumulative changes to this provider type and make some adjustments.

Recommendation: CMS reexamine the Q code and implement the full update immediately. NAPXP would also like to CMS to re-examine the methodology used to establish the RVU and share this information with NAPXP.

II. Clarification of current IDTF standards

A. LIABILITY INSURANCE

CMS has clarified standards it believes already exist. In particular, the CY 2007 final rule required comprehensive liability insurance in the amount of at least $300,000 that covers both the suppliers place of business and all customers and employees of the supplier. CMS has revised the standard in this proposed rule to read as follows, the supplier has a comprehensive liability insurance policy in the amount of at least $300,000 per incident that covers both the suppliers place of business and all customers and employees of the supplier and ensures that this insurance policy must remain in force at all times. The IDTF must list the Medicare contractor as a Certificate Holder on the policy and promptly notify the Medicare contractor in writing of any policy change.

While NAPXP does not have any issue with the requirement of

CMS-1385-P-15298-Attach-1.DOC

15298

August 30, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore Maryland 21244-1850

RE: CMS-1385-P – Proposed Physician Fee Schedule fro CY 2008

Dear Acting Administrator Norwalk:

The National Association of Portable X-ray Providers (NAPXP) is submitting our comments on the proposed physician fee schedule for Calendar year 2008 (72 FR 38121). NAPXP is a national non profit association representing portable/mobile x-ray providers. The members of the NAPXP are largely small and micro businesses whose companies provide services to the elderly in a safe, convenient fashion, as they, literally, provide care at patients' bedsides. Portable x-ray providers allow for the Medicare and Medicaid programs to obtain cost savings (estimated at $2 billion annually) as well as patient convenience (patients do not need to leave the nursing home or their own home in order to obtain the necessary services). They are the "specialty 63" providers who, in order to provide other modalities (such as ultrasound), are forced to become Independent Diagnostic Testing Facilities (IDTF). As such, many NAPXP members are IDTFs and are impacted by the proposed rule and specifically the IDTF standards.

We have divided our comments into three parts. First, our general comments. Second, our comments regarding the clarification of certain IDTF standards. Finally, our comments addressing the new standards identified in the proposed rule.

I. General Comments

Over the past several years, the portable x-ray provider community has taken a significant hit on reimbursement. There are multiple examples that can be provided, however we will focus our attention on one in particular - the Q code. Since 1991, there was no update on the Q Code which provides payment for the set-up of x-ray proceedures. Part of the reason for the lack of an upate was that no RVU is associated with the Q code. However, CMS created a formula/methodology in order to establish an RVU. So, finally in 2006 there was an update on the code, but the update is being phased in over 4 years. Over the 4 years there was to be an 8% increase in the RVU but then the physician fee schedule included a 10% decrease in the technical component – which we completely oppose. As such, instead of obtaining an 8 % increase (which we believe should be

effective immediately and not phased in over time), providers essentially received a 2% decrease. This taken with all the Medicaid cuts, Deficit Reduction Act cuts and other glitches in the system which have caused cash flow problems is creating financial hardships for NAPXP members. We request that CMS examine all the cumulative changes to this provider type and make some adjustments.

Recommendation: CMS reexamine the Q code and implement the full update immediately. NAPXP would also like to CMS to re-examine the methodology used to establish the RVU and share this information with NAPXP.

II. Clarification of "current" IDTF standards

A. LIABILITY INSURANCE

CMS has "clarified" standards it believes already exist. In particular, the CY 2007 final rule required "comprehensive liability insurance in the amount of at least $300,000 that covers both the suppliers place of business and all customers and employees of the supplier." CMS has revised the standard in this proposed rule to read as follows, "the supplier has a comprehensive liability insurance policy in the amount of at least $300,000 per incident that covers both the suppliers place of business and all customers and employees of the supplier and ensures that this insurance policy must remain in force at all times. The IDTF must list the Medicare contractor as a Certificate Holder on the policy and promptly notify the Medicare contractor in writing of any policy change."

While NAPXP does not have any issue with the requirement of liability insurance nor do we have an issue with the required amount of insurance, we have a significant issue with the revised language requiring IDTFs to have the Medicare contractor listed as a certificate holder on the policy. Currently, NAPXP members are obtaining insurance, but the carrier is not named in their insurance policy. Insurance companies will charge for those listed on the policy. Therefore, this provision will increase business costs for IDTFs and will have a compounding effect on those companies providing services in multiple states with multiple carriers. In addition to imposing an additional financial obligation on IDTFs, NAPXP is unclear on what the carriers are going to be insuring if they are listed in the policy.

Recommendation: As stated, NAPXP understands why there should be liability insurance and has no issue with the amount required. NAPXP recommends CMS issue a final rule that requires liability insurance in the amount in the proposed rule, but does not require the Medicare contractor as a certificate holder on the policy.

B. TIMELY REPORTING OF CHANGES.

CMS provided clarification on the requirement that suppliers ensure timely reporting of changes/events. Specifically, CMS is now requiring that suppliers must "provide complete and accurate information on its enrollment application. Changes in ownership,

changes of location, changes in general supervision, and adverse legal actions must be reported in 30 calendar days of the change. All other reportable changes must be reported within 90 days."

Recommendation: NAPXP applauds the requirement and believes that suppliers should be able to provide the appropriate changes in the timeframe identified by CMS. NAPXP recommends CMS issue a final rule consistent with the requirements of the proposed rule.

C. BENEFICIARY QUESTIONS

CMS also revised the standard requiring answers to beneficiary questions. Specifically, CMS is now requiring that the following requirements are included: answer, document and maintain documentation of beneficiaries questions and responses to their complaints at the physical site of the IDTF. CMS is now requiring that IDTFs document their compliance process. According to CMS, the IDTF will be responsible for maintaining certain following information on all written and oral beneficiary complaints.

NAPXP does not have a problem with the requirement per se, but would like further clarification regarding the type of calls/questions that would be required to have documented. For example, if a beneficiary calls to see how much money they owe, does this have to be documented as identified in the proposed rule?

Recommendation: NAPXP would like to recommend that CMS further clarify the type of information required to be documented. NAPXP believes that general questions should not have to be documented. NAPXP further believes that complaints and responses to complaints should be documented as proposed.

D. IDTF SITES/SUPERVISING PHYSICIAN

Finally, while CMS is no longer requiring that the IDTF supervising physician be responsible for the overall operation and administration of the IDTF, CMS has expanded the definition of what constitutes "three IDTF sites". It appears from the CMS definition that a piece of equipment is considered a site. NAPXP completely disagrees with CMS on the definition of what constitutes a site and urges CMS to redefine what is considered a site.

NAPXP believes a site should be the physical location of an IDTF and not the equipment the IDTF uses to provide their services. This definition is consistent with provider enrollment in the Medicare program in which a provider is issued a provider number based on a physical location rather than for each piece of equipment that a facility utilizes (however, the equipment is registered to that site). To that end - if there are any issues with the equipment, it is the physical location that would be cited.

If the site would be considered the equipment rather than the physical location of the IDTF, NAPXP is concerned that the shortage of specialty physicians, for example

radiologists and cardiologists, will have a negative impact on access. A physician that is the IDTF's medical director is expected to adhere to the standards/requirements set forth in the CMS regulations regarding supervision. Specifically, a medical director must have the ability to interpret and direct the technologist studies. Most physicians specialize in a particular field and it is often difficult to identify physicians with the specialties required.

If CMS were to base the definition of a site on the equipment, the NAPXP believes there would be serious access, quality and cost implications. For example, if a provider has ten pieces of equipment, they would be required to have four physicians in a supervisory capacity in order to meet the site definition – even though they have only one physical site. This is extremely problematic. A significant burden would be placed on the provider, many of which are small businesses. Financially the IDTFs would have to pay for multiple physicians – which is extremely costly. In addition, an IDTF would have to hire a number of qualified physicians for the supervisory role. The number of qualified physicians is limited and as such, an IDTF would be restricted in the amount of services it could provide based on the number of qualified physicians it could hire. If the services the IDTF provide is limited, access to those services would then be limited. When IDTFs are hiring multiple medical directors, the medical directors will not want to assume a medical director role for just three pieces of equipment because it would not be financially feasible for them to do so. The physicians would in turn want the IDTFs to pay them more money because the amount of business that they would conduct would be limited to the three pieces of equipment. As stated above, this poses additional problems for the IDTF as they would have to try to locate more medical directors and then would be required to pay more money in order to meet this requirement. We urge CMS to define a site based on the physical location of the provider and not the equipment.

Mobile providers offer a valuable service to a specific population – those that need it the most – the frail and elderly residing in nursing facilities and other long-term care settings. If the services are limited, that population would be required to be transported to a hospital or another location (at a higher cost) to obtain the same services. If moved from their location in a long-term care setting, studies show that the patient usually gets confused by the change of venue and interruption of their daily activities of life. Additionally, one needs to be concerned about transporting a vulnerable patient to an acute facility that can expose the patient to a host of infections,

Recommendation: NAPXP believes it is not Medicare's intent to increase the amount of money that the program pays for services or to create access or quality issues. The consequences of defining a site to the equipment rather than to a physical location are significant. Therefore, NAPXP urges CMS to define an IDTF site as a physical location.

III. Proposed new IDTF Standards

A. INITIAL ENROLLMENT DATE

The proposed standard in which Medicare will establish an initial enrollment date for all IDTFs is a standard that NAPXP agrees with and applauds. However, NAPXP is concerned that applicants are provided with a timely response regarding their enrollment status. A prolonged response may place a provider into a situation where they are providing services but are uncertain if Medicare payment will cover the services. To eliminate this situation NAPXP believes providers should be given a response to their enrollment application with a 60-day period.

Recommendation: NAPXP recommends CMS require that applicants be notified of their enrollment status within 60-days of submitting the application.

B. NO SHARING OF SPACE EQUIPMENT OR STAFF

CMS is also proposing that providers do not share space, equipment, or staff or sublease its operations to another individual or organization. CMS has specifically stated in the proposed rule, that while this new standard only applies to only fixed-based (physical site) locations, Medicare also believes that it should apply to mobile IDTFs. CMS is specifically seeking comments on whether this proposed standard should apply to mobile IDTFs. The NAPXP does not believe that it should.

Many NAPXP members are portable x-ray providers and are also classified as an IDTF. They operate out of the same location and may have the same billing staff and other administrative staff, but different technicians. If this requirement were applied to mobile IDTFs, they would have to have a separate location – although the business is owned and operated by the same person. They would also be required to have different staff. All of these requirements are very costly. As mentioned previously NAPXP members are small and micro businesses and the added financial burden would likely put some of these providers out of business. In addition, this would eliminate the ability of a provider to operate two IDTFs at the same location that service distinct areas .This would cause a significant financial hardship and simply does not make sense. Simply put, NAPXP opposes restrictions on the sharing of space and staff because it runs counter to efficient business practices that enable small businesses to operate effectively. We believe CMS should continue to permit mobile IDTFs to continue sharing space and staff. If CMS were to impose any restrictions on mobile IDTFs, NAPXP believes the sharing of space and staff should be permitted as long as: 1) the relationship is disclosed, and 2) the equipment stored in shared space not be used for testing on-site.

Recommendation: NAPXP strongly recommends CMS not restrict mobile IDTFs ability to share space, equipment and staff. Should CMS adopt this policy, NAPXP recommends the sharing of space and staff should be permitted as long as: 1) the relationship is disclosed, and 2) the equipment stored in shared space not be used for testing on-site. Finally, NAPXP would like to have some clarification/discussion as to why CMS believes that this requirement apply to mobile IDTFs.

IV. Conclusion

The NAPXP appreciates the opportunity to comment on the proposed physician fee schedule regulation. There are several provisions that significantly impact our membership. While we applaud CMS on several of the provisions, we have significant issues with others. We look forward to continuing to work with CMS in resolving these issues. If you would like additional information or have any questions on any portion of our comments, please do not hesitate to contact us.

Sincerely

Zach Evans
Chairman
Board of Directors
NAPXP
NAPXP
5201 Babcock Street NE Suite 2
Palm Bay, FL 32905

Bruce Cotti
President
NAPXP
NAPXP
5201 Babcock Street NE Suite 2
Palm Bay, FL 32905

Submitter : Ms. Nancy Nelson **Date:** 08/31/2007

Organization : Illinois HomeCare Council

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15299-Attach-1.DOC

CMS-1385-P-15299-Attach-2.DOC

15297

ILLINOIS HOMECARE COUNCIL
NATION'S FIRST HOMECARE ASSOCIATION

August 31, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD, 21244-80-18

Dear Sir or Madame:

Thank you for this opportunity to comment on proposed regulations entitled "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; etc." published in the Federal Register on July 12, 2007 (Vol. 72, No. 133). The Illinois HomeCare Council (IHCC) is a trade association representing over 200 providers and suppliers of home care services in Illinois. These comments were developed by IHCC's Regulatory and Reimbursement Committee.

THERAPY STANDARDS AND REQUIREMENTS

IHCC has carefully reviewed CMS' proposed changes to the Medicare Conditions of Participation for Home Health Agencies (42 CFR 484) as they relate to minimum personnel qualifications for therapists working in home health agencies. IHCC recognizes and supports CMS' intention to standardize the minimum personnel requirements for Medicare services they purchase across settings. However, IHCC has some concerns about the approach that CMS has proposed.

IHCC members support CMS intention to require that professionals entering practice on or after January 1, 2008 must be licensed by the State in which they are practicing. IHCC believes that compliance with state licensure requirements should be sufficient in those states that license these disciplines, and opposes applying the added education and testing requirements that are included in the proposed rule to agencies in these states.

Illinois has had licensure laws for physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants and speech/language

600 South Second Street • Springfield, IL 62704 • (217) 753-4422 • FAX (217) 528-6545 • w ww.ilhomecare.org

pathologists for many years. Illinois' laws and regulations recognize the accredited educational programs identified by CMS in the proposed rule as meeting State standards for professional education. Illinois law also recognizes the same credentialing examination that CMS cites for OTs and OTAs and requires successful completion of a credentialing examination for PTs and PTAs administered by the Federation of State boards of Physical Therapy. It was not possible to ascertain for the purposes of this letter whether this is the examination that is approved by the American Physical Therapy Association (APTA). Under Illinois' home health agency licensing rules, In order to work in a home health agency in Illinois individuals in these professional categories must be licensed.

It certainly appears that Illinois providers would not have any difficulty meeting the proposed regulations should they be implemented. Concerns about compliance are not the basis for IHCC's opposition to the proposed education and testing requirements. Rather IHCC's opposition is based on the belief that professional credentialing is a state responsibility. When states have met this responsibility, IHCC members believe that their credentialing programs should be sufficient for the Medicare program.

IHCC is also concerned about the potential record-keeping requirements that may arise from this proposed rule. IHCC members envision a situation in which they will be required to demonstrate that professionals who began their practice prior to January 1, 2008 meet the requirements specified for the earlier time period when, in fact, Illinois licensure has been the local standard for many years. It seems unreasonable to expect agencies to track compliance with these intricate requirements dependent, in some instances, on organizations that do not even exist any longer, when everyone state providing the services in a state must be licensed by that state.

Finally, the 1997 proposed revision to the home health agency conditions of participation included state licensure for professional disciplines as the minimum qualification for service delivery in a Medicare certified home health agency, a proposal which was strongly supported by the industry. No rationale has been provided for why the earlier proposal would not serve as well today as it would have in 1997.

Recommendations:

IHCC recommends that CMS revise the proposed rule to recognize state professional licensing laws and regulations, or their equivalents, as the minimum standard for therapists providing services in home health agencies in states where such laws and regulations exits. CMS should only establish education and testing credentials for those states in which licensure is not required.

IHCC also recommends that if CMS proceeds to adopt the proposed education and testing requirements for PTs and PTAs clarification should be provided regarding the credentialing examination(s) that are acceptable. IHCC review of the APTA website revealed no information about approved credentialing examinations.

Sincerely,

Nancy Nelson
Executive Director

Submitter : **Dr. Thomas Bernasek** **Date: 08/31/2007**

Organization : **Dr. Thomas Bernasek**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

PHYSICIAN SELF-REFERRAL PROVISIONS

I would like to provide comments being sought by CMS regarding potential changes to the In Office Ancillary Serviees Exception. I do not support any change that would exclude Therapy Services from this exception. In my practice we offer Physical and Occupational Therapy Services to our patients. We hire Licensed Physical Therapists and Licensed Oceupational Therapists to provide and oversee the Rehabilitation services in our practice. Communication is excellent between the Therapists and the Physicians regarding patient progress. Our physicians can intervene much sooner when needed to provide additional support and direction to the therapists to better care for the patient. Our physicians have a better understanding of the underlying pathology and can better communicate our findings to the Therapists to assist in making treatment plans, which benefits the patient. If I have questions regarding the patients Therapy I can call the Therapist down to the office and discuss the patient treatment directly, and my patients appreciate this. Our therapists are knowledgeable with our post surgical treatment protocols and stay within the treatment guidelines making the Therapy safer and more effective. In outside facilities, many times I ve had patients progressed too quickly, where the Therapy I felt was too aggressive, causing them harm during their post operative recovery.

The transition of the patient from the Physician office to the Therapy treatment center is seamless in our facility when ordered. Therapy intervention can begin more quickly, and patients can be progressed safely when monitored more closely by the physician. This leads to a faster recovery by our patients, shorter stays in Therapy and overall reduced costs on the healthcare system.

Thank you.

Submitter : **Dr. Jeffrey Becker** **Date: 08/31/2007**

Organization : **Delaware Valley Urology, LLC**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Mr. Kuhn:

I am a urologist in clinical practice in Southern New Jersey. Our former practice recently merged with several other groups for the purpose of providing outstanding care to the local community (who previously felt the need to cross the Delaware River to seek care at one of the University Hospitals in Philadelphia). We care for a substantial Medicare population as there are many retirement communities in our area.

The changes proposed in these rules will have a serious impact on the way our group practices Urology and will not lead to the best medical practices. Specifically, with regard to the in-office ancillary services exception, the definition should not be limited in any way.

We currently have the ability to provide in-house pathology services to our patients - this allows for a rapid turnaround time, an extremely important factor to the patient. It also allows for a more personal, face-to-face relationship between the urologist and pathologist.

As a physician who sees a lot of elderly men with prostate cancer, I have seen many turning toward less invasive means of cure such as external radiation therapy or seed implantation. In our current system, there is a lot of red tape which needs to be cut in order to get to the endpoint. The patient must get an appointment with the radiation oncologist (often takes several weeks). If a patient chooses seed implant, there are often severe scheduling constraints causing another delay of several months. Having this modality "closer to home" would allow us to have a more personal relationship with the radiation oncologist and streamline patient care. The same goes with external beam radiation therapy.

There are many other tests/ services that might be severely limited if the definition of an in-office ancillary service were limited to those tests and services that are needed to immediately diagnose or treat a patient. We routinely wait 20-30 minutes for results of bloodwork (often ordered 6 months before). This clearly is not emergency bloodwork, but the fact that results are not available (they would be if they were offered in-house) is detrimental to both the physician and the patient, whose visit often depends on the results of that bloodwork.

I hope you will consider these and other examples from other physicians, whose practices will be adversely affected if the proposed changes to the physician fee schedule rules concerning Stark and reassignment and purchased diagnostic test rules is passed.

Sincerely,

Jeffrey Becker, M.D.

Submitter : Mr. Angus McFarlane **Date:** 08/31/2007

Organization : Select Medical

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I have been a licensed physical therapist for 40 years and have worked in a hospital, owned a private practice, and am currently an administrator with Select Medical, Inc.

I am concerned about the July 12 proposed 2008 physician fee schedule rule, especially the issue surrounding physician self-referral and the 'in-office ancillary services' exception.

Many physicians across the state have opened their own physical therapy units during the past five years. I see all sorts of opportunity for fraud when anyone owns or has a vested interest in a site that provides ancillary services to their primary business. I am well aware of the possibility of prescribing more treatments than necessary for a patient, thereby fraudulently increasing revenue for the physical therapy clinic and ultimately for the physician. I know of a therapist who works for a chiropractor and sees patients only for their initial visit; yet the patients are charged for treatment as if seen by a licensed physical therapist.

The out-patient facility for whom I work provides closely supervised and monitored patient treatment only by licensed physical therapists and physical therapy assistants. Our charges and treatment programs are in compliance with Medicare regulations. I am opposed to competing with facilities that choose to 'manipulate the system' to their advantage.

I encourage you to remove physical therapy as a designated health service permissible under the in-office ancillary exception of the federal physician self-referral laws.

Thank you for your consideration of this matter.

Sincerely, Angus McFarlane, PT

Submitter : Nitin Saxena **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15303-Attach-1.DOC

15303

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Nitin Saxena
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam

I am a physical therapist in an independent practice in Little Rock, Arkansas. I am writing today to voice my opinion in regard to the in-house referral of physical therapy services by physicians. I was under the impression that the Stark Laws were initially intended to lessen the chance of fraud and abuse of physical therapy services by not allowing physicians to refer to a facility where they had a vested financial interest.

Two years ago, I was interviewing a physical therapist in our community who worked for a physician owned practice. This individual told me that she signed off on 40-60 patient charts a day. There is no way that one can oversee and direct the care of that many clients without doing group exercise or signing off on patients they do not see. I am not opposed to having other qualified professionals, such as certified athletic trainers and licensed massage therapists working under the direction of a physical therapist in a physical therapy clinic. However, I do have a problem with a physical therapist who obviously is not involved in that patient s care, just signing off on charts. I find it extremely challenging to maintain a patient load of 12 to15 patients a day, but then I actually treat the patients I see. The physician owned practices have certainly affected our referral base and we continue to see more physicians in various settings opening up their own clinics. They may say that this is for patient convenience, but the reality is that it is for the revenue it can bring into the facility. The other concern that we have seen is that physicians often will keep the patient s that have minimal problems and run protocol therapy and only refer their most difficult patients out to other facilities. For the above reasons, I feel physical therapy should be excluded from in-office ancillary services.

Submitter : Mr. Aaron Terranova **Date:** 08/31/2007

Organization : UNC-Greensboro

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Aaron Terranova and I am a Certified Athletic Trainer working at the University of North Carolina at Greensboro. I have been a Certified Athletic Trainer for 8 years, and I am writing today to discuss a matter of grave importance.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As a Certified Athletic Trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Aaron Terranova, MEd,ATC,LAT

CMS-1385-P-15306

Submitter : Ms. Kate Romanow **Date:** 08/31/2007

Organization : Remote Cardiac Services Provider Group

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15306-Attach-1.DOC

Remote Cardiac Services Provider Group

August 31, 2007

Submitted Electronically To:
http://www.cms.hhs.gov/eRulemaking

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS 1385-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: 2008 Medicare Physician Fee Schedule Rule: CMS-1385-P; Resource Based PE RVUs; IDTF Issues

Ladies and Gentlemen:

The Remote Cardiac Services Provider Group (the Provider Group) appreciates this opportunity to submit comments on the 2008 Physician Fee Schedule Rule, as published in July 12, 2007 Federal Register. The Provider Group consists of nine companies, which comprise the largest providers of remote cardiac monitoring services and which furnish the majority of remote cardiac monitoring services in this country including cardiac event monitoring, pacemaker monitoring, holter monitoring, and INR monitoring. The Provider Group members are all enrolled in Medicare as independent diagnostic testing facilities (IDTFs). They all operate on a 24-hour 7-day per week basis because the services that they provide require round-the-clock service. In that way, they are very different from physician offices and other IDTFs.

Millions of Americans, including Medicare beneficiaries, suffer from cardiac conditions related to arrhythmias each year and the cardiac monitoring services provided by members of the Provider Group are essential to the timely diagnosis and treatment of these illnesses. Our comments focus on practice expense RVUs, as well as the proposed revisions of existing performance standards and creation of new standards for IDTFs and the impact these revisions and proposed standards will have on remote cardiac monitoring services.

I. Practice Expense RVUs

A. Background

The services furnished by the Provider Group are all technical component only services and had previously been in the non-physician work pool. When the NPWP was proposed for elimination in the 2006 physician fee schedule, remote cardiac services were scheduled to undergo cuts of between 40% and 75% for all services, when fully implemented. As a result of practice expense data submitted by the Provider Group, much of which was accepted by CMS, some of these cuts were reduced. However, holter monitoring services would still by cut by almost 50% by 2010; one of the cardiac event monitoring codes would fall by over 30% and the other by nearly 15%. (*See* Table below)

Proposed Reimbursement Comparisons[1]

Type of Service	Code	Medicare PE RVU Payment in 2006	Medicare PE RVU Payment in 2010 (proposed)	% Decrease in PE RVU Payment
CEM	93012	$228.52	$155.39	-32%
CEM	93271	$227.40	$195.19	-14.59%
Holter	93226	$82.99	$43.59	-47.49%
Holter	93232	$77.70	$43.59	-47.49%

Members of the Provider Group operate on extremely tight financial margins and, unlike many physician office practices, do not provide other health care services against which these losses could be offset. Moreover, the payment allowances of many private payers are tied to Medicare payment rates. Thus, it will be impossible for Provider Group members to absorb cuts of this magnitude. The result will be reduced access to these services and Medicare patients with cardiac arrhythmias may not receive the diagnostic and preventive services they need. This will inevitably lead to increased emergency room visits and hospitalizations and ultimately increased mortality due to failure to timely diagnose and treat life-threatening cardiac conditions. These severe reductions in reimbursement for remote services, which allow patients to be monitored in the home, are entirely at odds with current health initiatives promoting the use of telehealth services.

Historically, remote cardiac services were never properly valued by CMS or the AMA RUC process. To the extent that the RUC has reviewed practice expenses for these services, it was done through a process which almost entirely excluded IDTFs, relied on limited data from a

[1] Based on 2006 Conversion Factor ($37.8975) and without factoring in the statutory 10% negative update to the SGR.

few physician practices, and where the RUC included IDTF information it excluded IDTF's unique costs. Therefore, in 2006, the Provider Group, at CMS' suggestion, decided to undertake a larger survey which looked at a broader range of services and which also gathered company-wide cost data. Seven companies[2] in the Provider Group participated in the survey which was administered by Doane Marketing Research, Inc. The survey gathered cost data similar to that in the AMA SMS survey (without the physician component) and also gathered service sector and code specific information (*e.g.*, cardiac event, pacemaker) such as the number of technicians, total technician hours, equipment costs, equipment licensing and upgrade fees, supply costs, telephone transmission costs, and costs of lost and damaged equipment. This data was used to develop the Provider Group's practice expense recommendations for the 2007 proposed PFS that were, to a large extent, accepted by CMS.

The Provider Group appreciates the efforts CMS has made to work with us to properly value the services we provide. Our services and the structure of our industry are very different from those of a physician's office and we appreciate CMS' willingness to recognize this when valuing our services. We believe there are several direct costs incurred by providers of remote cardiac services that are not currently recognized by CMS and thus not reflected in the PE RVUs. Each of these is discussed below along with our recommendations.

B. Direct Cost Recommendations

1. Telephone Transmission Costs

One of the direct costs on which the Provider Group submitted data for the 2007 PFS was telephone line costs associated with the transmission of clinical data. These costs can easily be allocated to the service level and are entirely related to providing the clinical service to patients. For reasons that are not clear, CMS did not accept these costs for the 2007 PFS. However, in the proposed 2008 PFS notice, the agency has specifically requested comments on telephone line costs.

Cardiac event monitoring services and Pacemaker monitoring services are provided trans-telephonically. Therefore, providers of these services must maintain several toll-free lines that patients can call to transmit data from home. For cardiac event monitoring services, during the 30-day test period, the patient calls the monitoring center whenever clinically significant events occur, whether patient or device-initiated, and the ECGs are transmitted telephonically to the event monitoring provider that operates 24 hours a day, 7 days a week. The data is immediately reviewed and analyzed by specially trained personnel and the technician's analysis is sent to the treating physician for interpretation and follow-up. If the data shows the patient's heart rhythm is malignant the technician calls 911 and may remain on the line until assistance arrives. The number and length of transmissions during a 30 day test period will necessarily vary from patient to patient. However, the typical number of transmissions is 7-8 and the typical length of a

[2] Two additional members joined the Provider Group after the survey was completed.

transmission is 7-8 minutes. Therefore is also a base line transmission of 7 minutes for a total of approximately 65 minutes.

Pacemaker monitoring services also rely on trans-telephonic transmission of data to monitor and evaluate whether the patient's pacemaker is working properly. These monitoring sessions, which are typically done four times a year, but can be done more often if ordered by the physician, take, on average, 17 minutes.

Based on information provided by members, the average 800 number line charge per minute is 3.9 cents.

We believe it is appropriate to treat these costs as direct supply costs because they are an integral and essential part of the clinical service, which is, by definition, a trans-telephonic monitoring service. Moreover, the costs can easily be directly allocated at the service level.

Recommendations:

Cardiac Event Monitoring (CPT Codes 93271 and 93012): Include $2.53 for phone line transmission costs based on 65 minutes of transmission time.

Pacemaker Monitoring (CPT Codes 93733 and 93736): Include $0.66 in phone line transmission costs based on 17 minutes of transmission time.

2. Costs of Web-Based Storage, Maintenance and Access to Clinical Information

In the proposed 2008 PFS notice, the agency specifically requested comments on web access and storage of clinical information.

It is standard in the industry for providers of remote cardiac services to provide the patient's physician with internet or web-based access to the IDTF's report and analysis as well as other patient clinical information gathered as a result of the test. Physicians are provided with software and a password that allows them to log on to a secure website maintained by the IDTF and retrieve the analyses and reports prepared by the IDTF technician in addition to the actual transmission data or ECG tracings. The web-based data and reports are also capable of integration with the physician's electronic health records. All of the members of the Provider Group store, maintain, and provide access to clinical information electronically through secure websites. The costs associated with internet or web-based access were not surveyed by the RCSPG in last year's survey and thus were not included in our comments on the proposed 2007 fee schedule. However, the Provider Group did survey them this year. Data was obtained from Provider Group members related to software, licensing and other costs associated with storage of clinical information and providing physicians with access to web-based clinical information. These costs include, to a large extent, software and software licenses and may include other costs

associated with maintaining privacy of clinical information (*e.g.*, firewall, DMX, routers, switches), disaster recovery (software, off-site storage) and virus protection. Each company's total annual costs were allocated to the service level based on its total annual utilization (*i.e.*, number of services provided). The Table below shows the average cost per category of service (*i.e.*, cardiac event monitoring, pacemaker and holter monitoring).

Average Web Access Costs per Claim (mean)	Holter Monitoring 93226 and 93232	Pacemaker Monitoring 93733 and 93736	Cardiac Event Monitoring 93012 and 93271
	$2.31	$0.65	$2.50

These costs are not indirect costs. They are directly related to providing the clinical service of analysis and reporting of patient information obtained through the device and can be allocated to the service level. We believe it is most appropriate to treat these costs as direct **supply costs** although we recognize that these costs to not fit neatly into either the equipment or supply category. Treating these costs as equipment costs assumes that there are discrete pieces of equipment to which precise minutes of use can be assigned. This is not the case. Rather, provision of web-based access is carried out through a complex and interrelated network of hardware, software and software licenses. Although we understand that supply costs are typically associated with a one time use, we believe the supply category is the better fit for these types of costs than equipment.

Recommendation: Include the costs, as set forth in the table above, as direct supply costs.

3. Holter Monitoring Device (CPT Codes 93226 and 93232) - Minutes of Use

Holter monitors are portable recording devices that use tape or digital media to continuously record ECG activity over 24 hours (although occasionally physicians order tests for 48 hours). There are three components to the test: (1) the hook-up of the patient; (2) the analysis of the ECG waveform and report preparation; and (3) the physician interpretation. Each component has a separate CPT Code and can be paid separately or globally under a global code.

The first part of the test – the hook-up of the patient to the holter monitoring device – is generally done in the physician's office by physician office clinical personnel using a device that is provided to the physician's office by the IDTF. After being hooked up to the device, the patient is sent home and is instructed to return the device after the 24-hour test is completed. If the test is performed using analog technology, the patient's ECG activity is recorded on a cassette, which, upon return of the device to the physician's office, is sent to the IDTF for analysis. If digital technology is used, the physician's office transmits information from the device electronically to the monitoring center (*i.e.*, the IDTF).

Recommendation: For CPT codes 93226 and 93232, increase minutes of use for holter device from 1440 minutes to 2880 minutes to reflect time device is with the patient and not available for use by anyone else.

4. Cardiac Event Monitoring Device (CPT Codes 93271 and 93012) – Minutes of Use

Similarly, the number of minutes of use assigned to cardiac event monitoring devices should be increased to reflect the additional time for the patient to mail the device back to the IDTF at the conclusion of the 30-day test period. (Unlike holter devices, the cardiac event monitor is returned directly to the IDTF and not the physician's office.) Currently, CMS recognizes 30 days of use (*i.e.*, 43,200 minutes). However, once the test is completed, the patient is required to mail the device back to the IDTF. We have not surveyed our members on the actual number of days it takes the patient to return the device to the IDTF. However, we believe, on an interim basis, until more accurate data can be obtained, that it would be reasonable to recognize an additional five days (*i.e.*, 7,200 minutes) of use, which would at least capture the typical amount of time it takes for the device to be mailed to the IDTF assuming the patient mails the device immediately upon completion of the test.[3] During this time, the device is not available for use by anyone else.

Recommendation: For CPT codes 93271 and 93012, increase the minutes of use for the cardiac event monitor device from 43,200 minutes to 50,400 minutes to reflect time device is with the patient or in the mail and thus not available for use by anyone else.

5. INR Monitoring (G0249) – Minutes of Use

The Provider Group supports the proposal to increase the minutes of use for the PT/INR home monitor device from the current 32 minutes to 1440 minutes to reflect the fact that the device is provided to the patient in their home on a continuous basis for as long as the patient is in need of PT/INR monitoring. We believe this will result in more equitable payment for this important service.

Recommendation: For HCPCS G0249, increase the minutes of use for the PT/INR home monitor device from the current 32 minutes to 1440 minutes.

C. Indirect Costs

The Provider Group continues to have serious concerns with the use of physician work RVUs to allocate indirect costs. This allocation methodology significantly disadvantages technical component services such as those furnished by the Provider Group, which do not have

[3] The five days is the typical allowance for mailing time used by CMS in connection with provider appeals of denied claims. See Medicare Claims Processing Manual, Pub. 100-4, Ch. 29.

physician work RVUs. Moreover, unlike a physician practice, the Provider Group does not provide other services with physician work that might help offset the underpayment of indirect costs. We do not believe there is a rational relationship between physician work and indirect costs of providing a service. This approach especially disadvantages IDTFs that furnish remote cardiac services and which, unlike physician offices or other IDTFs, operate 24-hours a day, 7 days a week. Maintaining a 24/7 operation adds additional and significant indirect costs that are not captured in the existing CMS methodology, which is based on a physician practice model. These incremental costs associated with operating round the clock include additional heating and cooling costs, payroll costs of clinical supervisory personnel who must be available at all hours, and payroll costs for administrative personnel – primarily in the IT area. For example, Provider Group members estimate that utility costs (*e.g.*, heating and cooling) are twice what they would be if they only operated during normal business hours. These additional costs are not offset by revenue resulting from the IDTF being able to provide more services because of longer operating hours. Members of the Provider Group are required to maintain a 24-hour service – they have no choice. Further, payment is a fixed amount for the 30-day test regardless of how many transmissions take place. Thus, there is no countervailing benefit to being open 24-hours.

In summary, providers of remote cardiac services incur much higher indirect costs than physician offices or other IDTFs that are open during normal business hours. The current methodology used for allocating these indirect costs based on physician work and direct costs does not result in a fair distribution of indirect PE RVUs to providers of remote cardiac services.

Although we appreciate that CMS has assigned the cardiology PE/hour and IPCI to many of the services furnished by the Provider Group, and that it is using clinical labor RVUs instead of physician work RVUs for TC-only services, we still have serious concerns about the inherent unfairness of the existing methodology given the fact that physician time is valued at a significantly higher rate than clinical staff time.

For example, a level 4 outpatient office visit (99214) has 40 minutes of physician time for 1.42 work RVUs. In contrast, the holter monitoring code 93326 has no physician work and 52 minutes of RN/LPN/MA time which translates into $19.24 (52 times $0.37) or 0.51 RVUs. Further, direct costs are subject to a scaling factor or adjustment of close to 50% where the scaling factor for physician work is only 11%. Thus, not only is physician time valued much higher than clinical staff time, but the scaling factor applied to clinical labor time is almost five times that applied to physician work RVUs. Thus, in the above example, physician work RVUs (reflecting 40 minutes of physician time), after budget neutrality would be approximately 1.26 RVUs whereas clinical staff time would be only .25 RVUs. We do not believe there is any rational justification for such an enormous disparity in the treatment of clinical staff time compared to physician time in the allocation of indirect PE RVUs.

We suggest CMS consider further refinements to its indirect allocation methodology to correct this gross inequity. One option the agency might consider is removing (or at least discounting) clinical staff time from the allocation of indirects for codes with physician work

(provided work RVUs exceed clinical labor RVUs). Another option might be to apply a multiplier to clinical labor RVUs for codes with no physician work for purposes of allocating indirect PE RVUs. A third option might be a decrease in the scaling factor applied to clinical labor RVUs used to allocate indirect RVUs. We urge that CMS consider these and other options with a goal toward achieving a more equitable and more resource-based reimbursement system.

II. IDTF Issues

A. Background

We support CMS's goal of ensuring that IDTFs meet minimum standards to protect beneficiaries and the Medicare Program, but we feel that some standards may require certain modifications so as not to negatively impact the appropriate provision of services to Medicare beneficiaries. **Certain provisions of the Proposed Rule will increase the administrative burden on IDTFs. We believe that these provisions will provide little increase in protections to the Medicare program at a time when reimbursements are being dramatically reduced.** Consequently, the Provider Group is offering the following comments and recommendations regarding the Proposed Rule in an attempt to mitigate the harmful effects of some of these provisions and work with CMS to achieve the goals of each.

B. Revised Existing Performance Standards

1. Supervising Physician

Currently under 42 C.F.R. § 410.33(b)(1), the supervising physician at an IDTF is responsible for its overall operation and administration, but the Proposed Rule would eliminate this requirement. The Provider Group supports this revision. The responsibilities included under the current regulation are similar to those performed by someone with training in business administration and operations rather than the practice of medicine. Since physicians are generally not trained or experienced in business administration, such responsibilities should remain in the hands of business experts and that the supervising physician should be responsible only for the clinical services provided by the IDTF. Therefore, the Provider Group thinks that the elimination of this requirement is appropriate and consistent with the role of the supervising physician of an IDTF.

Recommendation: The Provider group supports this change.

2. Liability Insurance

42 C.F.R. § 410.33(g)(6) currently requires an IDTF to maintain a comprehensive liability insurance policy in the amount of $300,000. Under the Proposed Rule, CMS would clarify that the policy must provide coverage "per incident" instead of aggregate as it could now

be interpreted. The Provider Group is opposed to this change because it believes a lower per incident amount is sufficient. A standard liability policy should have $100,000 per incident and $300,000 aggregate. We believe that requiring a higher per incident amount is not necessary under the circumstances. Therefore, the Provider Group supports a change in the coverage requirements to $100,000/$300,000.

An IDTF would also be required to list the Medicare contractor as a certificate holder on its policy and notify the contractor of any policy changes or cancellations. CMS does not define what the term "certificate holder" would entail. The purpose of listing the contractor as a certificate holder is to ensure that CMS's "contractor will be able to verify coverage with the underwriter at the time of enrollment and as the need arises throughout the year." 72 Fed. Reg. at 38169. Furthermore, under the Proposed Rule, an IDTF would be responsible for supplying the contact information for the policy's insurance agent and underwriter to allow the Medicare contractor to verify that the policy was issued. This provision is reasonable and should be sufficient to provide notice to the contractor, and therefore should not require a provider to add a contractor as a certificate holder.

However, if CMS decides to keep the "certificate holder" requirement, it should clarify that the contractor will be added on the insurance policy only for notification purposes, and will not have contractual rights. Otherwise, it may be difficult for IDTFs to convince insurance companies to list the contractor as a certificate holder because of concern that the contractor may have rights under the policy. Also, CMS should clarify that the IDTF's responsibility is to notify the contractor if the person who is listed by the IDTF as the contact for the policy's insurance agent and underwriter is no longer available (for example, if the contact leaves his or her job). An IDTF may not become immediately aware that the contact person is no longer available.

CMS also states that the proposed revision "will not preclude the use of self insurance to demonstrate compliance with the comprehensive liability insurance policy as long as CMS or our designated contractor can verify that policy and its coverage provisions with an independent underwriter." 72 Fed. Reg. at 38169. We request that CMS clarify what is meant by "self-insured." It is unclear what the policy and coverage provisions would need to look like and what the underwriter would need to provide. In addition, a company that chooses to self-insure may not have an independent underwriter, so we request that CMS further define what it means by an "independent underwriter."

Recommendations: IDTFs comprehensive insurance policy should be at least $100,000 per incident, $300,000 aggregate. IDTFs should not be required to list Medicare contractors as certificate holders on its liability insurance policy, but if CMS makes this a requirement, it should specify that contractors are to be listed as certificate holders for notification purposes only. Also, CMS should allow IDTFs at least 90 days to report changes in contact information to the contractor. CMS should further define what the policy and coverage requirements are for self-insurance and what is meant by an "independent underwriter."

3. Enrollment changes

Under 42 C.F.R. § 410.33(g)(2), an IDTF must report any changes in its enrollment application within 30 days of the change. The Proposed Rule would revise this by requiring an IDTF to report changes in ownership, changes of location, changes in general supervision, and adverse legal actions within 30 calendar days, and all other changes would need to be reported within 90 days. We are supportive of this change because we believe that 90 days is a more reasonable time frame for reporting all changes in the enrollment information of IDTFs. In the alternative, we support quarterly reporting of any changes that have occurred in the preceding quarter.

Recommendations: All changes should be required to be reported to CMS within 90 days, or in the alternative, IDTFs should report quarterly any changes that have occurred in the preceding quarter.

4. Questions and Complaints

The Proposed Rule also makes changes to 42 C.F.R. § 410.33(g)(8). Currently, under 42 C.F.R. § 410.33(g)(8) an IDTF must "answer beneficiaries' questions and respond to their complaints." The Proposed Rule would expand this requirement, and an IDTF would be required to "answer, document, and maintain all beneficiaries' question and responses to their questions at the physical site of the IDTF." 72 Fed. Reg. at 38170. We strongly oppose this change. First, we recommend that instead of this revision, IDTFs be required to develop and adhere to a complaint policy that includes documentation of material medical or billing complaints. If CMS decides not to take our suggestion of allowing IDTFs to develop their own complaint process and instead keeps its revisions, we have additional recommendations set forth below.

IDTFs deal with patient questions on a regular basis. These questions are related to treatment or billing and very few are complaints. For example, IDTF clinical technicians receive many questions from patients about the remote diagnostic service and how to use the cardiac device. If relevant clinical care is involved, documentation of the discussions are kept in the patient's clinical file. If the question relates to billing it would be kept in the patient's billing file. We do not think an IDTF needs to maintain a separate file for responses to typical questions unless those questions are complaints. Therefore, we recommend that the word "questions" be changed to "complaints". Of course, we understand that IDTF staff would still need to respond to questions from beneficiaries.

We also suggest in lieu of maintaining these documents at the physical facility that IDTFs be given two business days to retrieve records that are older than 30 days upon request by CMS or its designated fee-for-service contractor as allowed for retrieving medical records under current performance standard 13 (42 C.F.R. § 410.33(13)). The volume of such documentation could easily exceed the capacity of a typical physical facility to easily store and manage within a

short period of time. Requiring that the documentation be maintained on-site would result in substantial inconvenience and may ultimately interfere with efficient provision of IDTF services to beneficiaries as the amount of documentation in storage continued to grow and increase costs in the face of shrinking reimbursement. Furthermore, CMS should specify how long IDTFs will be required to keep such documentation and whether these specific types of complaints should be kept separately from other kinds of complaints.

Under the Proposed Rule, the IDTF would be required to maintain certain information on the complaints, including the insurance claim number. A health insurance claim number would only be involved if a billing claim were at issue. CMS should clarify what is meant by a complaint, for example, whether a complaint that does not involve an insurance claim number will still need to be documented. If so, CMS should further clarify that IDTFs will not always be required to document the health insurance claim number.

Recommendations: Instead of CMS's proposed revision, IDTFs should be required to develop and adhere to a complaint policy that includes documentation of material medical or billing complaints. However, if CMS decides instead to keep its current proposed revisions, CMS should change the word "questions" to "complaints". IDTFs should be allowed to keep documents that are older than 30 days at a site other than the IDTF's physical location, and CMS should clarify how long IDTFs are required to keep such documentation and whether such complaints need to be separated from other complaints. CMS should also further clarify what is meant by a complaint, and whether an IDTF will be required to record the insurance claim number for each complaint.

C. Proposed New Performance Standards

1. Enrollment Date

Currently, an IDTF can bill retroactively for services that were provided up to 27 months prior to the IDTF's enrollment in Medicare. Under proposed 42 C.F.R. § 410.33(i), the regulation would read as follows:

> (i) *Effective date of billing privileges.*
>
> The effective date of billing privileges for a newly enrolled IDTF is the later of the following:
>
> (1) The filing date of the Medicare enrollment application that was subsequently approved by a fee-for-service contractor;
> (2) The date the IDTF first furnished services at its new practice location; or
> (3) The filing date of the Medicare enrollment application or the date that the Medicare fee-for-service contractor receives a signed provider enrollment application that is able to process for approval.

72 Fed. Reg. at 38222.

We believe that (i)(3) is an error, and was meant to be a definition of "date of filing." In the Proposed Rule, CMS states that :

> . . .Medicare will establish an initial enrollment date for an IDTF that would be the later of: (1) the date of filing of a Medicare enrollment application that was subsequently approved by FFS contractor; or (2) the date an IDTF first started rendering services at its new practice location. We also propose to define "date of filing" as the date the Medicare FFS contractor receives a signed provider enrollment application that the Medicare FFS contractor is able to process for approval.

72 Fed. Reg. at 38170.

This new rule would impose a great hardship on IDTFs, in particular smaller businesses. An IDTF could comply with all the performance standards but may have its enrollment date delayed if the Medicare application is rejected for any reason, including technical errors. Smaller IDTFs will not have the financial resources to wait for delayed enrollment dates. The effective date of billing privileges for an approved application should be the date the Medicare fee-for-service contractor receives a signed provider enrollment application, not "the date that the Medicare fee-for-service contractor receives a signed provider enrollment application that is able to process for approval."

As currently written it is unclear whether the date of filing for an application that may require technical corrections would be 1) when the application was submitted, or 2) when the technical issues had been addressed. We do not think that that the Medicare contractor should be given so much discretion after the application is filed. The Carrier already has the discretion to deny the application. Therefore, we strongly believe that the filing date of the Medicare enrollment application is the date that the Medicare fee-for-service contractor receives a signed provider enrollment application and the phrase "that is able to process for approval" should be deleted from any such definition. Also, rejections and denials of applications should be reasonable, not arbitrary. Furthermore, a contractor may not be able to immediately review an application, and it is unfair to an IDTF include such 'lag time' in the definition of "date of filing."

Recommendations: The effective date of billing privileges for an approved application should be the date the Medicare fee-for-service contractor receives a signed provider enrollment application. CMS should revise proposed 42 C.F.R. § 410.33(i) clarify that (i)(3) is a definition, and the definition should state "The filing date of the Medicare enrollment application is the date that the Medicare fee-for-service contractor receives a signed provider enrollment application." Also, contractor lag-time in reviewing an

application should be excluded when determining what the date of filing is, and CMS should explain which entity will make the decision about initial enrollment dates. In addition, rejections and denials of applications must be reasonable, not arbitrary.

2. Sharing Prohibited

Under the proposed new performance standard at section 410.33(g)(15), IDTFs with fixed-site locations would not be allowed to "share space, equipment, or staff or sublease its operations to another individual or organization." 72 Fed. Reg. at 38171. CMS states that this prohibition applies to supervising physicians, nonphysician personnel, receptionists, and waiting rooms.

We request that CMS further clarify this new performance standard. For example, an IDTF's supervising physician may also be part of a physician group. As currently proposed, this standard may require an IDTF to find a supervising physician who is not part of a physician group. Furthermore, the Proposed Rule is not clear about whether this prohibition on sharing staff applies to supervising physicians who are supervising more than one site (as allowed under the Proposed Rule's revisions to 42 C.F.R. § 410.33(b)(1)). We are not sure whether this new standard would only allow a supervising physician to supervise multiple sites when the sites were all owned by the same entity.

Also, there are situations where an IDTF may share staff, space, or equipment with a related entity. For example, an IDTF may have its own separate office space in a building that is also occupied by its parent company. In this type of situation, there may be a common receptionist at the entrance of the building to direct visitors to the different entities within the building. Also, an IDTF may share a copier or an information technology technician with the parent company. In these types of scenarios, an IDTF is not at risk of committing fraud and abuse.

In addition, we are not able to specifically determine who "nonphysician personnel" would apply to. For example, an IDTF that has its own physical site in an office building might use the same cleaning personnel used by another business in the same office building. Also, as stated above, an IDTF may use the same information technology technician as another entity, such as a parent company or a completely separate company.

By prohibiting these and other similar arrangements, CMS is limiting an IDTF's ability to lower costs through sharing arrangements at a time when reimbursements are being dramatically reduced. Many IDTFs enter into sharing arrangements where no referrals to lower their cost of service, and to provide better and more efficient service for beneficiaries. As our members provide 24-hour, 7-day per week service it is critical to share resources, space, and staff in order to survive, and these sharing arrangements in no way reflect an attempt to undermine the integrity of the Medicare program.

In response to CMS's request for comments on whether this standard should also apply to mobile IDTFs, we recommend that it should not.

Recommendations: CMS should permit an IDTF to share space, equipment, and staff with an entity that is related to the IDTF, such as through common control or ownership. CMS should also clarify in what situations an IDTF could not share staff, in particular supervising physicians and nonphysician personnel. This new performance standard should not apply to mobile IDTFs.

D. Other Comments

The current IDTF performance standards require IDTFs to maintain a physical location:

> The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.

42 C.F.R. § 410.33(g)(3). We request that CMS revise this performance standard to state that the requirements for hand washing and patient privacy only apply to IDTFs that see patients. IDTFs that only perform remote services do not see patients in their facilities, and therefore should not be required to have facilities for hand washing and patient privacy. In the past, CMS has confirmed that these two items (hand washing and patient privacy) are not required for IDTFs that do not see patients.

Also, CMS should clarify that being able to access records electronically fulfills the requirement of storing business and medical records. CMS has encouraged providers to keep records electronically.

Recommendations: Revise 42 C.F.R. § 410.33(g)(3) to state that the requirements for hand washing and patient privacy only apply to IDTFs that see patients. Also, clarify that being able to access records electronically fulfills the requirement of storing business and medical records.

****

We thank you for the opportunity to comment on these important issues. If you have any questions about these comments, please contact our Washington representatives Jim Jorling, Esq. or Rebecca Burke, Esq. at 202-466-6550.

Sincerely,

David Bondietti, Senior Vice President
Biomedical Systems
St. Louis, MO

Phillip Leone
Vice-President
Cardionet
Conshohocken, PA

John Nasuti, President and CEO
ECG Scanning & Medical Services, Inc.
Dayton, OH

Richard Edwards, Owner & CEO
Life Support Systems, Inc.
Clearwater, FL

Leigh Ann Kelly, Vice President
LifeWatch, Inc.
Rosemont, IL

Dan Balda, MD, President
Medicomp, Inc.
Melbourne, FL

Frank Movizzo, CEO
Mednet Healthcare Technologies, Inc.
Ewing, NJ

Angie Nauful
PDSHeart
West Palm Beach, FL

Robert Sass, General Manager
Raytel Cardiac Services, Inc.
Windsor, CT

Submitter : **Ms. Erin Weaver** **Date: 08/31/2007**

Organization : **Charleston Southern University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I work at Charleston Southern University as an Assistant Athletic Trainer. I cover Women's Soccer and Track and Field.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Erin Weaver, ATC

Submitter : Mrs. Lauren Rubinson **Date:** 08/31/2007

Organization : Medical Express Ambulance Service

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15308-Attach-1.DOC

CMS-1385-P-15308-Attach-2.DOC

15308

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Re: CMS-1385-P: "Geographical Price Cost Indices"

Dear Mr. Kuhn:

This letter serves as our comments on the "Geographical Price Cost Indices" section of the Proposed Rule (CMS-1385-P). Our organization strongly opposes any reductions in Medicare reimbursement for ambulance service providers which would have an adverse impact on patient access to vital emergency and non-emergency ambulance care. The Proposed Rule would unfortunately cause that exact effect in areas where providers would receive lower reimbursement as a result of the updated Geographical Price Cost Index (GPC) figures.

While we recognize the statutory requirement for CMS to update the GPCI, any reductions in reimbursement would be in direct contradiction to the findings of the May 2007 Government Accountability Office (GAO) report entitled "Ambulance Providers: Costs and Expected Medicare Margins Vary Greatly" (GAO-07-383) which determined that Medicare reimburses ambulance service providers on average 6% below their costs of providing services and 17% for providers in super rural areas. For those ambulance service providers who would receive lower reimbursement as a result of the changes to the GPCI, the Proposed Rule will further exacerbate the problems already caused by below-cost Medicare reimbursement.

The GAO recommended that CMS monitor the utilization of ambulance transports to ensure that negative Medicare reimbursement does not impact beneficiary access to ambulance services. We believe that the Proposed Rule would have a considerable impact on beneficiary access in all areas adversely affected by the changes in the GPCI. We implore CMS to take this into consideration as it finalizes the Proposed Rule and alleviate any harmful impact these changes in the GPCI will have on providers while ensuring that those

providers who would benefit from the changes receive the proposed increases which are desperately needed.

While the GPCI is the representative of all goods and services, Chicago, IL and its surrounding suburbs have some of the highest gas prices in the nation. For an ambulance service provider that is a disproportionate amount of our operation costs.

Thank you for your consideration of these comments

Sincerely,

Submitter : Jullia Lonergan **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15309-Attach-1.DOC

15309

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Jullia Lonergan
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Dr. Richard Hellman** **Date: 08/31/2007**

Organization : **American Association of Clinical Endocrinologists**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment which contains comments on multiple issues addressed in the proposed rule for the 2008 Medicare Physican Fee Schedule.

CMS-1385-P-15310-Attach-1.DOC

15310

American Association of Clinical Endocrinologists

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August 31, 2007

Mr. Kerry Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
7500 Security Boulevard,
Baltimore MD 21244-1850

RE: CMS-1385-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 and Other Changes to Payment Under Part B; Proposed Notice

Dear Mr. Weems:

The American Association of Clinical Endocrinologists (AACE) represents over 6000 endocrinologists in the United States and around the world, and it is the largest association of clinical endocrinologists in the United States. AACE members concentrate on the treatment of patients with endocrine and metabolic disorders and are committed to providing the highest quality of care to the patients they serve. AACE appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Notice on the revisions to Medicare Part B payment policies under the Physician Fee Schedule for calendar year 2008, published in the July 12, 2007 *Federal Register*.

CPT code 77080 – Central DXA for Bone Mass Measurement

Summary

Osteoporosis causes fractures in approximately half of women and one quarter of men. Over 20% of adults who sustain a hip fracture die within the following year and many more never regain independence. Annual direct health care costs for fracture care in the United States currently approximate $16.9 billion a year and are projected to exceed $25 billion by 2025. Despite the epidemic proportions of osteoporosis, the test used to diagnosis this preventable disease, and hailed by the Surgeon General in 2004, as "one of the most significant advances in the last quarter century," is in danger of not being offered as a result of Medicare payment policies. The test, DXA (Dual Energy X-Ray Absorptiometry) (CPT code 77080), is critical for the diagnosis of osteoporosis and monitoring the response to treatment.

The current Medicare Physician Fee Schedule reimbursement for DXA has been a concern for those working on the quality and safety issues surrounding osteoporosis diagnosis and management. There is widespread agreement that severe gaps in care exist for patient with osteoporosis. This is a national concern. As a result, in 2006, the Physician Consortium for Performance Improvement (Consortium) developed a physician performance measure set to address these gaps in care surrounding osteoporosis diagnosis and management, and referred the measure set to the National Quality Forum (NQF) for approval and implementation by appropriate organizations. The Consortium and NQF agreed that the central issue was underdiagnosis of osteoporosis. Current estimates are that only 20% of patients with osteoporosis are aware that they have the condition and need appropriate treatment and follow-up. The incorporation of the osteoporosis measures into the Physician Quality Reporting

Program (PQRI) measure set further highlights the need to correct the multiple problems in osteoporosis diagnosis and treatment in the United States today. However, since proper diagnosis is a prerequisite for decisions on therapy, DXA studies are the necessary first step for appropriate decision making regarding therapy. In 2006, only 9.4% of women enrolled in Medicare were being tested. It is clear that an increase in the numbers of DXA studies being done will be a necessary first step if we are to improve this gap in medical care. Paradoxically, the current payment policies are projected to decrease the numbers of patients receiving DXA measurement. It can be reasonably anticipated that this will worsen the gap in care and increase the number of preventable fractures. **(Please see attached Commentary)**

The 40% reduction in the Medicare Physician Fee Schedule reimbursement for DXA in a non-facility setting (implemented in 2007 with the Deficit Reduction Act) has already caused some physicians and, more worrisome, some large, low cost providers of DXA services to discontinue offering this vital service. By 2010, DXA reimbursement will have dropped 75%. With reimbursement far below operating costs, this essential preventive service will largely disappear from the non-facility environment, as over 90% of physicians have indicated that they will stop performing DXA studies by 2010. The current DXA payment policy contradicts CMS prevention efforts and initiatives, such as the Physician Quality Reporting Program (PQRI), to enhance quality of care in the Medicare program. DXA is considered the "gold standard" for the diagnosis of osteoporosis and is a recognized quality measure under the CMS PQRI for osteoporosis screening and therapy for women aged 65 years and older, and for management following a fracture. Compliance with these quality measures depends heavily upon the availability of DXA scans and the ability of the physician to get the patient to have a DXA scan.

Most patients who need evaluation for osteoporosis to prevent morbidity, mortality and increased costs to Medicare are not receiving timely diagnosis and appropriate treatment. According to CMS claims data, approximately 20% of eligible Medicare beneficiaries are currently being diagnosed as the result of receiving a DXA scan.

AACE supports the public education campaign initiated by the Department of Health and Human Services (HHS) earlier this year to improve osteoporosis care and emphasize the importance of early diagnosis to prevent fractures. The current Medicare payment policy for DXA however, will decrease access and exacerbate the very problem the public education campaign is trying to correct.

We will provide information regarding methodology and results from three surveys AACE has participated in within the last 16 months that identify flaws in data input, data omission, and erroneous assumptions that have contributed to the incorrect calculation of reimbursement for DXA .These surveys include the following:

- a clinical society survey in 2006 of physician work and direct practice expense,
- a clinical society survey in 2007 of physician responses to the scheduled DXA reimbursement cuts to be phased in over the next 4 years
- an analysis of the total cost of providing DXA in the office-based, non-facility setting performed by the Lewin Group

When more appropriate values are input for physician work, direct and indirect practice expense, the reimbursement for DXA more closely approximates the 2006 Medicare reimbursement rate of $139. This figure is also close to the Lewin cost estimate of $134 as well, which encompasses expenses per procedure for physician work, practice expense and malpractice expense.

AACE, in conjunction with the American College of Rheumatology (ACRh), the International Society for Clinical Densitometry (ISCD) and The Endocrine Society (TES) commissioned the Lewin Group to conduct a survey of physicians in the non-facility setting. One of the purposes of this study was to determine the true operating costs for DXA and VFA. The Lewin Group concluded that DXA operating costs in the non-facility setting were $134, far exceeding not only CMS recommendations for reimbursement in 2010 but also current (2007) reimbursement rates.

While CMS has an obligation to review all comments received during the rule making process, the stakes are particularly high for DXA. We call on Medicare to carefully consider the requests contained in this document as this particular payment policy will undermine a major aspect of the agency's preventive health care agenda as it relates to osteoporosis care. Moreover, if DXA is not fairly valued and the operating costs are grossly underestimated, then CMS is not serving the people's mandate as articulated by the Medicare Payment Advisory Committee (MedPAC) in their March 2007 report to Congress:

"The Commission is concerned that differences in the profitability across physician services create financial incentives for physicians to favor furnishing some procedures and services over other, less profitable ones. In this environment, beneficiary access to relatively undervalued services-and to the providers that perform them—may be threatened. Misvalued services should be identified and payments corrected....Also, revisiting the RBRVS may be needed to explore the possibility of including other factors—in addition to input costs—in the pricing of individual services."

Undervalued services, especially those involving costly technology, often will result in a decline in volume. In the case of DXA, this would undermine CMS' own efforts to improve recognition of osteoporosis through increased DXA testing.

AACE requests that CMS reevaluate the following:

1. The Direct Practice Expense RVU for 77080 (DXA):

   A) The equipment type for DXA should be changed from pencil beam to fan beam with a corresponding increase in equipment cost from $41,000 to $85,000; (Clinical Society Survey 2006; Lewin Group survey 2007)

   B) The utilization rate for preventive health services involving equipment designed to diagnose and treat a single disease should be calculated in a different manner than other utilization rates so as to reflect the actual utilization of that service. In the case of DXA, the 50% utilization rate should be changed to reflect the actual utilization rate for DXA of 13%; (Lewin Group Survey)

   C) The technician time to perform a DXA study should be increased from 31 minutes to 43 minutes as approved by the RUC in April of 2007. Current CMS documents fail to reflect this change.

   D) Maintenance contracts for DXA should approximate 8%, not the 5% as listed, reflecting current costs (Clinical Society Survey 2006).

2. The Physician Work RVU for 77080 (DXA) should be increased from 0.2 to 0.5, consistent with the most comprehensive survey data available (Clinical Society Survey of 2006).

3. Application of section 5012 (b) of the Deficit Reduction Act of 2005 to DXA CPT Code (77080). We believe DXA should not be considered an imaging service within the meaning of this section of the law.

4. The flawed direct practice expense inputs and the work value assigned to DXA should be revised based on current survey data in order that DXA is appropriately valued and reimbursed.

1. <u>Direct Practice Expense Issues</u>

A) Equipment Cost for CPT code 77080

DXA is used to measure bone mass as a test for osteoporosis and is also used to monitor response to treatment. Physicians who provide central DXA predominantly use a fan beam DXA which reflects

newer technology and is, therefore, the preferred equipment over the older, obsolete pencil beam machine. The fan beam DXA machine costs $85,000 as opposed to the older pencil beam instrument, which cost $41,000. In the final rule published for the 2007 Physician Fee Schedule, CMS appropriately recognized the newer, preferred fan beam equipment and incorporated the $85,000 equipment cost in calculating practice expense.

In CMS-1385-P published in the July 12, 2007 *Federal Register*, the equipment cost listed for central DXA was changed back to $41,000 with no explanation given. Since the publication of the proposed rule, it has been discovered that the revision to the equipment cost was forwarded by the RUC, was based on an inadvertent typographical error on a spreadsheet submitted on behalf of several clinical societies to the RUC for a discussion about technician time at the February 2007 RUC meeting. The code for the pencil beam equipment (ER024) was incorrectly listed on the spreadsheet for CPT codes 77080 and 77081 (peripheral DXA). The issue of equipment cost was not raised during the discussion at the February 2007 RUC meeting and, as a result, the error on the spreadsheet was not noticed until just recently.

Several surveys of central DXA providers confirm the wide-spread use of the newer fan beam equipment. Last summer, a multi-clinical survey of 453 practitioners conducted by the International Society of Clinical Densitometry (ISCD) in cooperation with AACE, the American Society for Bone and Mineral Research, (ASBMR), The Endocrine Society (TES), the North American Menopause Society (NAMS), and the American College of Rheumatology (ACRh) revealed that 93% of respondents have the fan-beam axial DXA system valued at $85,000. Only 7% of survey respondents currently use the older pencil-beam system valued at $41,000.

Moreover, the multi-specialty survey conducted by the Lewin Group this summer reported that eighty-one percent (81%) of the 163 respondents indicated use of the fan beam equipment in their office.

Clearly, the fan beam is the predominant piece of equipment used to perform a central DXA and should be incorporated into the calculation for practice expense. Our clinical societies will be raising this issue at the September RUC meeting and will ask that they forward a recommendation to CMS that corrects this inadvertent equipment cost error.

We urge CMS to correct the equipment cost for CPT codes 77080 and 77081 by reinstating the $85,000 cost for the fan beam instrument as part of the practice expense calculation in the final rule for the 2008 Physician Fee Schedule.

B) Utilization Rate

Medicare currently assumes that all imaging equipment is in use 50% of the time, including central DXA. Applying a 50% utilization rate to all procedures ignores the fact that imaging procedures, such as DXA used strictly for osteoporosis testing and treatment, are unlikely to be utilized as much as an MRI or CT used to detect and diagnose a variety of diseases. Indeed, in its June 2006 report, the Medicare Payment Advisory Committee (MedPAC) stated that in six major markets surveys show that MRI and CT equipment is operated significantly more than 50% of the time. (MRI utilization rate on average is 90% and CT utilization rate on average is 70%).

Unlike these high volume procedures where patients are referred to dedicated imaging centers, central DXA in the non-facility setting is performed by endocrinologists, gynecologists, internists, family practitioners, and rheumatologists and offered as point-of-care service. Based on 2002 Medicare data, 70% of DXA studies are performed in office (30% in hospital settings) and 60% are performed by non-radiologists.

From the point of view of the patient, decentralization of the site of DXA measurement appears to be a much more convenient and effective way to receive testing, diagnosis, and treatment. There is

evidence that with more options of sites for diagnosis, although there are fewer tests done per facility, the total number of tests increases. Since the primary problem in the United States is underdiagnosis, decentralization and an increase in the number of facilities is an appropriate strategy, providing the quality of care at each facility can be assured, by appropriate use of physician performance measurement.

By providing these services in the physician office, the health care provider who best knows the patient's medical history and current condition can perform a central DXA, interpret results and initiate treatment, if necessary, in the scope of one office visit. Consequently, the volume of procedures performed in physicians' offices will tend to be lower than in imaging centers.

The multi-specialty survey conducted by the Lewin Group confirms an even lower utilization rate of 13% for central DXA. The median number of DXA procedures performed by respondents in this survey was 768 per year, or 64 procedures per month. Practices indicate that DXA was available on average 1519 hours per year out of the average hours practices are open of 2190 (or 69% of the time). For DXA procedures, this results in an overall utilization rate of 13% (192 hours per year / 1519 available hours)

However, it is important to recognize the efficiencies and quality of care that occurs in the physician office setting by eliminating referrals for DXAs that result in multiple service encounters, additional claims and increased administrative paperwork. More importantly, patients are much more likely to have a DXA and be diagnosed if the service is convenient. Patients are less likely to be diagnosed if it is a burden or inconvenient to seek an appointment for a DXA referral in another location at a later date.

Patient access to diagnostic and therapeutic services such as central DXA in the physician's office represents high quality, cost-effective care. We understand that utilization of imaging equipment is under review due to concerns about over-utilization or inappropriate utilization of imaging services. We suggest that these concerns simply are not relevant to the performance of central DXA.

As previously mentioned, CMS data indicates that two-thirds of DXA machines used for bone mass measurement in testing for osteoporosis and determining efficacy of treatment are in physician offices, as opposed to the remaining one-third that are located in the hospital setting. As previously mentioned, CMS claims data indicates that less than 20% of Medicare beneficiaries eligible to have a DXA actually receive this procedure. Clearly this is not a procedure that is typically overutilized and abused for illegitimate claims or expenses.

Numerous studies point to the benefits of early testing to prevent fractures and avoid costly treatment and services. DXA is recognized by the medical community as the preferred bone mass measurement test and is a recognized quality measure under the CMS Physician Quality Reporting Initiative (PQRI) for osteoporosis screening and therapy for women aged 65 years and older, and for management following a fracture.

As CMS pursues quality enhancement initiatives throughout the Medicare program, policies should promote and not curtail the use of an identified quality indicator for osteoporosis care.

We request that CMS adopt a different method for calculating the utilization rate for imaging services based on procedure specific data as opposed to the current one size fits all approach. CMS should consider the importance of the preventive benefits it promotes as part of the agency's disease prevention and health promotion activities when looking at assigning appropriate utilization rates, particularly if those preventive benefits – like DXA - are currently underutilized. A more appropriate utilization rate for DXA is 13%.

C. Technician Time

In December, 2006, CMS invited interested parties to present concerns about DXA practice expense issues to the RUC for review. In February, 2007, AACE, along with the International Society for Clinical

Densitometry (ISCD), the American College of Radiology (ACR) the American College of Rheumatology (ACRh), and the Endocrine Society (TES) requested that the non-physician work time allocated to DXA should be increased to 43 minutes based on results from the ISCD clinical society survey. This recommendation was approved at the RUC April 2007 meeting.

AACE urges CMS to increase the technician time to perform a DXA study from 31 minutes to 43 minutes as approved by the RUC in April of 2007.

D. Maintenance Rate

CMS currently applies a rate of 5% for the cost of contracts for equipment maintenance. The results of the clinical society survey of 2006 concluded that median service contracts cost $5,000 and that software upgrades cost $2,000 per year. These expenses, however, have not been accounted for in the calculation of equipment maintenance. We believe that the current equipment maintenance figure of 5% should be increased to a more appropriate 8%.

We request that CMS re-evaluate the cost of maintenance contracts and apply a more appropriate cost rate of 8% for equipment maintenance.

2. Physician Work RVU

As part of the five-year review process all procedures paid under the Medicare Physician Fee Schedule, The American College of Radiology (ACR) conducted a survey of 51 radiologists regarding the physician work component for DXA Radiologists comprise only 40% of physicians performing the procedure and less than 25% of those physicians submitting claims in 2004 in the non-facility setting. The survey concluded that the work RVU for DXA remain at 0.3. Subsequently, a working group comprised of six RUC members recommended that the work value be reduced 0.3 to 0.2. (the 25th percentile of the ACR survey) stating that "...the (RUC) workgroup believed that the actual work is less intense and more mechanical than the specialty society's description of the work." This RUC subcommittee was comprised of a vascular surgeon, anesthesiologist, general surgeon, pulmonologist, psychiatrist, and a family practitioner. Only one of these physicians, the family practitioner, could be expected to be knowledgeable about DXA interpretation. Reflecting their lack of knowledge that quality DXA interpretation requires specialized knowledge and expertise the subcommittee inappropriately substituted their personal opinion for empirical survey data.

In CMS proposed rules regarding the 2007 Physician Fee Schedule issued in August and October of 2006, (CMS-1512-P and CMS-1321- P), CMS adopted the RUC recommendation to reduce the physician work RVU for DXA. Several clinical societies, patient advocacy groups and other interested stakeholders urged CMS to reconsider the reduction in the work RVU. The clinical society survey referenced earlier in these comments, which was almost identical to the 2005 ACR RUC survey, supported this recommendation.

Briefly, this survey of 453 physicians from multiple specialties who perform DXA concluded the Physician Work RVU should be **increased** from 0.2 to 0.5, which is substantially higher than the median work RVU of 0.3 recorded in the ACR survey. The responding physicians noted that DXA complexity has increased, rather than decreased. These survey results clearly refute the perception of mechanical simplicity apparently underlying the proposed, and subsequently implemented, reduction in work RVU from 0.3 to 0.2. A comprehensive analysis of DXA results and report is both complex and time consuming. We recommend that the RVU be set at a level appropriate for a detailed analysis and that a performance measure be developed for accountability to be sure that the analysis is appropriate and thorough.

In response to the large number of comments on this issue, CMS convened a Refinement Panel to consider the work RVU for DXA and VFA on September 26, 2006. CMS asked the American College of Rheumatology to present information regarding the reduction in work RVUs to the panel. In

summary, the American College of Rheumatology presented information from both surveys- the ACR survey of 51 radiologists that supported maintaining the work RVU at 0.3 and the clinical society survey of 453 physicians that supported increasing the work RVU to 0.5. The Refinement Panel rejected all empirical survey data presented and affirmed the CMS proposal to reduce the work RVU to 0.2.

AACE urges CMS to increase the physician work RVU for 77080 (DXA) from 0.2 to 0.5, consistent with the most comprehensive survey data available (Clinical Society Survey of 2006).

3. Section 5102 of the Deficit Reduction Act of 2005

The proposed rule references the definition of imaging services under Section 5102(b)(1) of the Deficit Reduction Act (DRA). In addition, it sets out the criteria and analysis to determine which imaging services will be included in order to implement the DRA as well as those imaging services that are to be exempt from the DRA's definition.

Under the DRA, imaging services are defined as "imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography". In the rule, CMS articulates the analysis that it will use to determine which CPT codes are to be included under the DRA definition, as well as those codes that are to be considered exempt from the law. CMS states, "we believe that imaging services are those that provide visual information, thereby assisting in the diagnosis or treatment of illness or injury".

CMS notes the following procedures as examples of exceptions to the definition of imaging services under the Act: bronchoscopy with or without fluoroscopic guidance and upper gastrointestinal endoscopy with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s). CMS articulates the rationale for these exceptions: **"In these cases, we are unable to clearly distinguish imaging from non-imaging services because, for example, a specific procedure may or may not utilize an imaging modality, *or the use of an imaging technology cannot be segregated from the performance of the main procedure.*" (emphasis added).**

Therefore, applying this CMS analysis, CPT Code 77080 (DXA) should be excluded from the definition of imaging services in the diagnosis and treatment of osteoporosis. The DXA test uses equipment that produces a numerical value of bone mass (in units of gram/cm.^{2}) which is compared to young normal controls to derive a T-score). This number is used to diagnose bone disease. Although the DXA equipment also generates an image, the image itself is not used to diagnose bone disease and therefore cannot be segregated from the main procedure which forms the basis for the diagnosis.

We request that CMS reverse its earlier decision and exclude CPT Code 77080 (DXA) from the definition of imaging services under the DRA.

4. DXA Operating Costs – The Lewin Group Survey

AACE, along with the International Society of Clinical Densitometry (ISCD), the American College of Rheumatology (ACR), and The Endocrine Society (TES), commissioned The Lewin Group to survey office-based providers of dual energy x-ray absorptiometry (DXA) to develop estimates of the costs associated with providing the DXA services.

From the basis of the provider, Lewin was asked to estimate all costs associated with providing DXA, including practice expense, malpractice expense and physician work. Practice expense and malpractice expense estimates were generated by a Lewin Group survey. The methodology used in this analysis is detailed in Appendix A to this report. The survey document is contained in Appendix B to this report.

Physician work estimates were based on a separate clinical survey of multi-specialty densitometry professionals, which provided time required for clinical input (in minutes) for all aspects of DXA provisions. These components were summed to yield total costs. Finally, Lewin compared these costs to the global reimbursement for DXA services in the office-based setting.

Findings

The Lewin analysis yields a 2007 median total cost per procedure for DXA of $134.13; $5 less than the 2006 Medicare reimbursement and about $50 more than the 2007 reimbursement. The 2007 payment of $82 represents 61% of our median cost estimate. This payment level also represents 86% of the 25th percentile cost ($95.07) and 42% of the 75th percentile costs ($195.02) (Figure 1).

Figure 1: Ratio of 2007 Payment to Cost per DXA Procedure by 25th, 50th and 75th Percentile

25th percentile	$95.07	$82	$13.07	360	86%
50% (Median)	$134.13	$82	$52.13	768	61%
75th percentile	$195.02	$82	$113.02	1572	42%

In 2007, only 14% of respondents are being reimbursed by Medicare at or above their costs. No provider will be adequately reimbursed at the fully implemented payment rates in 2010 of $35.

There is a wide variation in the cost of providing DXA procedures, with a minimum value of $42.57 and a maximum value of $788.09 (Figure 2).

Figure 2: 2007 Median Cost per DXA Procedure

		Cost per Procedure		
DXA	768	$134.13	$42.57	$788.09

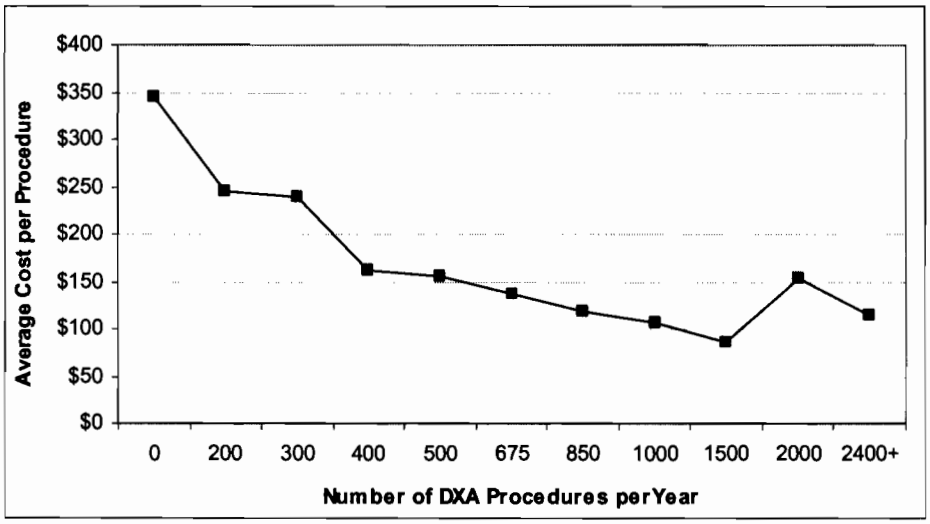
As Figure 3 demonstrates, there is an inverse relationship between average cost per procedure and the number of DXA procedures performed per year. There is a steady decrease in the average cost per procedures as practices increase the number of procedures performed per year, until they reach 1500 procedures per year. Procedures in excess of 1500 per year often have a higher per procedure cost, possibly attributed to the extra fixed costs and overhead that is associated with operating a practice that can handle the capacity. Providers with high procedure volume are typically identified as efficient and operating with fewer costs per procedures. Across all practices represented in the survey, there is an overall utilization rate for DXA machines of 13%, defined as total annual hours equipment is used for patient-care divided by total annual hours equipment is available for DXA.

Of those practices that have costs under $82, they perform, on average, 2125 procedures per year. This average number of procedures per year is influenced by a number of practices performing DXA in excess of the 90th percentile of procedures performed in a year. This procedure volume is significantly higher than the median number of procedures performed per year of 768, or approximately 3 procedures per day. There are still many providers, however, that are contained in the 86% of providers who have costs that are not covered by payments.

As a result, industry research indicated that many large providers have closed their doors and eliminated DXA as a provided service. (We noted these closures during the conduct of our survey.) After accounting for cost inflation and the continual decline of DXA payments through 2010, even fewer

providers will be able to sustain providing DXA services to Medicare beneficiaries in the coming years. The active closure of larger, efficient providers validates our study in that providers typically are not adequately reimbursed for performing DXA.

Figure 3: Relationship between Number of DXA Procedures Performed and Average Cost per Procedure



a. Sensitivity Analysis

In creating the NPRM, CMS assumed indirect expenses account for 63% of the total practice expense. Indirect as direct expenses are defined as the following:

Figure 4: Components of Practice Expense, Indirect and Direct

Non-clinical (administrative) labor	Direct labor for clinical personnel
Office Space	Equipment Expenses
All other expenses not related to directly performing the procedures	Medical Supplies and Equipment

Results of the Lewin survey yield a median indirect percentage of 36% of the total practice expense cost, or $34 dollars of the median cost of $134. This may be slightly conservative since some portion of the clinical personnel expenses excluded from our analysis may be attributed to indirect labor. Overall, practice expense represents 70% of the total DXA per procedures cost. As a test of sensitivity, we imputed the survey data to reflect the CMS distribution of direct and indirect costs.

Figure 5: Allocation of Practice Expense by Allocation Methodology, Lewin Survey vs. CMS NPRM Inputs

		Practice Expense			Physician Work	Malpractice
Lewin Survey	$134.13	$34.17	$60.12	$94.29	$38.49	$1.34
CMS NPRM	$202.33	$102.37	$60.12	$162.50	$38.49	$1.34

CMS methodology yields a total cost of $202 per procedure, with $152 allocated to practice expense (Figure 5). Furthermore, this imputation results in an indirect cost per procedure of $102.37, about $68 higher than the Lewin results demonstrate. Overall, this analysis yields a higher total cost per DXA procedure of $202.33 compared to the Lewin analysis of $134.13.

The 2007 multi-specialty survey of densitometry professionals from AACE, ACRh, ISCD and TES measured the potential impact of DXA reimbursement cuts being phased in over the next four years as part of the Medicare Physician Fee Schedule. Seven percent (7%) of the 757 respondents indicated that they have already discontinued performing DXA studies in their office. Thirty-seven (37%) responded that they would stop performing DXA by the end of 2007 and 73% indicated the payment cuts will cause them to curtail professional development and quality enhancement activities (i.e. CME and facility accreditation) in the field of osteoporosis. By 2010 when the Medicare Physician Fee Schedule cuts are fully realized, 93% of the 757 physicians indicated they will no longer provide DXA services.

As noted from this survey, cuts in DXA reimbursement are already impacting patient access to care. Although smaller clinics with less efficient operations and smaller volumes of studies will be significantly impacted, larger clinics are not immune from these cuts. For example, the largest osteoporosis center in the state of New Jersey which performed over 6,000 studies annually has cut its services dramatically due to reduced reimbursement. A facility in Boston that performs over 7,000 studies in three separate locations has cancelled their purchase of an additional machine at one location. In the Florida panhandle, a clinic that served patients in rural areas with mobile vans closed in March.

The elimination of services by many DXA office-based providers will create significant issues related to patent access to this preventive service and result in the failure of CMS disease prevention efforts.

The Lewin Group also conducted a Congressional Budget Office (CBO)-style scoring analysis of 5 year costs to Medicare if the DRA and Medicare Physician Fee Schedule reimbursement cuts were reversed, thus restoring the DXA reimbursement rate to the 2006 level of $139. The Lewin analysis found that program costs over a five-year period resulting from the increase in direct DXA payment would equal $648 million. However, after accounting for savings associated with avoided fractures and the cost of treating at-risk individuals, restoring DXA payments will actually save the Medicare program $1.14 billion over the same five year period. (See Appendix C - Executive Summary of the scoring analysis and a discussion of the analysis methodology and model prepared by the Lewin Group)

The survey concluded that limiting patient access to a DXA procedure is contrary to federal prevention initiatives that seek to increase the number of women diagnosed and treated for osteoporosis, and likely to increase the burden of osteoporotic fractures in terms of personal injury and costs to the health care system. What may appear to be short term cost savings will actually increase Medicare program costs significantly if DXA reimbursement is cut below operating costs and is no longer performed in the physician office.

We urge CMS to review the flawed practice expense inputs and re-evaluate the work value assigned to DXA in order that DXA is appropriately valued and reimbursed, consistent with the findings of the Lewin Group survey.

Education and Training for Patient Self-Management

AACE would like to take this opportunity to revisit a specific coding issue related to education and training for patient self-management. CPT® 2007 includes the following codes for the reporting of education and training for patient self-management:

98960 Education and training for patient self-management by a qualified, non-physician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient

98961 2–4 patients
98962 5–8 patients.

In the final rule for 2007, CMS assigned a status indicator of "B" for these services, stating "they are bundled into another covered service under Medicare." We question this conclusion and would like to note that these services would seem to fit into the Medicare statutory benefit category of "incident to" services. Also, there should be no question about the clinical value of these services for patients with conditions such as diabetes and asthma where education and training have been demonstrated as contributing to improved health outcomes and where such services have been incorporated into nationally recognized clinical practice guidelines, including some developed and disseminated by the National Institutes of Health.

CMS has recognized the importance of diabetes outpatient self-management training services by conforming CMS regulation in the current proposed rule to be consistent with Section 5114 of the Deficit Reduction Act of 2005 (DRA) that adds diabetes self-management training services to the list of Medicare covered and reimbursed services under the Medicare Federally Qualified Health Center benefit. AACE commends CMS for this action and asks that the same consideration be given to diabetes outpatient self-management training services when billed under the Physician Fee Schedule.

Coverage of codes 98960 – 96962 will support the implementation of this benefit through the physician office and will improve access to proper medical care and prevent delayed disease complications. Furthermore, several private insurance carriers are recognizing the importance of this patient education service and are reimbursing physicians for these codes. CMS already supports G0108 and G0109 codes and these codes extend that principle of providing and documenting nationally approved curricula for the improvement of our patients' health.

AACE requests that CMS reconsider its decision and change the status of these codes from "bundled" to "active" and separately payable under the Medicare Physician Fee Schedule. The AMA Relative Value Update Committee (RUC) recommended RVUs could then be considered for assignment to these codes.

Work Budget Neutrality Adjustment

As a result of increasing the work RVUs for anesthesia services by 32% as recommended by the RUC, a budget neutrality adjustor (0.8816) will be applied to all physician work RVUs for all codes in the Medicare physician fee schedule as proposed in CMS-1385-P. AACE acknowledges that by law, CMS must implement work RVU adjustments on a budget neutral basis.

AACE believes that implementing the budget neutrality adjustor by changing the conversion factor is a more favorable approach because it would: (i) have less impact on other payers who use the Medicare RBRVS, along with their own conversion factor; (ii) be consistent with the notion that budget neutrality is mandated for monetary reasons, and since the conversion factor is the monetary multiplier in the Medicare payment formula, this is the most appropriate place to adjust for budget neutrality; and (iii) be consistent with CMS' goal of transparency in the Medicare payment system.

AACE urges CMS to re-consider this proposal and apply the budget neutrality adjuster to the physician fee schedule conversion factor.

Sustainable Growth Rate (SGR) Issues

AACE believes the Medicare Sustainable Growth Rate (SGR) formula used to calculate annual physician payment updates is flawed and should be repealed. Physicians once again face an annual cut in reimbursement – calculated at 9.9% in 2008 – based on a methodology that has no bearing on the medical needs of patients or the cost of providing care.

AACE continues to work with the AMA, on behalf of organized medicine, in urging Congress to pass legislation to replace the SGR formula with a system that reflects actual physician practice costs. Continued utilization of this formula and failure to enact meaningful fixes to the system will negatively impact quality through limited access to care.

Until Congress acts to replace the SGR, AACE urges CMS to use its administrative authority to make adjustments to the SGR methodology, such as removing Part B drug payments from the calculation of expenditures and including the full cost of new Medicare benefits and coverage decisions in the SGR target. Congressional leaders from both parties have called on CMS to take similar action through correspondence and more recently by incorporating this action in legislative language.

AACE urges CMS to take these necessary administrative steps to mitigate the 9.9% physician payment cut scheduled for 2008. The promise of health care made to older Americans will be undermined if annual physician payment cuts resulting from the SGR formula are not addressed.

AACE appreciates this opportunity to comment on these important issues. We welcome any further dialogue with CMS regarding the issues we have outlined in this letter. Please contact me at rhellman@nkcendo.com or (816) 421-3700, or Sara Milo at smilo@aace.com or 904-353-7878 with any questions.

Sincerely,

Richard Hellman

Richard Hellman, MD, FACP, FACE
President

Attachments:
Commentary
Appendix A – Lewin Group Survey Methodology Discussion
Appendix B – Lewin Group Survey Instrument
Appendix C - Lewin Executive Summary of Scoring Analysis

cc: Mr. Herb Kuhn, Acting Deputy Administrator, CMS
Mr. Donald Thompson, Center for Medicare Management, CMS

Commentary regarding the quality and safety issues regarding osteoporosis diagnosis and care in the United States

Richard Hellman, MD, FACP, FACE
Clinical Professor of Medicine, University of Missouri-Kansas City School of Medicine
President, American Association of Clinical Endocrinologists
Member, Executive Committee, Physician Consortium for Performance Improvement

In 2006, the Physician Consortium for Performance Improvement voted to proceed with a performance measure set in osteoporosis. Their primary reason was that osteoporosis care in the United States is so seriously deficient, that the gaps of care had reached a point that was considered a very high priority for quality improvement and increased accountability of the physicians and clinics. The data was startling. 80% of those with osteoporosis were undiagnosed. Even when a woman of Medicare age was admitted to the hospital following an osteoporotic hip fracture, nearly 75% of the time after surgery was performed, the patient would leave the hospital either without a diagnosis of osteoporosis or without appropriate treatment for osteoporosis. Other studies indicate that the degree of underdiagnosis of osteoporosis among men is even higher, and by age 80, the incidence of osteoporosis in men roughly approximates that in women.

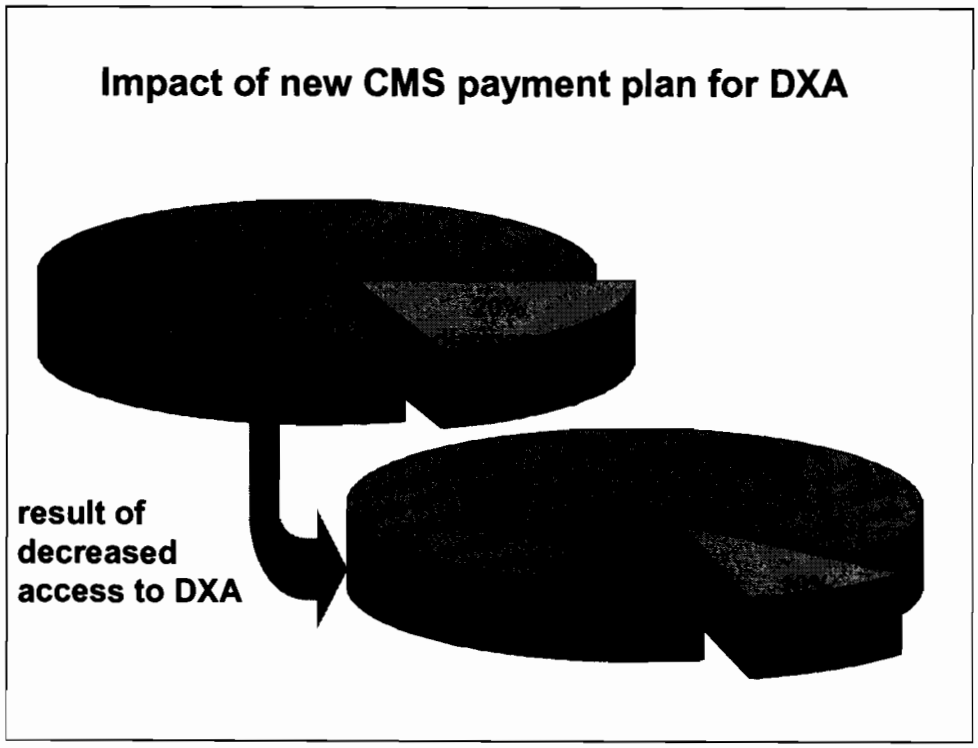
Five organizations asked to be co-leads for the measure set that was being developed: the American Association of Clinical Endocrinologists, the American Academy of Family Physicians, the American College of Rheumatology, the American Academy of Orthopaedic Surgeons, and The Endocrine Society. The co-chairs of this Work Group were Dr. Steven Petak, President of the American Association of Clinical Endocrinologists and Past President of the International Society for Clinical Densitometry, and Dr. Kenneth Saag from the American College of Rheumatology. The Work Group was diverse in composition, including patient care representatives, such as the National Osteoporosis Foundation, as well as all the major bone organizations. The measures developed were unanimously approved by the Physician Consortium for Performance Improvement, which is a multi-specialty umbrella organization, and sent to the National Quality Forum (NQF) for review. NQF, which represents consumers, employers, insurance companies, and providers, quickly approved the accountability measures, and four were chosen by CMS for the 74 measures selected for the Physician Quality Reporting Program (PQRI). CMS has made it clear that osteoporosis diagnosis and treatment is a high priority because of the severe gap in care and the safety issues that have resulted from the largely preventable fragility fractures and the consequential morbidity and mortality.

The four measures include screening or therapy for women age 65 or older, osteoporosis diagnosis and management following fracture, pharmacologic treatment of osteoporosis, and counseling for vitamin D and calcium intake, and exercise. All four accountability measures were previously identified by the Physician Consortium and NQF as areas where suboptimal care was being provided and improvement was urgently needed. All four measures depend directly or indirectly upon DXA measurement for the diagnosis of osteoporosis. The first two explicitly report CPT-II codes indicating either a DXA ordered or results documented. The last two implicitly report DXA, because reporting of the therapy depends upon the correct diagnosis of osteoporosis.

Since most patients who currently need evaluation and appropriate treatment for osteoporosis are not receiving a timely diagnosis and appropriate treatment, correcting the gaps in care depends heavily on the availability of DXA measurement. Because patients often consider screening for osteoporosis a relatively low priority, since osteoporosis without complications is largely asymptomatic and their perception of risk is lower, the closer and more convenient the testing site is to the point of care the higher the likelihood that the patient agrees and has the test performed. It appears that the DXA measurement offered at or near the point of care tends to be a more effective way of achieving a higher frequency of testing for osteoporosis.

In the diagram below, the potential impact of decreased access to DXA is shown. Based on 2010 projections and a survey reported elsewhere in this document, given the current trends, the percentage

of people diagnosed with osteoporosis may actually decrease to 10% in the next 3 years if changes are not made.



SUMMARY:

From a quality and safety standpoint, the current payment policy regarding DXA measurement is creating a barrier to the efforts of many organizations to improve the quality of care for osteoporosis and prevent fragility fractures. Based on survey data, the evidence appears to be that even physicians who have made the capital expenditures for instrumentation to perform DXA studies believe that the current payment plan will make it impossible for them to continue to provide these services. Already there is erosion in the number of high quality centers available to patients for this testing. A payment policy should not worsen the gap in care in one of the more seriously deficient areas of medical care in the United States. CMS should seriously consider revisions to provide a more equitable payment policy so that the present policy does not have the harmful effects that it appears to be likely to cause.

Appendix A

I. Methods Used In The Lewin Group Survey

We discuss the methodology for each component below:

b. Practice Expense and Malpractice Expense

1. Survey Administration

The Lewin Group survey was distributed electronically to 14,537 members of AACE, ISCD, ACR and TES. The survey was accessible via the internet, with the option of completing the survey on paper and faxing a copy to The Lewin Group. The survey collected information on the characteristics of the practice and physician (e.g., specialty, geographic region, hours practice is open and available to perform DXA), as well as equipment expenses and financial information (e.g., total salaries, office expenses, malpractice insurance). See Appendix B for the survey collection instrument.

One-hundred sixty three useable surveys were received representing approximately 1% of the sample. Respondents who provided incomplete survey data were contacted via telephone for clarification. Any respondent who was not able to be contacted was excluded from our analysis. As an incentive to complete the survey, The Lewin Group offered to provide the individual practice's cost of providing DXA to the physician at the completion of the survey analysis.

2. Generating Practice Expense and Malpractice Expense Cost Components

The Lewin survey collects expenses for entire individual practices[1]. The analysis consists of first estimating total aggregate DXA costs and then generating a practice expense and malpractice cost per DXA procedure for each practice. We report the median cost, 25th percentile and 75th percentile statistics. Lewin also investigated the range of expenses for different cost categories and the effect procedure volume has on per DXA procedure costs. Consistent with CMS methodology, Lewin used the median as our metric of central tendency to reduce the effect of data outliers.

Financial and utilization measures were collected for the most recent complete fiscal year. To make the costs comparable to the current 2007 payments for DXA, practice expense and malpractice expense cost categories were inflated by the CPI-U, approximately 4.1% for 2007.

Total practice expense and malpractice expense per procedure is calculated based on the sum of the three cost components, divided by the total number of DXA procedures performed annually for each practice. We describe each component below:

- Equipment Costs
- Space allocated to DXA
- An allocation of overhead expenses attributed to DXA (e.g., malpractice expense, non-clinical labor and expenses, medical supplies and materials)

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[1] For the purpose of this survey, "practice's expenses" are defined as all expenses that are captured in a Profit and Loss (Income) Statement for all services the practice provides. Respondents were not to differentiate between divisions that provide DXA and all other services provided.

Equipment costs

Equipment costs contain expenses that practices incur annually in the maintenance and upkeep of their DXA machines. These expenses for DXA machines include: 1) cost of interest on loans used to purchase the DXA machine; 2) cost of service contracts; 3) costs of software upgrades; and the 4) cost of the last PAC/DICOM upgrades. These expenses were totaled at the practice level for all machines reported.

Space allocated to DXA

Respondents indicated the total amount of square footage in their practice as well as the square footage attributed to providing DXA. Respondents were to only include areas that are solely used for DXA (i.e., area where the machines are located, and exam rooms that are reserved for DXA patients). The square feet allocated to DXA multiplied times the indicated lease per square foot is included in the cost for providing DXA to be allocated back to the procedure cost. As noted below, we also used the proportion of square feet attributed to DXA services provisions to allocate indirect expenses back to DXA procedures.

Allocation of overhead expenses attributed to DXA

Practices incur numerous indirect expenses that need to be allocated back to providing DXA. Based on the proportion of square feet attributed to DXA to the total number of square feet in the practice, overhead expenses were allocated. Costs included in this allocation include:

- professional medical liability/malpractice insurance;
- salaries for administrative and clerical staff;
- non-clinical office expenses;
- medical materials and supplies; and
- all other indirect expenses.

Survey respondents additionally provided total clinical non-physician payroll expenses (i.e., radiology technicians and registered nurses) and total provider (i.e., physician, physician assistants) payroll expenses. To eliminate the potential for "double-counting" salary expenses for personnel who provide direct labor in DXA procedures, the non-clinical non-physician payroll expense category was excluded in its entirety, due to the inability to indicate which percent of the expenses are attributed to indirect supports. Additionally, total provider payroll expenses were excluded with the assumption that time spent by the physician would be captured in "physician work" on a per-task basis.

As a result, the percent of indirect costs allocated back to DXA may be conservative, for we expect some personnel in these categories to provide DXA services that are not identified in the task breakdown. Additionally, bad debt expense was excluded from the analysis, consistent with CMS' methodology for identifying reimbursable expenses.

c. Physician Work

1. Survey Administration

Physician work was derived from a 2006 clinical survey of multi-specialty densitometry professionals. Administered by ISCD, this survey was distributed electronically to 2884 office-based providers of DXA who were members of AACE, ACR, ISCD, TES, American Society for Bone and Mineral Research (ASBMR), and North American Menopause Society (NAMS). The survey collected

information on the characteristics of the practice and the average time and personnel required to perform each task associated with performing one DXA procedure. Four-hundred fifty-three useable responses were received, or 15% of the sample.

Survey data on the average time it takes to perform each task was analyzed, yielding an estimate of a median time per task (in minutes). The proportion of the total time personnel types were performing indicated tasks was calculated as well (i.e., What percent of the time are technician performing this task compared to registered nurses?). The required personnel included physician time, as well as clinical and non-clinical staff.

2. *Generating Labor Costs Attributed to Providing DXA*

To cost the labor associated with physician and other clinical work, The Lewin Group analyzed the raw data from the 2006 clinical survey of multi-specialty densitometry professionals. Personnel salary data were provided by the United States Department of Labor, Bureau of Labor Statistics (BLS), May 2006, "National Occupations Employment and Wage Estimates". Benefit costs were also provided by BLS in their "Employer Costs for Employee Compensation" survey, September 2006, and included in the salary estimates. A weighted average annual salary was generated based on the proportion of time each personnel category was responsible for performing an indicated task. The annual weighted salary was then calculated as a per minute cost (based on the number of hours the practice was open) and multiplied by the median number of minutes reported for each task. All tasks were totaled to generate a total "labor cost" per procedure.

This labor costing methodology generates a conservative estimate for the cost per procedures. Some practices indicated that they were open in excess of 8 hours a day. In theory, this could require two staff members, rather than just one. Dividing the annual salary per staff member by fewer hours open would result in a higher cost per minute, and ultimately a higher cost per task and procedure. Being unfamiliar with the structure of each practice and the number of staff members providing the service, we assumed one staff member per task, regardless of the number of hours open.

d. Generating a per Procedure DXA cost

Survey respondents indicated an average number of DXA procedures performed per month per DXA machine. Lewin calculated the average number of DXA procedures per year for each practice. This calculation is used to denominate the sum of the practice expense, malpractice and physician work costs to derive cost per DXA procedure.

e. Utilization Rate

Lewin calculated an overall utilization rate for DXA machines based on the number of hours DXA equipment was used to provide patient care and number of hours equipment is available to provide DXA:

- **Total available equipment hours**: We calculated total available equipment hours for each practice by multiplying the reported hours available each week by the total indicated hours per year the practice is open for in each practice.

- **Total patient-use equipment hours**: We calculated the hours for total patient-use by multiplying the number of DXA procedures performed per year by the RUC approved time per procedure (15 minutes). Due to the inability to estimate the amount of time DXA machines are used in each practices, this estimate may be conservative.

- **Utilization Rate**: Total patient-use equipment hours divided by total available equipment hours.

II. Sample characteristics

Both survey efforts captured data from numerous specialties that provide DXA services. Responses to The Lewin Group survey were received from 8 different specialties. Rheumatology represents 37% of the sample while Primary Care (Internal Medicine, Family Medicine and Gynecology) collectively represent 39% of the responses (Figure 6). Based on 2004 claims data for office-based services, 28% of claims are from Internal Medicine while 24% are Radiology. As a test for representativeness, we re-weighted the final results of our study based on the CMS claims data distribution by specialty and obtained comparable median costs per DXA procedure. This ensured that specialty distribution did not affect our analytic results.

Figure 6: Distribution of Specialty for Lewin and Multi-specialty Survey Compared to 2004 CMS Claims Analysis

Specialty	Lewin Survey (2007)	Multi-Specialty Densitometry Study (2006)	CMS Claims Analysis (Office-based in 2004)
Rheumatology	37%	37%	12%
Internal Medicine	20%	11%	28%
Endocrinology	13%	22%	5%
Family Practice	10%	7%	11%
OB/GYN	9%	9%	7%
Other	6%	6%	14%
Radiology	3%	5%	24%
Orthopedics	2%	3%	-

Responses from the 2006 clinical survey of multi-specialty densitometry professionals represented 18 specialties, which were aggregated in Figure 6. Rheumatology represents 37% of the sample (identical to the Lewin survey) whereas Endocrinology represents 22%. Primary Care (Internal Medicine, Family Medicine and Gynecology) collectively represents 27% of the total sample.

Appendix B

Office Based (Non-Facility) DXA Cost
Survey Questionnaire
July 9, 2007

Thank you for agreeing to participate in this important survey to help understand DXA costs.

Instructions

To accurately assess DXA costs, we need to collect information on a variety of clinic operating expenses. To ensure the most accurate information, **we suggest that you share this survey with your clinic administrator and/or business manager so they can assist you in its completion**. Please make sure you include all of your practice(s)'s expenses (unless specified), not just those attributed to DXA. The time spent completing this will be invaluable in arriving at a true cost analysis that may **result in a more accurate reimbursement**.

This survey will collect practice level information regarding procedure volume and equipment costs and professional expenses for your most recently completed fiscal year.

To submit this paper survey:

- **Print, complete and fax responses to Audrey El-Gamil at The Lewin Group at 703-269-5501, or**
- **Complete electronically and email responses to Audrey El-Gamil at The Lewin Group at audrey.el-gamil@lewin.com.**

Please make sure that you insert your log-in information at the top of the first page of the survey!

Again, we assure you that The Lewin Group is treating all information as confidential. Under no circumstances will individual practice information be reported or shared with anyone. Furthermore, The Lewin Group will provide only aggregated data across providers.

If you have questions or wish to discuss any issues related to the survey, please call Audrey El-Gamil at The Lewin Group between the hours of 9 am ET and 6 pm ET, or leave a message, at (703) 269-5771. Alternatively, you can email Audrey at audrey.el-gamil@lewin.com.

Information about You

(Please complete this survey only if you are not a hospital based practice billing under the Hospital Outpatient Prospective Payment System (OPPS))

A-1	**Your name:**

A-2	City where practice is located:
A-3	State where practice is located:
A-4	Zip code of practice:
A-5	Location of practice: (check one) ____ Urban ____ Suburban ____ Rural
A-6	Specialty you practice: (check one) ____ Endocrinology ____ Family Practice ____ Gynecology ____ Internal Medicine ____ Orthopedics ____ Rheumatology ____ Radiology ____ Other (specify:_____)
A-7	Years practicing specialty: _____ years
A-8	Are you ISCD Certified as a CCD (Certified Clinical Densitometrist)? ____ Yes ____ No
A-9	Is your practice based in a hospital? ____ Yes ____ No If yes, do you bill for DXA using the Hospital Outpatient Department (HOPD) rate also referred to as the Hospital Outpatient Prospective Payment System (OPPS)? ____ Yes ____ No *If you answered "yes" to both questions, please do not complete the rest of the survey. This survey is only for office-based/non-facility based practices whose payment is based on the Medicare Fee Schedule. Thank you for your time! Please fax your responses to Ted Kirby at 703-269-5501.*

Information about Your Practice

B-1	How many: _____ physicians are in your practice? _____ of those physicians, how many are reading DXAs?

	Do you have non-physician providers (NP, PA) who read DXAs? ____ Yes ____ No If yes, how many? _____ non-physician providers
B-2	Which central sites do you routinely measure? _____ spine only _____ one hip only _____ spine and one hip _____ spine and both hips
B-3	Do you do forearm DXAs? _____ Yes _____ No* *Skip to Question B-6*
B-4	If you do forearm DXAs, do you do them: _____ in all patients having central DXA?* *Skip to Question B-6* _____ only in selected patients?
B-5	If only in selected patients, what percent of patients having central DXAs also have forearm DXAs? _____ percent having central DXA and forearm DXA _____ percent having only forearm DXAs
B- 6	How much of your DXA volume comes from your own practice and how much is referred to you from outside of your practice? (total must equal 100%) _____% from your practice _____% referred to you
B-7	When you bill for DXA, do you bill the global fee or the professional component? _____ global fee _____ professional component only (-26)
B-8	What is the average number of hours per week that your office is open for business? _____ hours per week
B-9	How many days of the week is your office open for business? _____ days of the week

B-10	**How many weeks of the year is your office open for business?** **_____ weeks of the year**
B-11	**What is the average number of hours per week that DXA is available/offered in your office?** **_____ hours per week**
B-12	**How many central DXA procedures are performed in an average month per machine?** **_____ procedures**

Information about VFA

C-1	**Do you have VFA capability?** **_____ Yes** **_____ No**
C-2	**Do you read VFA?** **___ Yes** **___ No* *Skip to next section***
C-3	**How many VFA procedures are performed in an average month per machine?** **_____ procedures**
C-4	**How many machines are used for VFA?** **_____ machines**
C-5	**What percent of central DXA patients receive VFA?** **_____%**

For the next sections, we suggest that you share the questionnaire with your clinic administrator and/or business manager so they can assist you. The time spent completing this will be invaluable in arriving at a true cost analysis that may result in a more accurate reimbursement for central DXA.

Information about Your Equipment Costs

Total number of DXA machines in your practice: _____

Please fill out one row in the following table for each DXA machine in your practice.

Please specify if the manufacturer is:

- **Hologic,**
- **Norland/Cooper, or**
- **GE/Lunar**

D-1

Machine Number	Manufacturer	Fan or Pencil Beam	Year Purchased	Original Cost	
1					
2					
3					
4					

D-2 **Cost per year of interest on loan(s) used to purchase your DXA machine(s):**

$_____ per year

D-3 **Cost per year of any service contract(s) for your DXA machine(s):**

$_____ per year

D-4 **Cost per year of software upgrade(s) for your DXA machine(s):**

$_____ per year

D-5 **Cost of the last PAC/DICOM upgrade(s) (ability to transmit radiographic images electronically):**

$_____

Information about Your Professional Expenses (your last full fiscal year)

Please answer the remaining sections based on your last full fiscal year. Make sure to include your entire practice's expenses, rather than those just attributed to DXA. We will use this information to calculate the proportion of your clinic's overhead expenses that are attributed to DXA procedures.

For the purpose of this survey, "practice(s)'s expenses" are defined as all expenses that are captured on your Profit and Loss (Income) Statement for all services your practice provides. Do not differentiate between DXA and all other services provided. We list some examples of expenses you should and should not include in your totals:

Do include:

- *Rent and utilities for your entire practice, not just areas attributed to DXA services*
- *Salary amounts (and benefits) for visiting physicians or support staff that are paid by your practice, but also serve or support other practices*

Do not include:

- *Salaries for visiting physicians that use your clinic space but are not paid a salary from your practice*
- *Rent for neighboring practices that share space (i.e., waiting rooms)*

If you have any further questions, please call Audrey El-Gamil at The Lewin Group at (703) 269-5771

E-1	**What is the start and end date of your last full fiscal year?** **Start Date: Month_____ Year _____** **End Date: Month_____ Year _____**
E-2	**What is the total square footage for your practice?** (If practice has more than one location include total square footage of all offices) _____ **sq ft.** **What is the total square footage attributed to DXA use?** (If an exam room is set aside for DXA only, then you would provide the square footage of the exam room itself. If part of the room where DXA machine is located is used for other purposes, then you would list the square footage of that portion of the room reserved for DXA. If practice has more than one DXA machine include square footage reserved for each machine.) _____ **sq ft.** **What is the lease per square foot for your practice(s)? $_____**
E-3	What was your practice's **professional medical liability or malpractice** insurance premium for your last full fiscal year, to the nearest thousand dollars? **$_____ Premium Amount**
E-4	What were your practice's **non-clinical non-physician** payroll expenses for your last full fiscal year were solely for individuals involved with administrative, secretarial, or clerical activities (to the nearest thousand dollars)? Include all sites for which your practice bears these costs (e.g. practice managers, schedulers, billing personnel, record clerks, clerical, etc.). **$ _____**
E-5	What were your practice's total **clinical non-physician** payroll expenses for your last full fiscal year, including fringe benefits (to the nearest thousand dollars)? Include all sites for which your practice bears these costs (e.g. nurses, technicians). **$_____**

E-6	What were your practice's total **provider** payroll expenses for your last full fiscal year, including current or deferred compensation (to the nearest thousand dollars)? (Physicians, Nurse Practitioners, Physician Assistants). Include all sites for which your practice bears these costs (e.g. salaries, bonuses, dividends, and pension funds). $_____
E-7	What were your overall practice's expenses for **medical materials and supplies** not separately reimbursable that are used for clinical purposes for your last full fiscal year (to the nearest thousand dollars)? Include all sites for which your practice bears these costs (e.g. X-ray films, processor chemicals, laundry and disposable medical supplies). Do not include expenses for non-clinical office supplies or medicines which are separately reimbursable. $_____

Information about Your Non-Clinical Expenses (your last full fiscal year)

F-1	What were your practice's **non-clinical office** expenses for your last full fiscal year, including non-clinical office equipment and supplies, rent, mortgage interest, depreciation and maintenance costs on office and medical buildings, commercial property insurance, property taxes, utilities and telephone, supplies for billing, scheduling and business functions (to the nearest thousand dollars)? Include all sites for which your practice bears these costs. $_____
F-2	What were your practice expenses for **all other** expenses for your last full fiscal year, including marketing expenses, legal fees, accounting, office management services, contracted billing expenses, professional car upkeep and depreciation, professional association memberships, professional journals, continuing education (CME), all employee-provided insurance other than malpractice, and other expenses that have not been listed (to the nearest thousand dollars)? $_____
F-3	What were your practice's **bad debts** for services provided in your last full fiscal year (to the nearest thousand dollars)? $_____

Do you have any additional comments?

Congratulations, you have finished the survey!

Thank you for your responses.

To submit your complete survey, please fax it to

Audrey El-Gamil at the Lewin Group, 703-269-5501

Appendix C

Estimating the Costs and Potential Savings of Holding DXA Payment at 2006 Levels –

Methodology and Results from a CBO-Style Cost Accounting Analysis conducted by The Lewin Group

Executive Summary

The Lewin Group used a cost accounting methodology similar to that used by the Congressional Budget Office (CBO) to determine the impact on the federal budget of a proposal to maintain Medicare payment for DXA at 2006 levels in the non-facility setting. Using a combination of secondary data and expert judgment, we developed an algorithm to determine the budgetary impact to Medicare if DXA reimbursement was restored to $139.46.[2]

We found that this proposal would increase direct DXA payments by **$648 million** over the five year period. However, after accounting for savings associated with avoided fractures of approximately **$2.1 billion**, and the cost of pharmaceutical treatment of at-risk individuals (**$294 million**), this proposal could save the Medicare program **$1,145 million**.

The analysis consisted of the following three steps:

1. Develop a baseline estimate of Medicare spending for axial DXA under the current reimbursement for the five years 2008-2012.

2. Develop an estimate of Medicare spending under a proposal to maintain payment for axial DXA at a level that is not less than 100% of the reimbursement rate as of December 31, 2006 for the five years 2008-2012 or $139.46.

3. Develop an estimate of potential savings to the Medicare program of avoiding osteoporotic fractures by identifying and treating those at risk beneficiaries using DXA.

Potential savings accrue from the avoided cost of osteoporotic fractures for a subset of the identified population, taking into account the costs of implementing the proposed legislation and the costs of providing pharmaceutical treatment to the identified at-risk population. Approximately 71% of the two million annual osteoporotic fractures are among individuals aged 65 and older. We then increased this number each year of the period. This calculation was based on the compound rate of growth in peer reviewed literature of 0.0459 corroborated with growth in the beneficiary population from the Medicare Trustees Report (2007) and cost of fractures inflated at CPI.[3]

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[2] In addition to a focused search of the literature, we used secondary Medicare claims and preliminary Part B Extract and Summary System File (BESS) data for 2006, the results of a clinical survey of multispecialty densitometry professionals conducted in early 2007, the 2007 Medicare Trustees Report, CMS changes to physician payment under Part B rulemaking, and the Medicare Fee Schedule contained in the 2006 Federal Register. In addition, we used evidence contained in the peer reviewed literature.

[3] Burge R, Dawson-Hughes B, Solomon D, et al. (2007) Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. Journal of Bone and Mineral Research 22(3): 465-475.

We then estimated the number and cost of osteoporotic fractures avoided through "recovered" procedures under the restored payment rates. This calculation was based upon evidence contained in the peer reviewed literature[4] wherein in 2008, if approximately 361,000 individuals were scanned, approximately 18,048 fractures would be prevented through at-risk individuals initiating a medication to improve bone density. (In essence, we assume that for every 100 DXAs, 5 fractures would be prevented.)

This calculation is dependent upon the mix of osteoporotic/osteopenia individuals screened and also the compliance rate of those given a prescription. Compliance rates have been observed to be generally low for patients who are prescribed bone enhancing medications. We expect that because alendronate will be available in generic form in 2008, compliance rates will improve significantly, improving the chance of preventing osteoporotic fractures.

What follows is a detailed description of the methodology employed in the analysis and the model.

[4] King AB, Saag KG, Burge RT (2005). Fracture reduction affects Medicare economics (FRAME): impact of increased osteoporosis diagnosis and treatment. *Osteoporosis Int.* 16: 1545-1557.

Methodology

In this study, The Lewin Group used a cost accounting methodology similar to that used by the Congressional Budget Office (CBO) to determine the impact on the federal budget of a proposal to freeze DXA rates at 2006 levels. This methodology entails first estimating both the **price** and **volume** of the services that are or would be provided under the baseline scenario. In this analysis, the baseline scenario reflects the cuts made in reimbursement from both the DRA and the changes in the Medicare Physician Fee Schedule. Table A-1 contains the reimbursement rates for DXA that were used in the baseline scenario.

Table A-1: Baseline Reimbursement for DXA

Year	DXA Payment
2007	$82.33
2008	$81.66
2009	$56.82
2010 - 2012	$35.48

Using a combination of secondary data and expert judgment, we developed an algorithm to determine the budgetary impact to Medicare if DXA reimbursement was restored to $139.46. Our methodology is presented in two sections: first, we present the methods used to estimate one and five year costs of the proposal. Then we present the methods used to estimate the potential cost offsets from identifying and treating beneficiaries at risk of an osteoporotic fracture. Potential savings accrue from the avoided cost of osteoporotic fractures for a subset of the identified population, given the costs of implementing the proposed legislation and the costs of providing pharmaceutical treatment to the identified at-risk population.

Step One: Estimate Medicare Spending under DRA and other cuts for 2008-2012

- Number of procedures: uses CMS Preliminary Part B Extract and Summary System File (BESS), 2006 and Q1 2007. Approximately two thirds of procedures are performed in physician offices, and one third in hospital outpatient departments. Reduction in the number of procedures beginning in 2007 is estimated using the results of an ISCD Task Force Survey dated March, 2007. The clinical survey of multispecialty densitometry professionals reported that eight percent of respondents had already stopped providing DXA in their offices due to cuts in Medicare reimbursement. Approximately 36 percent of respondents reported that they would stop providing DXA in 2008 and 2009, and by 2010, these services would not be provided at all by respondents in their offices.

- Medicare spending: uses BESS, 2006 and Q1 2007. Reimbursement rates for 2008-2010 from Medicare Physician Fee Schedule contained in Table A-1 above multiplied by the number of estimated procedures.

Table A-2: Medicare Spending under DRA and Other Cuts 2008-2012

	2008	2009	2010	2011	2012	Total
Global DXA payments under physician fee schedule 2008-2010, flat in 2011 and 2012	$81.66	$56.82	$35.48	$35.48	$35.48	
Estimated Number of DXA's (uses CMS BESS 2006 and Q12007 data as base, then clinical survey results)	1,236,298	927,223	695,418	625,876	563,288	4,048,103
Total baseline Medicare spending for DXA under the DRA and other cuts	$74,000,808	$38,617,982	$18,085,613	$16,277,051	$14,649,346	$161,630,800

Step Two: Estimate Medicare Spending under the Proposal to Freeze DXA Rates at 2006 Levels

Table A- 3: Medicare Spending under Proposal 2008-2012

	2008	2009	2010	2011	2012	Total
Global DXA payments under proposal 2008-2012	$139.46	$139.46	$139.46	$139.46	$139.46	
Estimated Number of DXA's (uses CMS BESS 2006 and Q12007, then escalation proportionate to growth in beneficiary population)	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
Total estimated Medicare spending for DXA under proposal	$203,462,305	$206,514,240	$209,611,953	$212,823,323	$216,084,879	$1,048,496,700

- Number of procedures: uses CMS BESS, 2006 and Q1 2007 inflated at projected rates of beneficiary population growth (1.5% per year until 2011 when rate increases to 3% obtained from Medicare Trustees Report, 2007).
- Medicare spending: uses CMS BESS, 2006 and Q1 2007. Reimbursement rates for 2006 frozen through 2012 per proposal.

Step Three: Estimate net Medicare Spending under Proposal and Number of Procedures "Recovered"

- Determine cost of proposal by taking the difference in spending for DXA between the baseline scenario in Step One and the estimates in Step Two.
- Deduct Part B premium adjustment equal to 25% of new spending.
- Determine net cost to Medicare of proposal.
- Determine number of DXA procedures "recovered" by proposal.

Table A- 4: Cost of Proposal 2008-2012

	2008	2009	2010	2011	2012	Total
Baseline spending for DXA under DRA and other cuts	$74,000,808	$38,617,982	$18,085,613	$16,277,051	$14,649,346	$161,630,800
Total estimated Medicare spending for DXA under proposal	$199,114,370	$202,101,086	$205,132,602	$208,209,591	$211,332,735	$1,025,890,385
Number of DXA procedures not lost due to DRA and other cuts	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
Gross cost of proposal	$125,113,563	$163,483,104	$187,046,990	$191,932,540	$196,683,389	$864,259,585
Net cost of proposal after Part B premium of 25%	$93,835,172	$122,612,328	$140,285,242	$143,949,405	$147,512,542	$648,194,689

Step Four: Determine potential cost offsets from reduced osteoporotic fractures using peer reviewed literature

- Determine both current and 2008-2012 number and cost of osteoporotic fractures among Medicare beneficiaries. Approximately 71% of the two million annual osteoporotic fractures are among individuals aged 65 and older. These calculations were based on the compound rate of growth in peer reviewed literature of 0.0459 corroborated with growth in beneficiary population from Medicare Trustees Report (2007) and cost of fractures inflated at CPI[5]
- Estimate number and cost of osteoporotic fractures avoided through "recovered" procedures. This calculation was based upon evidence contained in the peer reviewed literature[6] wherein in 2008, if approximately 361,000 individuals were scanned, approximately 18,048 fractures would be prevented through at-risk individuals initiating a medication to improve bone density. (In essence, we assume that for every 100 DXAs, 5 fractures will be prevented.) This calculation is dependent upon the mix of osteoporotic/osteopenia individuals screened and also the compliance

[5] Burge R, Dawson-Hughes B, Solomon D, et al. (2007) Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. Journal of Bone and Mineral Research 22(3): 465-475.
[6] King AB, Saag KG, Burge RT (2005). Fracture reduction affects Medicare economics (FRAME): impact of increased osteoporosis diagnosis and treatment. *Osteoporosis Int.* 16: 1545-1557.

rate of those given a prescription. Compliance rates have been observed to be generally low for patients who are prescribed bone enhancing medications. We expect that because alendronate will be available in generic form in 2008, compliance rates will improve significantly, improving the chance of preventing osteoporotic fractures.

- Estimate total cost savings from avoiding an increase in osteoporotic fractures. Per fracture cost calculated using peer reviewed literature (net $9,699 after beneficiary copayment and deductible of 20%).[7]

Table A- 5: Potential Cost Offsets from Avoiding Osteoporotic Fractures 2008-2012

	2008	2009	2010	2011	2012	Total
Number of osteoporotic fractures among aged 65 and older (71% of total)	1,592,181	1,665,262	1,741,698	1,821,642	1,905,255	8,726,039
Per fracture cost after beneficiary copayment and deductible of 20%	$9,699	$9,695	$9,690	$9,829	$9,970	
Number of DXA scans "recovered" under proposal	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
Number of fractures prevented by each scan: .05 (King et al, 2005)	18,048	34,699	47,505	53,451	59,123	212,826
Gross Savings to Medicare of avoiding osteoporotic fractures through DXA before cost of proposal and treatment of at-risk individuals	$175,040,214	$336,397,008	$460,350,535	$525,392,608	$589,477,113	$2,086,657,478
Net cost of proposal after Part B premium of 25%	$93,835,172	$122,612,328	$140,285,242	$143,949,405	$147,512,542	$648,194,689
Savings to Medicare after cost of implementing proposal	$81,205,042	$213,784,680	$320,065,293	$381,443,203	$441,964,571	$1,438,462,789

Step Five: Determine cost of treating identified at-risk individuals

- Determine gross cost of medications for beneficiaries found to be at risk of osteoporotic fractures under Medicare Part D. We used evidence from the FRAME study that showed that for one million individuals screened, 440,000 would be treated with a bone-specific medication. Annual cost of treatment assumed to be $900 per individual (assumes perfect compliance).

- Reduce gross cost of medications under Part D for enrollment (approximately 58% of beneficiaries enrolled in Part D) and for the plan cost management factor which is 27% discount on branded drugs achieved by Part D plans in 2007.[8]

[7] Burge ibid.

[8] Congress of the United States: Congressional Budget Office. A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit. July, 2004.

- Part D premium adjustment equal to 25.5% of new spending per CBO.
- Reduce net cost of generic medications beginning in 2008 by 60% [9] when alendronate goes off patent and the generic is available

Table A- 6: Estimated Cost of Treating Identified At-Risk Individuals 2008-2012

	2008	2009	2010	2011	2012	Total
Cost of treatment if .44 individuals are given Rx and all beneficiaries are covered under Part D	$142,936,697	$274,817,843	$376,242,932	$423,330,315	$468,250,309	$1,685,578,096
Cost of medications for the 58.5% of beneficiaries covered under Part D	$83,617,968	$160,768,438	$220,102,115	$247,648,234	$273,926,431	$986,063,186
Cost of medications after Part D premium of 25.5% per CBO	$62,295,386	$119,772,486	$163,976,076	$184,497,934	$204,075,191	$734,617,074
Cost of medications once generic alendronate is available (60% discount)	$24,918,154	$47,908,995	$65,590,430	$73,799,174	$81,630,076	$293,846,830
Net savings to Medicare after cost of implementing proposal and treating at-risk individuals	$56,286,888	$165,875,686	$254,474,862	$307,644,029	$360,334,495	$1,144,615,960

Step Six: Determine net cost (savings) from reduced osteoporotic fractures through "recovered" DXA procedures minus the cost of treatment

- Subtract cost of proposal and cost of treatment from the cost of the avoided fractures. Cost of proposal is based on the difference between the number of DXAs that we estimate would be performed under the DRA and other cuts and the number we estimate would be performed based on current utilization if reimbursement was frozen at 2006 levels. See Table A-7 on the following page.

[9] *Statement of Lester M. Crawford, D.V.M., P h H.D. Acting Commissioner of Food and Drugs before the Committee on the Judiciary, United States Senate on "The Law of Biologic Medicine". June 23, 2004: "Generic drugs cost 50-70% less than their brand-name counterparts."*

Table A- 7: Estimated Net Savings to Medicare after Cost of Proposal and Cost of Treating Identified At-Risk Individuals 2008-2012

	2008	2009	2010	2011	2012	Total
Gross Savings to Medicare of avoiding osteoporotic fractures through DXA before cost of proposal and treatment of at-risk individuals	$175,040,214	$336,397,008	$460,350,535	$525,392,608	$589,477,113	$2,086,657,478
Net savings to Medicare after cost of proposal	$81,205,042	$213,784,680	$320,065,293	$381,443,203	$441,964,571	$1,438,462,789
Cost of medications once generic alendronate is available (60% discount)	$24,918,154	$47,908,995	$65,590,430	$73,799,174	$81,630,076	$293,846,830
Net Medicare savings from reduced fractures after treatment cost	$56,286,888	$165,875,686	$254,474,862	$307,644,029	$360,334,495	$1,144,615,960

Model

Cost Estimation of Keeping 2006 Medicare DXA Reimbursement

	[illegible] Base Year	[illegible]	[illegible]	[illegible]	2010	[illegible]	[illegible]	Total [illegible]-2012
Baseline DXA Spending under DRA and Other Cuts								
Projected number of Medicare beneficiaries with Outpatient claims	34,796,514	35,318,462	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	
Decline from prior year		8%	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	
Number of central DXA procedures performed in physician offices	1,550,389	1,648,397	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Global DXA payments 2007-2010 per Medicare physician fee schedule		$82.33	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	
Allowed charges from CMS correspondence	$263,843,771	$135,712,535	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	$220,505,8
Total Medicare Payment for DXA from CMS correspondence	$193,272,703	$99,477,288	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Estimated DXA Spending Under Proposal to Freeze Rates at 2006 Levels (with proportionate escalation in procedure volume)								
Global payment for central DXA under proposed freeze in rates to 2006 levels	$139.46	$139.46	$139.46	$139.46	$139.46	$139.46	$139.46	
Number of central DXA procedures in physician offices under freeze holding 2006 payment levels with volume increases proportionate to beneficiary population growth	1,550,389	1,573,644	1,597,249	1,621,208	1,645,526	1,694,892	1,745,739	$8,304,6
Estimated Medicare spending in physician offices under freeze with volume increases proportionate with growth in beneficiary population	$193,272,703	$196,171,794	$199,114,370	$202,101,086	$205,132,602	$208,209,591	$211,332,735	$1,025,890,3
Difference between estimated spending under DRA and other cuts and spending under proposal to freeze rates (cost of proposal)	$0	$96,694,505	$125,113,563	$163,483,104	$187,046,990	$191,932,540	$196,683,389	$864,259,5
Total Estimated Medicare Spending for DXA under Proposal								
Total baseline Medicare spending for DXA under DRA and other cuts	$193,272,703	$99,477,288	$74,000,808	$38,617,982	$18,085,613	$16,277,051	$14,649,346	**$161,630,8**
Total estimated Medicare spending in physician offices under freeze with volume increases proportionate with growth in beneficiary population	$193,272,703	$196,171,794	$199,114,370	$202,101,086	$205,132,602	$208,209,591	$211,332,735	**$1,025,890,3**
Total difference in DXA and VFA spending under DRA and other cuts and spending under freeze(Total cost of proposal)	$0	$96,694,505	$125,113,563	$163,483,104	$187,046,990	$191,932,540	$196,683,389	**$864,259,5**
Net cost of proposal after beneficiary Part B premium	$0	$72,520,879	$93,835,172	$122,612,328	$140,285,242	$143,949,405	$147,512,542	**$648,194,6**

Cost Savings from Reduced Fractures after Implementation of Proposal								
ımber of annual osteoporotic fractures among aged 65 and older 1%) inflated by .0459 per year beginning in 2006 per Burge et al, 07	1,455,500	1,522,307	1,592,181	1,665,262	1,741,698	1,821,642	1,905,255	8,726,039
ınual cost to Medicare of osteoporotic fractures with $16.9 billion in 05 dollars (87% of costs for age 65+) increased by CPI and growth in neficiary population = roughly equivalent to .0466 compound rate of owth per year per Burge et al, 2007	$17,661,000,000	$18,463,692,450	$19,302,867,272	$20,180,182,589	$21,097,371,888	$22,382,201,836	$23,745,277,928	**$106,707,901,513**
ɛr fracture cost calculated, as. $12,134 per Burge, Dawson-Hughes, olomon et al, 2007.	$12,134	$12,129	$12,124	$12,118	$12,113	$12,287	$12,463	
ɛt per fracture cost after beneficiary Part B copays and deductibles 0%)	$9,707	$9,703	$9,699	$9,695	$9,690	$9,829	$9,970	
ımber of DXAs performed under DRA cuts - from above	1,550,389	1,648,397	1,236,298	927,223	695,418	625,876	563,288	4,048,103
ımber of central DXA procedures under proposal	1,550,389	1,573,644	1,597,249	1,621,208	1,645,526	1,694,892	1,745,738	8,304,613
ımber of central DXA procedures lost under DRA and other cuts proposal not implemented	0	-74,753	360,951	693,984	950,108	1,069,016	1,182,450	**4,256,510**
ımber of fractures prevented by each screen: .05 assumption of % women treated having osteoporosis and 25% having steopoenia per King et al sensitivity analysis	0	-3,738	18,048	34,699	47,505	53,451	59,123	**212,826**
ıtal net cost to Medicare of increased fractures from losing DXA ocedures under DRA and other cuts - after beneficiary copay	$0	-$36,266,280	$175,040,214	$336,397,008	$460,350,535	$525,392,608	$589,477,113	**$2,086,657,478**
ledicare savings from reduced fractures taking into account the cost proposal/ Cost of increased fractures minus cost of freeze- 2007 is a st to Medicare, outyears are savings	$0	-$108,787,159	$81,205,042	$213,784,680	$320,065,293	$381,443,203	$441,964,571	**$1,438,462,789**
Annual Cost of Treatment @ $900 per Beneficiary under Part D								
ost to Medicare of medications under Part D if all beneficiaries vered under Part D - for every scan (n=3,406,877), .44 prescriptions e written per King et al	$0	($29,602,066)	$142,936,697	$274,817,843	$376,242,932	$423,330,315	$468,250,309	$1,685,578,096
ost of medications with 58.5% beneficiaries in Part D - rest uninsured other plans	**$0**	**-$17,317,208**	**$83,617,968**	**$160,768,438**	**$220,102,115**	**$247,648,234**	**$273,926,431**	$986,063,186
and cost management factor per CBO - 27% discount on branded ugs from the plans prior to 2008	$0	-$12,641,562	$83,617,968	$160,768,438	$220,102,115	$247,648,234	$273,926,431	$986,063,186
and 25.5% beneficiary Part D premium for average cost plan per 30	$0	-$9,417,964	$62,295,386	$119,772,486	$163,976,076	[illegible]	[illegible]	$734,617,074
neric discount averaging 60% beginning in 2008	$0	-$9,417,964	$24,918,154	$47,908,995	$65,590,430	[illegible]	[illegible]	$293,846,830
ledicare savings from reduced fractures taking into account the ıst of the treatment - these are savings	**$0**	**-$99,369,195**	**$56,286,888**	**$165,875,686**	**$254,474,862**	**$307,644,029**	**$360,334,495**	**$1,144,615,960**

Submitter : Mrs. Melissa Ebig **Date:** 08/31/2007

Organization : Duquesne University

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I am a certified athletic trainer working at Duquesne University in Pittsburgh, PA. I hold a Masters Degree in Exercise Physiology and have been licensed in the state of Pennsylvania since 1991. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

I am both concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting and that these proposed rules will create additional lack of access to quality health care for my patients. As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam as well as the requirements for continued education to keep my certification ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards. The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are responsible for overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare part A or B hospital or rehabilitation facility.

Sincerely,

Melissa A. Ebig, MS, ATC

Submitter : **Mr. Jarod D'Agostino** **Date: 08/31/2007**

Organization : **Hartford Hospital**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Jarod D'Agostino. I am a certified athletic trainer with a MS in clinical exercise physiology. I am employed by Hartford Hospital in the cardiac rehabilitation program.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

Whilc I am concerned that thcse proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical expcrience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to eircumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be eoncerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jarod M. D'Agostino, MS, ATC

Submitter : **Kristine Lobotzke** **Date: 08/31/2007**

Organization : **Advanced Pain Management**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15315-Attach-1.DOC

1515

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Kristine Lobotzke
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Ms. Deborah Williamson** **Date: 08/31/2007**

Organization : **Foster, Swift, Collins & Smith, P.C.**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15316-Attach-1.DOC

1516

DEBORAH J. WILLIAMSON
Foster, Swift, Collins & Smith, P.C.
32300 Northwestern Highway, Suite 230
Farmington Hills, MI 48334-1571
Direct Phone 248-538-6352
Email: dwilliamson@fosterswift.com

September 14, 2007

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8018
Baltimore, Md. 21244-8018

RE: File Code CMS-1385-P
Comments on CMS's Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 ("2008 Proposed Physician Fee Schedule")

Dear Sir/Madam:

The following are our comments regarding the 2008 Proposed Physician Fee Schedule published in the Federal Register on July 12, 2007 (72 Fed. Reg. 133, pp. 38122-38395). We would appreciate your consideration of these comments made on behalf of our independent diagnostic testing facility ("IDTF") clients.

IDTF ISSUES

1. II. I. 1. a. (§410.33(g)(6)): Insurance Requirements. Our clients are concerned that listing the designated CMS contractor as a Certificate Holder on their liability insurance policies may result in additional insurance costs for IDTFs. Does CMS have a similar requirement for other Medicare providers and suppliers? Please explain the rationale for IDTF's to be subjected to this additional financial burden.

2. II. I. 1. d. (§410.33(b)(1)): Supervising Physicians. Please explain the rationale for limiting a physician providing general supervision to the oversight of three (3) sites.

3. II. I. 2. (§410.33(g)(15)): Prohibition Against Shared Space. In 42 CFR 410.33(g)(15), CMS proposes a new performance standard that would prohibit IDTF's from subleasing its "operations" to another person. Please clarify what is meant by "operations." For example, may an IDTF lease a piece of portable equipment on a part-time basis to another entity, such as another IDTF, a hospital or a physician practice which employs trained and certified technologists , otherwise has the space and facilities and performs diagnostic tests? Further, may an IDTF lease one of its technologists on a part-time basis to another entity, such

as another IDTF, a hospital or a physician practice which owns equipment and performs diagnostic tests?

In addition, CMS has requested comments with respect to establishing a requirement for mobile IDTFs that would prohibit the sharing of space, equipment or staff or the sublease of the mobile IDTF's operations to another individual or organization.

Please clarify that this proposal is not intended to prohibit an IDTF from leasing space, equipment and staff from another person. Mobile IDTFs and IDTFs with portable equipment make services convenient and accessible for patients and their physicians by bringing services directly to the patient, often by providing services at the practice location of the patient's treating physician. This benefits elderly Medicare and indigent Medicaid patients in particular who are less mobile and/or frequently must rely on relatives, friends or public transportation to take them to and from medical appointments. Prohibiting a mobile IDTF, or an IDTF with portable equipment, from leasing space, equipment and personnel located at a physician's practice will effectively eliminate this convenience since these IDTFs typically use the practice's exam room(s) or other facilities, and share reception areas, equipment such as telephones, faxes and copiers, and staff such as reception personnel. It would be impossible for these IDTFs to continue to provide services at such locations if they were prohibited from leasing/sharing any space, equipment and/or staff.

PHYSICIAN SELF-REFERRAL PROVISIONS

1. II. M. 1.: Anti-markup Provision. Please clarify that the anti-markup provision with respect to the professional component of diagnostic tests does not apply to an IDTF that purchases the professional component from the interpreting physician, particularly in states where the corporate practice of medicine prohibitd the IDTF from hiring the physician as an employee.

Thank you for your attention to our comments. Please do not hesitate to contact the undersigned if you have any questions regarding the above.

Very truly yours,

FOSTER, SWIFT, COLLINS & SMITH, P.C.

Deborah J. Williamson

DJW:aw

Submitter : **Mr. Tadd Turnquist** **Date: 08/31/2007**

Organization : **Charleston Southern University**

Category : **Other Health Care Provider**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I work at Charleston Southern University as a Certified Athletic Trainer and Athletic Training Professor. I cover Women's Volleyball and Baseball at CSU. I also teach athletic training classes in conjunction with covering sports.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Tadd Turnquist, ATC

1949

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely, Thomas E. Hennig, MD

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Roger Vick
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Ms. Nancy Davenport-Ennis** **Date: 08/31/2007**

Organization : **National Patient Advocate Foundation**

Category : **Other Association**

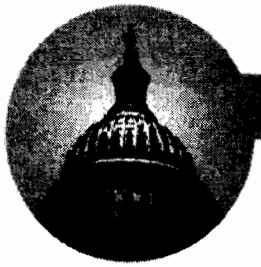
Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15321-Attach-1.PDF



NATIONAL PATIENT ADVOCATE FOUNDATION

A National Network for Healthcare Reform

HAND DELIVERED

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Kuhn:

The National Patient Advocate Foundation ("NPAF") would like to thank you for the opportunity to comment on Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007.[1] As requested, we have keyed our comments to the issue identifiers in the Proposed Rule. We hope CMS finds our recommendations helpful as it finalizes the physician fee schedule for 2008. Our concerns remain that reimbursement does influence access for Medicare beneficiaries whom we serve.

NPAF is a non-profit organization dedicated to improving access to healthcare services through policy reform. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive counseling, case management and co-payment relief services from our companion organization, the Patient Advocate Foundation ("PAF"), which specializes in mediation for access to care, job retention, and relief from debt crisis resulting from diagnosis with a chronic, debilitating or life-threatening disease. In fiscal year July 1, 2006 – June 30, 2007, PAF was contacted by 6.2 million patients requesting information and/or direct professional intervention in the resolution of access disputes. Of that number, 24.6% were Medicare beneficiaries and 78% were individuals dealing with a diagnosis of cancer.

IMPACT

NPAF Urges CMS to Use the TRHCA Discretionary Fund to Mitigate Looming Physician Reimbursement Cuts While It Works with Congress to Correct the Flawed Sustainable Growth Rate Formula

The Proposed Rule indicates the sustainable growth rate ("SGR") formula will require a 9.9% across-the-board reduction in payments for physician services effective January 1, 2008. Continuing payment cuts are projected to total 40% by 2015 even though the cost of providing patient care in the office setting is likely to increase by more than 20% over the same period. Unless steps are taken *now* to eliminate the adverse effects of the flawed SGR formula on physician reimbursement, we fear patient access to high-quality community-based care will be seriously compromised.

[1] 72 *Fed. Reg.* 38120 (July 12, 2007).

The Medicare Payment Advisory Committee ("MedPAC") shares our concern about consecutive annual reimbursement cuts threatening beneficiary access to physician services over-time.[2] Without prompt action, this concern could become a stark reality beginning next year as physicians facing financial hardships are forced to make painful choices about their ability to continue accepting new Medicare patients or continue treating those already on their patient rosters. A 2007 American Medical Association ("AMA") survey suggests 60% of physicians will be forced to limit the number of Medicare patients they treat should the proposed payment cuts go into effect.[3] Between now and 2015, eight in ten physicians also expect to reduce or delay purchases of new and innovative medical equipment and/or more sophisticated information technology.[4] Over half of physicians likely will reduce their staff. Such changes are not good for patients and they are not good for the country's health care delivery system as a whole.

Physician practices cannot implement meaningful quality-improvement programs if they cannot afford to retain staff or invest in the new technologies and the information systems necessary to support ever-evolving standards of care, efficient quality reporting, and ongoing quality benchmarking.[5] Simply put, we cannot ask physicians to invest in electronic health records, e-prescribing, and other health information technology that promises future improvements in patient safety, continuous quality improvement, and evidence-based medicine unless we are willing to ensure they are adequately reimbursed for the services they provide today. The magnitude of the Medicare reimbursement cuts physicians face under the existing SGR threatens to stymie progress that, in the long-term, promises improved patient care at lower costs. Our involvement in AHIC reflects our serious commitment to the value of EHR and PHR. These advances will be compromised unless we strike a balance in reimbursement with providers.

The Tax Relief and Health Care Act of 2006 ("TRHCA") explicitly allows CMS to direct a $1.35 billion fund towards the 2008 physician update.[6] Nonetheless, the Proposed Rule indicates CMS intends to apply this fund to expand the Physician Quarterly Reporting Initiative ("PQRI").[7] Even though NPAF supports quality-improvement programs and quality transparency,[8] we fear many physicians will not participate in the 2008 PQRI because the up-front cost of administrative staff time, information technology systems and other infrastructure necessary to monitor and report quality measures will likely exceed the 1.5-2% bonuses that will not be available to qualifying participating practices until sometime in the spring of 2009. Practices continue to reiterate that due to reduced funding of services, they are not expanding programs and services. This would require both of them.

NPAF is of the view that the TRHCA discretionary fund could be better spent by applying it to reduce the projected disparity between Medicare payments and physician practices expenses next year while understanding that the fund is not large enough to fully offset the projected reimbursement shortfall. Therefore, NPAF also strongly encourages CMS to work collaboratively with the physician community, the patient advocate community and Congress to develop a viable long-term plan that can be implemented beginning in 2008 to provide predictable positive payment updates for physicians, spur development of a permanent solution to the SGR problem, and facilitate voluntary physician participation through incentives that do not add costs for them to participate, across all specialties, in meaningful quality reporting and quality- improvement activities.

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[2] MedPAC, "Report to Congress: Medicare Payment Policy," chapter 2B, pg. 99 (March 2007), available at http://www.medpac.gov/documents/Mar07_EntireReport.pdf.
[3] 2007 AMA Medicare Physician Payment Survey, available at http://www.ama-assn.org/ama/pub/category/17649.html.
[4] *Id.*
[5] *See* the NPAF Statement of Principles of Health Information Technology, available at http://www.npaf.org/statements.php?p=453.
[6] Pub. L. 109-432 (Dec. 9, 2006).
[7] 72 *Fed. Reg.* at 38205-06.
[8] *See* the NPAF Statement of Principles on Pay for Performance, available at http://www.npaf.org/statements.php?p=455

NPAF Urges CMS to Take Steps to Improve Payment for Chemotherapy Drug Administration Services in 2008

Unfortunately, it does not appear to us that a statutory reversal of the negative update factor currently expected in 2008 will be enough to correct the serious reimbursement shortfall currently facing physicians who provide in-office chemotherapy. As a result of revisions to work RVUs for certain CPT codes, increases in the work of anesthesia services and the four-year phase-in of the bottom-up methodology for setting practice expenses, the impact analysis in the Proposed Rule projects an aggregate *reduction* in payments to the hematology/oncology specialties in 2008 of 1%.[9] This projection ignores the potentially disastrous effect of the 9.9% negative update factor that also will take effect January 1, 2008 absent Congressional action. The oncology shortfall is not limited to 2008. Rather, it will grow substantially through 2010 as the bottom-up methodology for setting practice expenses is implemented. This shortfall impacts patients as physicians make choices not to treat seniors.

NPAF believes statistics about the aggregate impact of the proposed 2008 payment changes on hematology/oncology fail to tell the whole story. They hide the significant financial challenges facing oncologists who continue to administer chemotherapy in their offices because of the much larger underpayments for drug administration services. Based on our discussions with the oncology community, we understand current Medicare payments fall substantially short of the costs of providing drug administration services. A Global Access Project study by the University of Utah entitled "*Documentation of Pharmacy Cost in the Preparation of Common Chemotherapy Infusions in Academic and Community-Based Oncology Practices*"[10] found that the total average "fixed costs" for the preparation of chemotherapy doses averaged $36.00 to $44.00 in both physician office and hospital outpatient settings. Because these costs are not fully captured in physician payments for the practice expenses associated with drug administration procedures under the fee schedule, they will contribute to losses on chemotherapy administration services that the office-based oncology community expects to total almost $1.5 million in 2008, assuming Congress acts to replace the SGR-mandated negate update factor with an increase of 0.5%. The magnitude of the underpayments medical oncologists will have to support – unless they decide to discontinue offering office-based chemotherapy – increases substantially when bad debt, attributable to the inability of many beneficiaries to meet the 20% cost-sharing obligation under Part B, is taken into account.

Underpayments for drug administration, even assuming Congress takes steps to reverse or mitigate the negative update factor in the Proposed Rule, are contrary to Congressional intent. When Congress enacted Section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"),[11] it wanted to better match Medicare reimbursement for drugs and for drug administration with the actual cost of each service component. Unfortunately, the amendments the MMA made to the methodology for setting drug administration payments have proven inadequate to account for incurred costs since the 32% 2004 transition payments ran their course. Subsequent changes in the physician fee schedule practice expense methodology have exacerbated the problem.

The 32% transition drug administration payment in 2004, the cancer quality demonstration project tied directly to drug administration services in 2005, and the revised cancer quality demonstration tied to evaluation and management visits in 2006 have masked the potential impact of the growing mismatch between the cost of drug administration services in oncologist offices and the reimbursement available from Medicare for these services. Physicians express to us concerns that their business models are three to five years while CMS presents only one year that if not replicated beyond one year impacts patient services and programs in longer term business models.

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[9] 72 *Fed. Reg.* at 38214.

[10] Gary Oderda, University of Utah Pharmacotherapy Outcomes Research Center, "Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusion in Academic and Community-Based Oncology Practices" (Feb. 8, 2005), prepared for the national patient Advocate Foundation and The Global Access Project, available at http://www.npaf.org/pdf/gap/utah_study.pdf.

[11] Pub. L. 108-173 (Dec. 8, 2003).

When MedPAC assessed the effects of the MMA-mandated change from an AWP-based to an ASP-based system for drug reimbursement in 2005, it found beneficiary access to chemotherapy services generally remained good and quality of care had not declined.[12] MedPAC did note, however, that in some areas, beneficiaries without supplemental insurance were more likely to receive chemotherapy in hospital outpatient departments rather than physician offices. A baseline study of 2004 Medicare claims data coupled with a Web-based convenience survey of Medicare beneficiaries in early 2005 conducted by the Duke Clinical Research Institute for the Global Access Project[13] came to similar conclusions. That study found no statistically significant differences in time to treatment or site of treatment for Medicare beneficiaries with cancer before the MMA and in the first year (2004) of the MMA's implementation.[14] But, like the MedPAC study, the Duke study noted some apparent dislocations in access in rural areas and among Medicare beneficiaries without supplemental insurance. The report recommended interpreting these findings with caution, however, because the relevant beneficiary subgroups were too small to permit the covariate adjustments needed to determine whether the findings reflected baseline differences between the pre-MMA and post-MMA cohorts. That said, the Duke report did conclude Medicare beneficiaries living in rural areas or not having the benefit of supplemental coverage "may be the most vulnerable to changes caused by the MMA. Further research in this area is warranted."[15]

While NPAF recognizes these early studies suggest the MMA has not lead to significant dislocations in access to oncology care or to a notable degradation in the quality of oncology care available to Medicare beneficiaries, we remain concerned that, absent action from CMS this year, cancer patients, particularly those living in rural areas and those without supplemental insurance, could be adversely impacted. The disparity in proposed 2008 payment changes for drug administration services in the hospital outpatient and physician office settings could exacerbate site of service shifts. Even though oncologists who provide chemotherapy services in their offices serve 80% of all Medicare beneficiaries with cancer, they are facing 2008 payment cuts that threaten to become unsustainable. At the same time, in a move which we heartedly endorse, CMS is proposing to increase reimbursement for the Ambulatory Payment Classification ("APC") groups for drug administration services in hospital infusion centers under Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates" ("2008 OPPS Proposed Rule")[16] anywhere from 1.6% to 12.2%. Because reimbursement and access are inextricably linked, the continuing trend of decreasing drug administration payments for oncologists who provide in-office chemotherapy should leave vulnerable elderly patients with fewer provider choices and less available treatment site options. We also suspect that increases in the proportion of cancer care provided in hospital outpatient departments could raise costs for both the Medicare program as a whole and for beneficiaries individually since hospital charges tend to be higher than office charges for the same service and since, in many hospital outpatient departments, beneficiaries still pay more than 20% of the costs of an outpatient visit.

We note that Reps. Lois Capps and Tom Davis have introduced the Comprehensive Cancer Care Improvement Act of 2007 (HR 1078), which would establish cancer care planning and the development of comprehensive cancer treatment summaries as reimbursable services under the Physician Fee Schedule ("PFS"). NPAF endorses that legislation. We urge CMS to actively support the bill and to work expeditiously to effectuate care planning payments in 2008 using temporary codes should the legislation be enacted this year. The approach taken in HR 1078 is generally consistent with a

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[12] *Medicare Part B Drugs and Oncology,* Testimony of Mark E. Miller, PhD, Executive Director of MedPAC, before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, July 13, 2006.

[13] *The Medicare Modernization Act and Changes in Reimbursement for Outpatient Chemotherapy: Do Patients Perceive Changes in Access to Care?*, Kevin A. Schulman *et al.*, Duke Center for Clinical and Genetic Economics, Duke Clinical Research Institute (Sept. 15. 2006), funded by The Global Access Project. For complete study, visit www.npaf.org.

[14] *The Medicare Modernization Act and Changes in Reimbursement for Outpatient Chemotherapy: Do Patients Perceive Changes in Access to Care?*, Kevin A Schulman *et al.*, Duke Center for Clinical and Genetic Economics, Duke Clinical Research Institute (Sept. 15, 2006), funded by The Global Access Project. For complete study, visit www.npaf.org

[15] *Id.*

[16] 72 *Fed. Reg.* 42626 (Aug. 2, 2007).

recommendation the oncology community – patients and providers alike – has made previously on a number of occasions for the establishment of a payment for a specified bundle of chemotherapy coordination services under the PFS akin to the monthly payment nephrologists receive when they treat patients receiving dialysis or the weekly payment radiation oncologists receive for managing radiation therapy.

Furthermore, we encourage CMS to take steps to ensure that the extensive pharmacy handling costs associated with cancer therapies, such as maintaining and managing drug inventories, drawing up and mixing drugs for administration, and operating quality assurance and drug safety programs, are adequately reimbursed in both the physician-office setting and the hospital outpatient setting. When the MedPAC studied the cost of pharmacy services in hospital outpatient departments in 2004, it concluded that those costs were "nontrivial" [17] and it recommended that CMS "define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs." [18] Implicit in MedPAC's recommendation is the recognition that pharmaceutical management and handling costs are linked to the nature of the drugs handled and to the complexities of drug protocol management, not to the setting in which the drugs are used. Therefore, the planned assessment of pharmacy services costs in hospital infusion centers discussed in the 2008 OPPS Proposed Rule should be reflective of the equally "nontrivial" costs that physician offices also incur when they handle similar drugs.[19]

We urge CMS to recognize the need to pay physician practices adequately for the pharmacy costs they incur when they administer chemotherapy in their offices. We hope the agency plans to use the data it expects to begin collecting from hospitals next year to work with the CPT Coding Panel and the RUC to establish codes and set appropriate payment rates under the PFS for drug handling services or to adjust appropriately the PE RVUs associated with the drug administration codes currently included on the PFS.

PHYSICIAN SELF-REFERRAL PROVISIONS

CMS Should Avoid Changing the In-Office Ancillary Service Exception in Ways that Would Prevent Patients from Receiving Comprehensive Cancer Care

The physician-self referral prohibitions at Social Security Act § 1877 and the implementing regulations at 42 C.F.R. § 411.350 *et seq.* (collectively, the "Stark Law") have always contained an exception for in-office ancillary services ("the IOAS exception"). Congress deliberately created a broad exception for in-office ancillary services to balance concerns about physician self referrals against the long-recognized Medicare mandates to defer to a physician's judgment regarding the practice of medicine and patient treatment and to preserve Medicare beneficiaries' freedom to access care from the provider of their choice. Congress sought to achieve this balance by purposefully limiting the scope of conduct prohibited by the Stark Law through the inclusion of a broad exception to the general rule that a physician cannot order a designated health service ("DHS") from an entity – including his or her own solo or group practice – with which the physician has a financial relationship.[20] In other words, the IOAS exception was designed to continue to allow physicians to determine how care should be delivered to their patients and to protect access by Medicare beneficiaries to appropriate care, provided in the most efficient and effective manner.

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[17] MedPAC, "Report to the Congress: Issues in a Modernized Medicare Program," chapter 6, p 142 (June 2005), available at http://www.medpac.gov/publications%5Ccongressional_reports%5CJune05_ch6.pdf.

[18] *Id.* at 2.

[19] NPAF intends to submit separate comments on the 2008 OPPS Proposed Rule and will discuss its views to CMS's plans for collecting data on pharmacy handling costs in those comments.

[20] DHS are defined broadly at 42 C.F.R. § 411.351 to include: 91) clinical laboratory services, (2) physical therapy services and supplies, (3) radiology and certain other imaging services, (4) radiation therapy services and supplies, (5) durable medical equipment and supplies, (6) parenteral and enteral nutrients, equipment, and supplies, (7) prosthetics, orthothics, and prosthetic devices and supplies, (8) home health services, (9) outpatient prescription drugs, and (10) inpatient and outpatient hospital services.

CMS too has been sensitive to the need for balance in the regulations it has promulgated to date to implement the Stark Law. It has consistently recognized that the IOAS exception is intended "to allow physicians to furnish DHS that are ancillary to the physicians' core medical practice in the location where the core medical services are routinely delivered."[21] To that end, CMS previously has narrowly tailored the restrictions it has imposed on the scope of permissible physician ancillary services. These restrictions have been designed to prevent sham arrangements such as loose affiliations of physicians coming together merely to capture the profits from ancillary services or to rein in the provision of ancillary services that are only tenuously related to a physician's office practice. However, these restrictions always have been carefully circumscribed so as to ensure they would not unduly limit physicians' clinical decision-making about the what, why, how and where of patient treatment.

Currently, the Stark Law and implementing regulations establish numerous standards that services must meet to qualify for the IOAS exception. These standards relate to how group practices offering DHS must be structured, what DHS are eligible for protection under the exception, how DHS furnished under the exception may be supervised, where excepted DHS may be provided, and how excepted DHS may be billed. When these standards were published, they were deemed to be sufficient to prevent abuse of the IOAS exception. In NPAF's view, at least with respect to oncology, that conclusion is still true today.

NPAF strongly encourages CMS to recognize the special needs of cancer patients and the physicians who treat them if it promulgates any changes to the IOAS exception in either the 2008 PFS Final Rule or in the Stark II/Phase III regulations expected later this year. Cancer is a complex array of diseases. It includes many of the most complicated and costly treatable diseases in medicine, and high-quality cancer care frequently involves a large number of specialties and services. New knowledge is continually accumulating as to cancer's biologic underpinnings and new treatment options and opportunities are emerging at an ever-accelerating pace. As a result, clinical outcomes are improving, as judged by steadily increasing survival rates. We would hate to see poorly thought-through changes in the Stark Law, made in the name of controlling fraud and abuse, curtail such progress.

Throughout the development of the Stark Law and its implementing regulations, it has always been acknowledged that oncology is a unique field that should be singled out for more flexible treatment in certain respects. For example, the House bill that was the basis, in large part, for the first Stark Law, enacted in 1989, contained an exception to the definition of a "referral" for a referral by a physician to a specialized cancer treatment pharmacy under certain conditions.[22] This provision ultimately was eliminated, presumably since the initial Stark Law was limited to clinical laboratory services. However, in 1993, when the Stark Law was expanded to additional DHS, "referral" was defined to exclude a request by a radiation oncologist under certain circumstances. That exception remains in the Stark Law to this day.[23]

The IOAS exception has proven to be essential to the provision of integrated, comprehensive, high-quality cancer care in the community-based setting. It allows medical oncologists and radiation oncologists and other types of physicians to work together cooperatively in multidisciplinary practices at cancer centers equipped to furnish both chemotherapy and radiation therapy services. Collaboration and communication between subspecialties – which is facilitated by practicing in a single group using common treatment protocols, information systems and a unified medical record – has grown increasingly important in a world where well over half of all cancer patients receive both chemotherapy and radiation therapy during the course of their treatment.

The IOAS exception allows medical oncologists to perform simple blood chemistries in their offices to assess whether patients scheduled for chemotherapy are fit to undergo treatment when they are scheduled, to determine whether patients need adjuvant therapy with white-and/or red-cell stimulating agents, and to set the appropriate dosage for a chemotherapy treatment.

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[21] 66 *Fed. Reg.* 856, 888 (Jan. 4, 2001).
[22] *See* Conference Report for the Omnibus Budget Reconciliation Act of 1989, p. 852.
[23] 42 USC § 1395nn(h)(5)(C).

The IOAS exception also permits medical and radiation oncologists to incorporate sophisticated imaging technologies for disease staging and treatment monitoring into their practices and to work collaboratively with radiologists familiar with the requisite cancer imaging that begins after the diagnosis has been made and treatment has begun. The role of imaging in cancer care is such that each imaging event is likely to reflect a critical point of clinical management, and imaging studies have become crucial tools for patient care management in modern cancer practices. Further, proper disease staging and progress monitoring, using both conventional and functional imaging, is central to the implementation of evidence-based cancer care using clinical practice guidelines like those developed by the National Comprehensive Cancer Network ("NCCN") or the American Society for Clinical Oncology ("ASCO") and used by CMS as the basis for the Cancer Care Quality Demonstration in 2006.

Any change to the Stark regulations that would exclude imaging from the list of DHS eligible for the IOAS exception would undermine the ability of oncology practices to follow appropriate treatment guidelines. Diagnostic imaging is routinely provided, generally as an incident-to service, in cancer care. It allows oncologists to assess treatment efficacy and to make clinically significant, timely corrections in treatment when a therapy is not working. Improvements in imaging have contributed significantly to many improvements in outcomes. As a result, today, numerous types of cancer are now being seen as treatable chronic diseases, rather than as a death sentence. The reality is that diagnostic imaging is truly ancillary to the oncologist's core medical practice. The oncologists tasked with making treatment decisions should be in a position to control how imaging equipment is calibrated, maintained and operated; how results of imaging studies are reported; how their patients are treated during imaging sessions; and how their patients are advised of the outcomes of their diagnostic procedures.

Being able to offer imaging under the IOAS exception facilitates timely receipt of diagnostic results and allows oncology practices to report results, answer patients' questions and, if necessary, realign treatment plans more rapidly. Changing the IOAS exception so as to impede the integration of diagnostic imaging into community-based oncology practices would be a disservice to Medicare beneficiaries and all patients, for in many instances the entire imaging program would be compromised without Medicare participants. Imaging is an important psychological event for most cancer patients. Being able to obtain needed imaging services within "their" oncology practice allows patients to interact with familiar staff attuned to explaining procedures, listening to patient concerns, and dealing honestly, openly, and sensitively with patients facing acute distress, fear of complications of treatment, fear of disease recurrence, and fear of death. Allowing imaging to be conducted within oncology practices under the IOAS exception reduces the psychological burden of cancer treatment on patients battling the disease and the burden on their caregivers. It also reduces productivity losses that occur when cancer patients (and their caregivers) have to expend extra energy and take extra time off work to be present for a series of tests at a variety of locations. In-office imaging access reduces risk of incorrect therapeutic interventions.

Clinical trial sponsors prefer to negotiate research contracts with investigators equipped to handle all aspects of a trial protocol, including imaging studies to assess the effectiveness of trial drugs or procedures. As a result, being able to furnish imaging services under the IOAS exception facilitates the ability of community-based oncologists to participate as investigators in clinical trials and, thus, to offer their patients – particularly their patients who have failed on conventional therapy – the opportunity to access treatments that would otherwise be unavailable to them unless they were able to travel to a major academic medical center, which might be hundred of miles away, to enroll in an appropriate clinical trial. We fear that any change in the IOAS exception which would impede the ability of community-based oncologists to offering imaging services could further exacerbate the challenges trial sponsors already face finding enough cancer patients to fill their trials.[24]

There are reportedly well over 400 new, potentially life-saving anti-cancer therapies currently in the research pipeline. Many of these experimental drugs are targeted at the most lethal and/or the most common forms of cancer. Nonetheless, nationally only about 3% of all cancer patients participate in

[24] ABC News, "Experts weigh In: Shortage of Patients in Cancer Trials" (Aug. 1, 2006), available at http://abcnew.go.com/print?=2261005.

trials.[25] Although the situation has improved since the implementation of CMS' clinical trial National Coverage Decision in 2000,[26] Medicare beneficiaries are still under-represented in the ranks of cancer trial participants relative to the prevalence of the disease in the Medicare population. Since nationally 63% of all cancer patients are Medicare beneficiaries, new Stark Law restrictions that adversely impact clinical trial accrual also could drive manufacturers funding their own trials to increase the proportion of trial participants recruited overseas, a fact that would not only robs Medicare beneficiaries of trial opportunities but also could undercut the ability of the Food and Drug Administration to adequately oversee non-governmentally funded trials.

Limiting DHS that qualify for the IOAS exception to those "needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan or treatment," as suggested in the Proposed Rule[27] also is misguided for often the patient need is of that of staged imaging, define relapse and outline appropriate protocols and could have a significant negative impact on quality of care. In-office ancillary services offer patients and their caregivers single visit co-payments thus reducing cost-shifting burdens. Nonetheless, many clinical laboratory and imaging services performed at one scheduled patient visit (*e.g.*, a chemotherapy visit) may be used to provide baseline data or other data that the patient's physician may not use until a subsequent patient visit.

We encourage CMS to support the unique role the IOAS exception plays in the provision of comprehensive, integrated cancer care in the community-based setting, thus acknowledging the balance Congress intended to achieve when it included the IOAS exception in the Stark Law.

RESOURCE-BASED PE RVUS

CMS Should Defer Any Decision about the Need for an IVIG Pre-Administration Service Fee in 2009 until Next Year

NPAF supports CMS' decision to continue reimbursing providers in 2008 for pre-administration services associated with intravenous immune globulin (IVIG) treatments and we encourage CMS to defer any decision about payment in 2009 until next year. We understand that oncologists are still having difficulty fully meeting their immune globulin needs through their primary suppliers and their staffs must frequently search for IVIG through secondary distributors. We support CMS's cautious, continual evaluation of the IVIG market and the continuing need for pre-administrative services in 2009. We further support CMS's assessment of the situation when it preparing the 2009 PFS Proposed Rule and proceed accordingly based on current data.

DRUG COMPENDIA

CMS Should Take Immediate Steps to Ensure at Least Three Compendia Are Available to Guide Coverage Determinations about Unlabeled Uses of Drugs in Anti-Cancer Chemotherapeutic Regimens

While NPAF is pleased CMS intends to establish a process for expanding the number of compendia that may be used to determine medically-accepted indications of drugs and biologics used in an anti-cancer regimen, we fear the proposed process is inappropriately bureaucratic and drawn out, particularly given the small number of compendia offered by the pharmaceutical reference industry. Social Security Act § 1861(t)(2) specifies three compendia for use in determining "medically acceptable indications" for anti-cancer drugs. One of the three (the AMA Drug Evaluations) is no longer being published. Furthermore, the U.S. Pharmacopeia-Drug Index ("USP-DI") has been acquired by Thomson Micromedex ("Thomson"), revamped and renamed. Unless CMS takes immediate action, only one compendium – the American Hospital Formulary Service – Drug

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[25] John McKenzie, ABC News, "So Few Volunteers for Cancer Studies" 9Aug. 1, 2006), available at http://abcnews.g.com/print?id=2261005 (quoting Dr. Robert Comis, Board President, Coalition of Cancer Cooperative Groups).

[26] "Impact of the Year 200 Medicare Policy Change on Older Patient Enrollment to cancer Clinical Trials," *J. Clinical Oncology*, vol. 24, pp. 141-44 (Jan. 1, 2006).

[27] 72 *Fed. Reg.* at 38181.

Information ("AHFS-DI") – will be a mandated reference for determining coverage of anti-cancer drugs prescribed for unlabeled uses.

NPAF believes it is critical that CMS recognize a number of compendia as the statute requires. If only one compendium is available, cancer patients will have limited therapeutic options further restricted by the process and timeliness of the one publication in the marketplace. Moreover, decisions as to "medically acceptable indications" would be left to a single, non-governmental organization. Having more than one compendium is important to ensure that the particularities of a single compendium (*e.g.*, how it selects and reviews clinical evidence, how it decides which uses are supported by that evidence, how it resolves any conflicts of interests among reviewers, etc.) do not inappropriately restrict Medicare coverage and payment. We urge CMS to take steps immediately to ensure that the number of approved compendia under § 1861(t)(2) does not fall to one.

To that end, ***we strongly urge CMS to use its discretionary authority immediately to designate the NCCN Drugs and Biologics Compendium as a mandated reference for CMS coverage determinations under § 1861(t)(2)*** without requiring the compendium to go through any further process. Section 1861(t)(2) of the Social Security Act provides CMS with the authority to review the list of referenced compendia for determining medically-accepted indications for drugs. Consideration of the NCCN Drugs and Biologics Compendium has been before the agency for quite some time. The cancer community is well aware of NCCN's application to CMS and is strongly supportive of CMS's adoption of the compendium. Both the AMA and the American Cancer Society have endorsed recognition of the NCCN Compendium. NPAF is of the same view.

CMS has worked with the Medicare Coverage Advisory Committee (MedCAC) to define desirable criteria for compendia and has commissioned an Agency for Health Research and Quality ("AHRQ") Technology Assessment to determine the extent to which various compendia comply with those characteristics.[28] The NCCN Drugs and Biologics Compendium received the highest rating of the six compendia AHRQ reviewed on each of the desirable characteristics. On what we consider to be the most important characteristic – the evidentiary basis of the compendium's recommendation – the NCCN Compendium was rated a 4.5 out of 5, with the next closest score being a 3.58. It is important to note that the NCCN Drug and Biologics Compendium ranked higher that the AHFS-DI or USP-DI.

The NCCN Clinical Practice Guidelines in Oncology are widely recognized and applied as the standard for oncology clinical practice in both the academic and community practice settings. Many private payers use the Guidelines as a basis to establish coverage for cancer therapy. There are 50 NCCN Guidelines panels, each composed of 20 or more experts who volunteer their expertise. The panels are multidisciplinary in composition and have broad geographic representation. The NCCN Drugs and Biologics Compendium translates recommendations from the NCCN Guidelines into a format that can be easily searched by drug or biological. This reality should make the Compendium user-friendly for CMS contractors tasked with coverage determinations. Recommendations in the NCCN Guidelines and Compendium are evidence-based and updated on a continual basis. This is critical in oncology where clinical evidence is constantly changing and developing.

CMS recognizes that "broad accessibility by the general public to information in the compendium may assist treating physicians, beneficiaries or both in choosing among treatment options".[29] NCCN serves as a valuable resource to cancer patients and their loved ones as they consider and weigh treatment options. It is easily accessible and, unlike all other compendia of which we are aware, is available free of charge to all visitors on NCCN website. Further, NCCN works collaboratively with the American Cancer Society to translate the professional guidelines it develops into patient guidelines intended for lay use.

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[28] Agency for Health Research and Quality, "*Compendia for coverage of Off-Label Uses of Drugs and Biologics in an Anticancer chemotherapeutic Regimen,*" available at https://www.cms.hhs.gov/mcd/viewtechassess.asp?where=index&tid=46

[29] 72 *Fed. Reg.* at 38177.

compendia to objective criteria and permit public comment on CMS' assessment. In this matter, timing is critical.

CMS Should Focus on Transparency of Compendia Processes, Not Specific Review Criteria beyond the MedCAC Desirable Criteria

NPAF is concerned that the proposed process for adding compendia could lead to arbitrary decisions and less transparency and thereby unnecessarily limit the number of approved compendia. In the Proposed Rule, CMS indicates it will consider various factors in addition to the MedCAC desirable characteristics. We agree the MedCAC criteria appear generally appropriate for determining whether a compendia should qualify as authoritative or otherwise be appropriate under 1862(t)(2).[33] However, CMS does not give any indication of how it will go about determining whether a compendium achieves the desirable criteria. Moreover, since AHRQ did not find that any of the compendia it reviewed met all of the criteria, it appears CMS will be compelled to exercise significant judgment regarding which criteria will be considered most important or how they will be weighted. Further, the additional factors CMS suggest it may consider are exceedingly vague and simply leave too much room for agency discretion. Unless objective criteria is clearly identified and used in a consistent way, the public cannot be assured candidate compendia will be evaluated fairly or similarly.

CMS proposes to consider a compendium's grading of evidence and the processes it uses. We think that it is most important that any compendium have a process for evaluating and weighing evidence that is transparent to the public. We are actually opposed to CMS defining a specific evidence threshold because doing so would limit an oncologist's ability to select and combine treatments from different compendia to meet the unique needs of their patients. Cancer patients have complex clinical circumstances and their risk tolerance levels may differ greatly from patient to patient. Many cancer patients may be willing to try an unlabeled use because it may be their only hope. Oncologists should be permitted to use their own clinical judgments about how and when to use anti-cancer agents based on their own evaluation of the evidence, compendia recommendations, their evaluation of the various compendia, and their professional experience and judgment. We believe cancer patients will be best served if more compendia are available to inform clinical decision-making so long as the compendia satisfy certain minimal standards reflective of general compliance with the MedCAC desirable criteria coupled with transparency in their processes.

CMS Should Revise its Definition of Compendium

CMS proposes that a compendium be indexed by a drug or biological, rather than by disease. NPAF believes a compendia indexed by disease is more useful to oncologists and cancer patients and their families. Requiring a compendium to be indexed by a drug or biological will make it more difficult for patients to be informed about available treatment options and to have meaningful discussions with their oncologists about their treatment option since today most protocols involve multiple drugs and are identified by disease. We understand that the currently listed compendia and the NCCN compendia are all available electronically and are searchable so that CMS and its contractors can easily locate a specific drug or biological.

We also fail to understand why CMS considers inclusion of dosage information and recommended or endorsed uses as an optional compendium feature, and not an integral part of the definition of a compendium. We recommend that CMS delete the requirement for indexing by drug or biological in its final approval process and require the inclusion of dosage information and recommended and endorsed uses for approved compendia.

CMS Should Not Delete Approved Compendia without a Notice and Comment Process

NPAF is deeply concerned that deleting compendia from any approved list of reference sources could be quite disruptive, not just to payment policy, but also to clinical decision-making and patient care. Once a compendium has been included in a list for use in determining medically accepted indications,

[33] We note that one of the characteristics is "quick throughput," the desirability of which and connection to the authoritative character of a compendium, depends, in part, on the definition of "quick."

it affects how clinicians treat patients and influences the standard of care. Approved compendia today have been used since at least 1994 and are critically important to determining coverage for anti-cancer treatments.

We recommend that CMS adopt a removal process that differs significantly from the process for adding compendia under Social Security Act § 1862(t)(2). Section 1861(t)(2) of the Social Security Act contemplates revision of the list of compendia in two ways. We believe that the explicit separation, in the statute, of the provision for adding "other authoritative compendia" from the provision for "revising" the list of compendia is important. Our interpretation is that Congress intended for CMS to establish different processes for accomplishing these actions.

We believe a compendium should only be removed from an approved list of reference materials after systematic review and evaluation demonstrates material failures in its reliability as authoritative, after the sponsor has been given an opportunity to address any ostensible deficiencies, and after notice to the public and full opportunity to comment on the agency's reasoning behind a proposed removal. The public's interest would be best served if this notice were accomplished by publication in the *Federal Register*. Removal of any compendium will necessitate revisions of local coverage policies, which is a time-consuming process involving its own notice-and-comment requirements, and CMS should make appropriate accommodation for this process in any proposed removal process timeline.

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In closing, NPAF would like to thank you for this opportunity to provide our comments on Proposed Rule CMS-1385-P. We strive to make dialogue with the agency about payment policies a constructive discussion that gives voice to the concerns of Medicare beneficiaries dealing daily with the burdens of a chronic, debilitating or life-threatening disease. We look forward to continuing our work with CMS to implement both the Part B and the Part D provisions of the MMA in ways that maximize Medicare beneficiary access to both the drugs and the high-quality, high-value professional services they need and deserve.

Respectfully submitted,

Nancy Davenport-Ennis
Chief Executive Officer

Submitter : Dr. Gonzalo Castillo **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15322-Attach-1.PDF

Gonzalo Castillo, M.D.
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Submitter : Tracy Morgan **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15325-Attach-1.DOC

ADVANCED PAIN MANAGEMENT

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August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Tracy Morgan
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Dr. Michael Huether **Date:** 08/31/2007

Organization : Arizona Skin Cancer Surgery Center, P.C.

Category : Physician

Issue Areas/Comments

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

The CMS plan to change the payment policy for Mohs surgery has the potential to negatively impact the care of our patients, and could add significant cost to an already stressed healthcare budget. This change would remove Mohs surgery from a longstanding exemption from the multiple surgery reduction rule. This is a departure from a longstanding exemption agreed to by CMS. The change proposed would eliminate the exemption and decrease reimbursement by 50% for either the Mohs excision or for the associated repair, and for Mohs excision of any additional cancers treated on the same day; such a decrease in reimbursement would not cover the cost of providing the service.

If this proposed change is enacted, we will no longer be able to provide the same kind of high-quality, cost-effective services for our patients in need. We will be forced to change the way we deliver care in order to cover our costs of providing this service.

In its review of the Mohs codes in 1991, CMS agreed that Mohs excisions are separate staged procedures; they will be paid separately with no multiple surgery reductions. This rule was placed in the Federal Register at that time (Federal Register, November 25, 1991, volume 56, #227, pg 59602). In 2004, the Mohs codes were added to the CPT Appendix E list of codes exempt from the -51 modifier and the multiple surgery reduction rule, to eliminate the occasional carrier misunderstanding when the multiple surgery reduction was applied to these codes. The July 2004 CPT Assistant article reviewed the rationale: The rationale for this policy is that for many surgical procedures some of the work of a procedure is not repeated when two or more procedures are performed. For these procedures the intraservice work is only 50% of the total work, while the other 50% represents pre- and post-service work that overlaps when multiple procedures are performed on the same patient on the same date of service. For Mohs surgery, however, greater than 80% of the work is intraservice work that does not overlap when two or more procedures are performed. The pathology portion of Mohs surgery constitutes a large portion of this total and also is not reduced with multiple procedures. The pre-service and post-service work values are small because there is a zero-day global period. Together there is very little overlap or reduction in work when two or more tumors are treated on the same patient on the same day. Therefore, Mohs surgery codes are exempt from the use of modifier 51.

The exemption of the Mohs codes from the MSRR has been maintained by CMS since 1992 and was not questioned during the CMS mandated five-year review of the Mohs codes undertaken last fall or during presentation of the new Mohs codes to the AMA Relative Value Update Committee (RUC) in October, 2006.

The consequence of applying the multiple surgery reduction rule to the Mohs codes would be a reimbursement reduction to a value less than the cost of providing the service. Therefore, providers will no longer be able to perform more than one Mohs procedure on any patient on a single day. Treatment of only one tumor per day will inconvenience many patients and their friends and families who accompany them for treatment. It will also inconvenience employers when workers are absent from work more frequently for multiple treatments. In addition to its application to multiple cancers treated on the same day, the MSRR would apply to repairs performed on the same day as Mohs surgery. Since costs would not be covered, this may require patients to have their Mohs surgery and their reconstruction done on separate days, or to be referred to other physicians for reconstruction, usually plastic, facial plastic, or oculoplastic surgeons, who work primarily in hospitals or ambulatory care centers where costs of care are higher. The result would be that healthcare costs will be higher than they are under the current policy of payment.

Submitter : **Mr. Anthony Barrueta** **Date: 08/31/2007**

Organization : **Kaiser Permanente**

Category : **Health Plan or Association**

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Kaiser Permanente appreciates the opportunity to comment on the proposed rule for the limited purpose of expressing concerns about the elimination of the exemption of computer generated fascimile prescriptions from the SCRIPT standard for electronic transmission of prescriptions.

While Kaiser Permanente has made a strong commitment to and investment in implementing and making as universal as possible the use of electronic prescribing meeting a common standard, we believe that there is a significant risk that not all providers -- partieularly long term care providers and home health agencies -- will be able to meet these standards prior to the deadline of January 1, 2009 set forth in the proposed rule. If these providers are not able to meet the standard, the far less preferable use of written prescriptions is likely to increase, with negative results in terms of patient safety and provider efficiency. In order to provide sufficient time for providers to comply with these requirements, we join other major developers and users of electronic prescription systems in recommending that the elimination of the exemption for facsimile prescriptions be delayed until January 1, 2010 at the very earliest. We further recommend that CMS examine the state of implementation of electronic prescribing systems in home health agencies and long term care facilities prior to eliminating this exemption. We do not believe that extending this exemption is likely to delay the roll-out of electronic prescribing systems. Instead, it will allow organizations the time to make necessary changes without significant disruption to pharmacy and provider processes.

Thank you very much for considering Kaiser Permanente's concerns. If you have any questions, please do not hesitate to contact me.

Anthony A. Barrueta
Vice President, Government Relations
Kaiser Foundation Health Plan, Inc.
510-271-6835
anthony.barrueta@kp.org

Submitter : **Mrs. Kelly Harkins** **Date: 08/31/2007**

Organization : **Charleston Southern University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I work at Charleston Southern University where I am the Athletic Training Education Program Director. I am the program director as well as professor for the Athletic Training Program. I also help cover athletics where I am needed.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Kelly Harkins, ATC

Submitter : **Mr. Chris Shaddock** **Date: 08/31/2007**

Organization : **Pearland ISD**

Category : **Other Practitioner**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a licensed and certified athletic trainer at the secondary school setting. I have a Bachlors degree from Stephen F. Austin State University where I completed an internship for the four years I was there. I then went on to practice as an athletic trainer, but before I could do that, I had to take the licensure exam by the Texas Department of Health Services. To further my credentials, I became nationally certified by the National Athletic Trainers Association Board of Certification.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Sincerely,

Chris Shaddock ATC, LAT

Submitter : **Date: 08/31/2007**

Organization :

Category : **Nurse Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

Although there may be a concern about fraud in the Medicare system, as may be the case in any large public or private endeavor, the appropriate solution is not to burden all providers with exessive regulation. I suggest the development and use of appropriateness criteria, credentialing and accreditation as reliable methods to ensure appropriate utilization and quality of care.

As the population of older Americans increases and lifespan lengthens, Cardiology as a speciality has seen significant growth. Caring for the elderly population comes at a price, and there will come a point where cardiologists and speciality allied health professionals will not be able to sustain services to their Medicare population should reimbursement for these beneficiaries continue to decrease. Physicians and allied health providers have not received a cost of living raise in several years although the cost of providing care has increased over these years. We encourage CMS to continue to work with Congress to find a permanent solution to the flawed Sustainable Growth Rate factor. Thank you for your consideration.

Submitter : **Mr. Jarred Gibson** **Date: 08/31/2007**

Organization : **Northwest Christian College**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Jarred Gibson. I am a Certified Athletic Trainer in my second full year at Northwest Christian College in Eugene, OR. My primary role as Certifeid Athletic Trainer is the general health care for over 120 student athletes participating in ten intercollegiate sports including prevention, evaluation, treament, and rehabilitation of injuries that may occur on and off the competitive areas. I have been a Certified Athletic Trainer since February 1998, through the National Athletic Trainers' Association Board of Certification and have worked in various settings for Athletic Training including clinical, high school, health club, and collegiate levels. I became certified through an educational program at Whitworth College in Spokane, WA, graduating in 1997 with degrees in Athletic Training and Physical Education, and wanted to expand upon that knowledge base and chose to further my education at the University of Oregon, graduating in 2002, with a Master's Degree in Exercise and Movement Science with an emphasis on Athletic Training.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Jarred Gibson, ATC

Submitter : **Date: 08/31/2007**

Organization :

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am currently a student at Minnesota State University, Mankato.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

Whilc I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Sincerely,

Zach Horning, Athletic Training Student

Submitter : Gabriella Bauer **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15333-Attach-1.DOC

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Gabriella Bauer
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Mr. W. Bradley Tully, Esq. **Date:** 08/31/2007

Organization : Hooper, Lundy

Category : Attorney/Law Firm

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

see attachment

CMS-1385-P-15334-Attach-1.DOC

CMS-1385-P-15334-Attach-2.DOC

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : Mr. Ryan Kling **Date:** 08/31/2007

Organization : Orthopaedic Center of Central Virginia

Category : Other Health Care Provider

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am an Athletic Trainer/Physician Assistant and I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Ryan Kling,ATC, PA-C

Submitter : **Mrs. Becki Flanagan** **Date: 08/31/2007**

Organization : **Metro Christian Academy**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Becki Flanagan, and I am a Certified Athletic Trainer in Tulsa, OK. I have a B.S. in Athletic Training and a M.S. in Health Care Adminstration. While I currently work in a private school setting, I have worked in numerous rehabilitation clinics and hospitals around the country.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Becki Flanagan, M.S.,ATC

Submitter : Jeanne Zabout **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15338-Attach-1.DOC

15036

A D V A N C E D P A I N M A N A G E M E N T

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

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I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Jeanne Zabout
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Takeila Gilbert **Date:** 08/31/2007

Organization : Student

Category : Individual

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Takeila Gilbert and I am writing today as a athletic trainer student, to voice my concerns to therapy and requirements in regards to the staffing provisions for rehabilitation in hospital and facilities proposed in 1385-P. The changes will have a tremendous effect on the workforce which will cause a lack of opportuninty for students like me in the future. As a healthcare provider our sole responsibilty is the patient. Therefore, it is in best interest that the patient receive the best in most affordable treatment available. I encourage CMS to look in to other opitions that are in the best interest of the patient.

Submitter : Dr. Paul Hawkins **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15340-Attach-1.PDF

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Paul Hawkins, M.D., Ph.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : **Mr. Paul Valentine** **Date: 08/31/2007**

Organization : **Sleep HealthCenters LLC**

Category : **Other Health Care Provider**

Issue Areas/Comments

IDTF Issues

IDTF Issues

1. Proposed Prohibition on Sharing IDTF Space, Staff and Equipment

CMS is proposing to add a new, 15th performanee standard which would prohibit an IDTF from sharing any of its space, staff or equipment with any other person or entity. Thus, to participate in Medicare, the IDTF must certify that it does not share space, equipment or staff or sublease its operations to another individual or organization. If adopted, this provision would apply regardless of the method for paying rent both per click and block leasing arrangements would be prohibited if the lab intends to enroll or remain enrolled in the Medicare program as an IDTF. CMS noted that shared facility arrangements raise concerns under the physician Stark law and the federal anti-kickback statute.

As a leading provider of sleep medicine services, including polysomnography, we would like to comment on how these proposals would adversely affect the delivery of sleep medicine services to Medicare beneficiaries.

Use of a hotel for services:
There is no compelling reason to prevent the use of a hotel for providing diagnostic sleep studies. Sleep labs are designed for the comfort of the patient, and, although they are clinical in nature, they do not require a sterile environment or anesthesia. Polysomnography is a very low risk diagnostic test. Often a hotel setting is preferred to that of a hospital department or laboratory setting, as patients can be more relaxed in a setting that is more home-like, and often get to reap the extra benefits of the hotel amenities afforded to guests. So long as such services comply with applicable state laws and regulations, there is no compelling need for Medicare to bar this practice with respect to polysomnography and other low risk physiological tests.

Shared waiting/patient rooms:
Polysomnography is usually carried out at night. This makes it possible for a sleep laboratory to lease office space for use during the evening and night hours when physician offices normally are closed. This dual use of space would seem to be a more efficient use of space. Patients from one practice would not be likely to encounter sleep patients as the timing of the visits would be at opposite times of the day. As well, in metropolitan areas where accessible and appropriate space is at a premium, shared use of space is a necessity.

In both cases, as long as the practices are consistent with state law, and any lease and other financial arrangements are compliant with both Stark and anti-kickback regulations, there is no compelling public health or fraud and abuse concern for Medicare to bar these practices. Barring these practices has the very real potential to create access and convenience problems for beneficiaries.

Submitter : Dr. John Kowalski **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15342-Attach-1.PDF

15342

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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John Kowalski, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : Gail Slaughter **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1385-P-15343-Attach-1.DOC

15343

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

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RESOURCE-BASED PE RVUs

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The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

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I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

ADVANCED PAIN MANAGEMENT

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Gail Slaughter
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Mr. Peter Stoloff **Date:** 08/31/2007

Organization : Peter F. Stoloff, P.C.

Category : Attorney/Law Firm

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Comments of Peter F. Stoloff, attorney at law: See attached Microsoft Word document dated August 31, 2007.

CMS-1385-P-15344-Attach-1.DOC

1041

PETER F. STOLOFF, P.C.
ATTORNEY AT LAW
BANK OF AMERICA FINANCIAL CENTER
121 S.W. MORRISON, SUITE 600
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PSTOLOFF@AOL.COM

LICENSED IN
OREGON
AND
IDAHO

September 14, 2007

BY ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: File Code CMS-1385-P: PHYSICIAN SELF-REFERRAL PROVISIONS

Dear Sir or Madam:

This letter contains my comments on issues in Section II.M (Physician Self-Referral Issues) in the proposed rule published in the July 12, 2007 Federal Register.

1. Services Furnished "Under Arrangements" (in paragraph II.M.11 beginning on page 38186 of the July 12, 2007 Federal Register). I respectfully request that CMS reconsider its proposed change to the definition of "entity" in 42 CFR Section 411.351. Beginning with the proposed Stark II rules which were published on January 9, 1998, CMS has correctly taken the position that an "entity" for purposes of Stark II is the organization that actually furnishes or provides for the furnishing of a designated health service ("DHS") to a Medicare or a Medicaid patient and bills for that service:

> "We believe that, absent an exception, the referral prohibition applies to a physician's referrals to any entity that directly furnishes designated health services to Medicare or Medicaid patients. We believe the prohibition also applies to referrals to any entities that arrange "for the furnishing of" these services to Medicare or Medicaid patients by contracting with other providers, whenever it is the arranging entity that bills for the services." See, January 9, 1998 Federal Register at page 1706 (column 3).

CMS further stated in the January 9, 1998 Federal Register that "this interpretation is consistent with the intent of the statute." Id.

CMS reaffirmed its interpretation in the January 4, 2001 final Stark II preamble, in which it stated:

> "We are clarifying in Phase I of this rulemaking that, for purposes of section 1877 of the Act, a person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf...." See, January 4, 2001 Federal Register at page 943 (column 1).

The final Stark II, Phase I rule as published on January 4, 2001 clearly states that "A person or entity is considered to be furnishing DHS if it is the person or entity to which HCFA makes payment for the DHS, directly or upon assignment on the patient's behalf...." See, 42 CFR Section 411.351.

The final Stark II preamble published in the January 4, 2001 Federal Register at page 943 (column 2) states that CMS will "apply the rules related to indirect financial relationships and indirect referrals" in addressing the question of when the owner of a DHS provider is considered to be the equivalent to the entity providing DHS.

In the preamble to the Interim Final Rule published on March 26, 2004, CMS reaffirmed the definition of "entity" by stating that: "The substance of the definition remains unchanged." See, March 26, 2004 Federal Register at page 16106 (column 3). Moreover, the preamble to the March 26, 2004 Interim Final Rule at page 16061 contains CMS's response to a comment concerning direct and indirect ownership interests and compensation arrangements. CMS's response distinguishes between a "DHS entity" and the "common venture" in the situation in which an imaging equipment leasing company is co-owned by a hospital (the DHS entity) and a referring physician. See, page 16061 (column 2). CMS stated that the co-ownership may create an indirect compensation arrangement, which means that in order for the arrangement to be Stark II compliant, the exception for indirect compensation arrangements would need to be met, as well as compliance with the anti-kickback statute. Id.

Accordingly, for nearly 10 years (since January 9, 1998), CMS has correctly taken the position that an "entity" for purposes of Stark II is the Medicare billing entity. Since January 4, 2001, CMS has correctly taken the position that the exceptions regarding direct and indirect compensation arrangements must be met in order for co-ownership of a non-Medicare billing entity by a DHS entity and a referring physician to be lawful under Stark II. These rules have been relied upon by hospitals, physicians, and other organizations in meeting the health care needs of Medicare patients, and it would be unreasonable and unfair for CMS to reverse its position after 10 years of industry reliance on CMS's reasonable interpretation of the meaning of "entity". If CMS changes the definition of "entity" as proposed in the July 12, 2007 proposed rule relating to the Medicare Physician Fee Schedule, it would require the unwinding and dissolution of numerous arrangements that have heretofore constituted lawful co-ownership of non-DHS entities. There are many legitimate reasons for co-ownership of non-DHS entities. Physicians are involved in such entities because they are licensed to practice medicine and to

provide DHS. The provider-based rules require that the hospital maintain the same monitoring and oversight of provider-based entities as it does for any other department of the provider, and that the professional staff of the facility have clinical privileges at the hospital. See, 42 CFR Section 413.65(d)(2). It would also be unreasonable and unfair for CMS to prohibit joint ownership of non-DHS entities between physicians and hospitals, because it will result in a diminution in access to quality health care at a reasonable cost by Medicare beneficiaries.

In addition, I respectfully request that CMS not take action to prevent or prohibit, through other regulatory changes, hospital and physician co-ownership of non-DHS entities.

I urge that CMS not adopt the MedPAC recommendation to prohibit "physician ownership of entities that provide services and equipment to imaging centers and other providers." Contrary to the MedPAC recommendation, such a prohibition would in fact reduce competition among health care facilities and reduce access to such facilities by Medicare beneficiaries. The Stark II rules requiring compliance with the exception for indirect compensation arrangements in 42 CFR Section 411.357(p) are sufficient to prevent program abuse, because those rules require that the compensation be at fair market value of services and items actually provided.

2. Unit-of-Service (Per-Click) Payments (in paragraph II.M.5 on pages 38182-38183). I respectfully request that CMS not prohibit the use of per-click payments in connection with space and equipment leases in situations in which a hospital is a lessor to a physician, and in situations in which a physician is a lessor to a hospital. It is my experience that such arrangements do not provide an incentive for overutilization. These arrangements are typical in the hospital/physician context. As long as the per-click payment complies with the fair market value and other standards that are included in the space lease and equipment lease exceptions, such arrangements should be permitted to continue.

Again, the industry has relied on CMS's position that per-click payments are permissible, and it would be unfair to reverse this longstanding position. There are sufficient safeguards in the space lease and equipment lease exceptions to prevent program abuse.

Moreover, the March 26, 2004 Interim Final Rule and the preamble thereto, reaffirmed that per-click payments are lawful as long as such payments fit within the fair market value standards imbedded in the space lease and equipment lease exceptions.

For example, on page 16059 (column 1) of the March 26, 2004 Federal Register, CMS stated that "time, unit-of-service, or other "per-click" based arrangements are generally permitted if they are at fair market value without reference to referrals..."

On page 16061 (column 2) of the March 26, 2004 Federal Register, CMS stated:

"In general, if the rental payment (frequently a "per-click" payment) by the hospital to the leasing company is fair market value (and the "per-click" fee does not vary over the term of the agreement) and does not otherwise reflect the volume or value of referrals, the indirect compensation arrangement would be excepted."

Contrary to the statement by CMS in the July 12, 2007 Federal Register on page 38183 (column 1), such per-click arrangements are not "inherently susceptible" to abuse, because the payment to the physician lessor would be limited to the fair market value of the equipment or space provided by the physician lessor to the entity lessee.

In conclusion, I respectfully request that CMS not change its longstanding policy with respect to per-click payments. Sufficient safeguards exist to prevent program abuse.

3. Set in Advance and Percentage Based Compensation: Section II.M.8 on page 38184. I respectfully request that CMS not limit percentage-based compensation only to paying for personally performed physician services. There are many other legitimate uses of percentage-based compensation, such as in equipment leases and in payments from physicians to a Management Service Organization ("MSO") for management services. There are sufficient safeguards in the space lease and equipment lease exceptions to protect against potential program abuse. Specifically, any space lease or equipment lease must be at fair market value. To the extent that the percentage compensation deviates from fair market value, such an arrangement would not fit within the applicable exception, and therefore would prevent referrals of DHS and would prevent any Medicare or Medicaid billings with respect to such prohibited referrals.

CONCLUSION

In conclusion, for the foregoing reasons, I respectfully urge that CMS not adopt the three proposed changes to the Stark II rules addressed in this letter. The proposed changes are unnecessary because sufficient safeguards against program abuse already exist in the Stark II rules and exceptions. Moreover, it would be patently unfair and unreasonable to make these changes after nearly 10 years of reliance on the existing rules by providers. Thank you for your consideration of these comments.

Sincerely,

Peter F. Stoloff

PETER F. STOLOFF

PFS:np

Submitter : Dr. Cezary Miskiewicz **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15345-Attach-1.PDF

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Cezary Miskiewicz, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : **Dr. Vanessa Vu** **Date: 08/31/2007**

Organization : **ORegon Surgery Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Vanessa T. Vu, M.D., Ph.D.

Submitter : Dr. Anang Chokshi **Date:** 08/31/2007

Organization : Fortanasce PT

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To whom it may concern,

This is a brief letter with regards to physician self referrals. With such a policy existing, it creates many issues with regards to the care of the patient in addition to the professional security of our profession.

By having self referral, physicians are hurting the private outpatient clinics by eliminating the source of our business. If the orthopedic physician refers a patient to their own clinic less patients are going to other therapist owned clinics in the area.

This also disregards the professional development and education of our profession. We are skilled in the asssesment of musculoskeletal abnormalities biomechanically. Our education entails thorough examinations of the patient , appropriate exercises and therapeutic interventions along with screening of further medical conditions which may be a source of the patient's issue but not within the scope of our practice. We are trained to know when it is proper to refer back to the physician if the case is not musculoskeletal in nature.

Having physicians refer to their own clinic creates a monopoly of the patient population and a source of "double dipping" per se. Many patients are not told by their physicians that they can seek therapy elsewhere besides the physician's facility hence making the patient an educated consumer.

Due to the extensive education of our profession in our field of expertise and the decrease in competetion it creates we hope that you will see that self referals for the patients is something we should not be having in the country.

Thank you

Submitter : Mr. J.Robert VanKirk **Date:** 08/31/2007

Organization : AANA

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
__J. Robert VanKirk, CRNA_____
Name & Credential
___8043 Creston Drive_____
Address
___Freeland, MI 48623_____
City, State ZIP

Submitter : **Mrs. Andrea Lucas** **Date: 08/31/2007**

Organization : **Laurel Health System**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Andrea Lucas and I work for Laurel Health System as an athletie trainer. My duties are to serve as the head athletic trainer for Wellsboro School district. I have been a Certified Athletic Trainer for 7 years. I attended Lock Haven University for my undergraduate degree and Bloomsburg University for my masters

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health eare for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Andrea Lucas MS, ATC

Submitter : **Dr. Noah Wasielewski** **Date: 08/31/2007**

Organization : **College of Charleston**

Category : **Academic**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To Whom It May Concern:

I am an assistant professor at an academic institution in South Carolina. I am an educator of future health care providers- athletic trainers to be specific. I have been a certified athletic trainer since 1995. I have 11 years of formal schooling at various institutions of higher learning.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Noah Wasielewski,PhD,ATC,CSCS

Submitter : Dr. Deborah Fritz **Date:** 08/31/2007

Organization : GlaxoSmithKline

Category : Drug Industry

Issue Areas/Comments

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

This is to clarify the public comment GlaxoSmithKline recently submitted regarding TRHCA-Section 101 (b): PQRI. We believe that physician led organizations such as the AMA PCPI have a significant role in the development of measures and for rapid program uptake and overall success. In the first of five conditions we list on page 13, we state that The PQRI measure development process should be physician led. By this we mean that significant involvement of physicians is important but do not mean that all measures must be developed by physician organizations. For example, measures developed by NCQA and PQA would also be appropriate for consideration.

Submitter : **Barb Behrand** **Date: 08/31/2007**

Organization : **Advanced Pain Management**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1385-P-15352-Attach-1.DOC

5352

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

4131 W Loomis Road * Suite 300 * Greenfield, WI 53221 * 414.325.PAIN * Toll Free 1.888.901.PAIN * Fax 414.325.3700

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these

ADVANCED PAIN MANAGEMENT

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services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a

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payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

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CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Sincerely,

Barb Behrand
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

CMS-1385-P-15353

Submitter : Dr. Lilly Moon **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15353-Attach-1.PDF

15353

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Lilly Moon, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : **Mr. Cory Pack** **Date: 08/31/2007**

Organization : **Midwestern State University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Cory Pack and I currently serve as the Clinical Education Coordinator for the Athletic Training Education Program at Midwestern State University in Wichita Falls, Texas. I am a BOC Certified Athletic Trainer and Licensed Athletic Trainer in the state of Texas. For the past ten years I have provided health care services to physically active populations in a variety of settings.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Cory Pack, ATC, LAT

Submitter : Mr. Matthew Schulze **Date:** 08/31/2007

Organization : American Society for Clinical Pathology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Unsure my first attempt to submit comments was successful so i'm double checking

CMS-1385-P-15355-Attach-1.PDF

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August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
7500 Security Boulevard
Baltimore, MD 21244-8015

Dear Mr. Kuhn:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide comment on the Centers' for Medicare and Medicaid Services (CMS) 2008 Physician Fee Schedule Proposed Rule ("Proposed Rule") [72 FR 38122]. Our comments focus on the anti-markup and reassignment provisions outlined in the section entitled Physician Self-Referral.

The ASCP is a nonprofit medical specialty society representing 140,000 members, including board certified pathologists, other physicians, clinical scientists, medical technologists and technicians. ASCP is one of our nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

I. Reassignment and Physician Self-Referral [72 FR 38179]

ASCP writes in strong support of CMS' efforts to block abusive billing arrangements that profit from the referral of pathology services. CMS has proposed some important patient and programmatic protections, and the Agency is to be commended for its efforts. That said, we believe that these proposals can and should be strengthened. It is our sincere hope that when CMS implements its 2008 Physician Fee Schedule final rule that it include its proposed reassignment and self-referral reforms, at a minimum.

The abuse of the reassignment provisions relating to pathology services is an issue of great concern to ASCP. We have been contacted by hundreds of our members on this issue urging that action be taken to prevent markup on pathology services. They are

acutely aware of the problems associated with these abuses, and many have witnessed them firsthand.

We concur with that the Department when it stated in this year's proposed rule that the 2004 "changes to [CMS'] rules on reassignment concerning the right to receive Medicare payment may have lead to some confusion as to whether the anti-markup and purchased interpretation requirements apply to certain situations where a reassignment has occurred under a contractual arrangement." We agree there is confusion. We do not believe that in most cases where clinicians may be engaging in any activities the Department may describe as "abusive billing practices" that these providers are doing so knowingly and willfully. We have heard that some providers may have been advised that profiting from the referral of certain medical services does not violate Medicare requirements.

A. What's Causing the Billing Abuses

The billing abuses with which ASCP is primarily concerned are those occurring as a result of providers who are profiting from the referral of pathology services. To accomplish this, clinicians are using contractual arrangements to secure the billing rights for pathology services. In part, this is accomplished by entities popularly referred to as "pod" labs. But other entities are seeking to facilitate other types of arrangements, some of which were described in the proposed rule, that can accomplish the same purposes.

Pod labs come in numerous shapes and sizes, but for the most part they are scaled down clinical laboratories, offering a limited menu of services such as analyzing biopsies. These entities, in many cases, may be little more than an office divided by cubicles with a microscope on a cart being wheeled from cubicle to cubicle by a pathologist who examines the specimens. These laboratories exploit a loophole in Medicare's assignment of benefit regulations, enabling referring physicians to profit from pod labs by extracting a portion of the revenue from Medicare designated for the performance of pathology services. These referring providers are engaging in unethical practices by profiting from the referral of the pathology services.

B. Impact of Self Referral

ASCP believes that allowing providers to profit form the referral of pathology services distorts medical decision-making, undermines patient trust in the medical profession, and can adversely affect patient care. As stated in the proposed rule, allowing such profits "may lead to patient and program abuse in the form of higher utilization of services and result in higher costs to the Medicare program." The U.S. Department of Health and Human Services Office of the Inspector General (OIG) has stated that these types of arrangements, which may violate federal anti-kickback statute, "can distort medical decision-making, cause overutilization, increase costs and result in unfair competition." OIG has also pointed out that the markups of Medicare reimbursed services "can also adversely affect the quality of patient care." These abusive billing practices may also adversely affect the practice of pathology and its ability to help diagnose and treat patient conditions and disease quickly and efficaciously.

C. Building a Foundation

Since CMS first warned of the potential for abuse of the reassignment rules in 2004, the specialty of pathology quickly witnessed the increased presence of business arrangements attempting to skirt the agency's physician self referral prohibitions. As this occurred, the U.S. Department of Health and Human Services' Office of the Inspector General (OIG) released a number of publications that stated that these mechanisms *appeared* to violate applicable anti-fraud requirements (OIG advisory opinions do not assess whether certain practices are *per se* illegal), such as the anti-kickback and anti-markup provisions. Not surprisingly, such efforts have had little impact in deterring abusive arrangements.

D. The Data

Despite anecdotal evidence that billing abuses were occurring, the Department lacked, until recently, data to assess the scope of billing abuses by providers seeking to profit from the referral of pathology specimens.

In June 2007, OIG published the results of three audits of physician group practices to examine their recent use of the reassignment provisions to bill for pathology services. While the three audits focused on urology, the same incentive to profit from the referral of pathology services would similarly affect other physician specialties relying on these services. The OIG audits reveal that *all* of the audited physician groups billed significantly more biopsies than the carriers paid on average to other providers—124%, 65%, and 58%.

All of the audited group practices substantially increased utilization after entering into a reassignment arrangements for pathology services—699%, 230%, and 26%. One pod lab went from one jar to almost 9 jars on average per patient. Another increased from an average of just under 4 jars of biopsies tissue to an average of almost 12 jars per patient. It is difficult to justify such significant increases in utilization over a 2 year period on changes in "clinical practice," considering the apparent lack of change in other provider billing behavior.

Compared to the OIG report that resulted in the first Stark physician self-referral restrictions, the recent findings reveal self-referral billing abuses on an even greater scale. That 1989 OIG report found that physicians with a financial interest in the clinical laboratories to which they "referred Medicare patients [ordered] 45 percent more laboratory services than did physicians who did not have such financial interests."[1]

Another report of interest, provided by the Center for Health Policy Studies, adds to this data. This study examined states that have "direct billing laws." Such laws require the pathologist or entity performing the ordered pathology services to bill for these services. These laws help prevent providers from profiting on the referral of pathology services. This study found that laboratory charges per enrollee under private health insurance programs were 41 percent higher in non-direct billing states than in direct billing states.

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[1] Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress. U.S. Health and Human Services Department Office of the Inspector General Office of Analysis and Inspections. May 1989.

Given the fact that the recent OIG data examines 2004 billing charges, we would encourage the Department to view this data as illustrative of the beginning of the trend, not its apex. Were more recent data available, the increases in utilization may be larger, as the entities promoting arrangements to capture pathology reimbursement appear to have increased their market presence.

In future studies of these practices we would suggest considering using earlier benchmark years to control for possible adjustments group practices may make to their billing practices prior to entering into a contractual arrangement. Such adjustments could mask the extent to which pathology services may be overutilized.

D. Ethical Considerations

The American Medical Association (AMA), through its Council on Ethics and Judicial Affairs (CEJA), has outlined a number of ethical practice policies that are directly or indirectly violated by entities engaged in abusive billing practices that pertain to pathology. For example, CEJA has stated that if anatomic pathology services are provided at a discount, the purchasing physician should not charge a mark-up.

Moreover, while the following opinions do not address markups per se, they do have application to the reassignment arrangements affecting pathology services. Opinion E-8.03 states that "[i]n general, physicians should not refer patients to a health care facility outside their office at which they do not directly provide services and in which they have a financial interest." In opinion E-6.03, CEJA states "clinics, laboratories, hospitals, or other health care facilities that compensate physicians for referral of patients are engaged in fee splitting which is unethical." Additionally, in Opinion E-6.02, CEJA states "[p]ayment by or to a physician solely for the referral of a patient is fee splitting and is unethical." While the later two opinions address fee-splitting, the underlying concern is that profiting from referrals is inappropriate.

Of particular concern is the fact that the financial incentive relied upon by these business arrangements can result in physicians selecting laboratories not on the basis of quality, but on the potential for profit. Consequently, test quality may suffer, increasing the risk of injury to the patient. AMA Opinion E-8.02 addresses this dilemma by stating that a "physician who disregards quality as the primary criterion or who chooses a laboratory solely because it provides low-cost laboratory services on which the patient is charged a profit, is not acting in the best interests of the patient."

E. Responding to Criticism of CMS' Proposed Rule

The arguments used by those opposed to the CMS proposal are insufficient to warrant abandoning or weakening these proposals. It should not be forgotten that those seeking to undermine these proposals desire to profit from referrals. This inherently causes numerous problems, such as overutilization, increased per test costs, etc. Some opposed to CMS' initiatives have argued that they are engaging in these arrangements to provide

necessary services to patients. Nothing in this rule, however, prevents providers from providing patient access to pathology services. It just prevents providers from profiting from these services.

Additionally opponents to the CMS proposals have argued the arrangements are needed to provide for specialized pathology services. This argument is weak as there are many national and regional laboratories and pathology groups that have pathologists who are subspecialty certified and perform pathology services only within those subspecialties. There is no evidence that the diagnostic rates of pod pathologists exceed that of subspecialty pathologists. Pathologists and laboratories should be selected on such criteria as diagnostic capability, quality, turnaround time, and service. Allowing profit to the referring provider or billing entity to serve as a new criterion in selecting the provider of pathology and laboratory services runs in stark contrast to the patients' best interests.

F. CMS's Proposed Reforms

To address abuse of the reassignment provisions, CMS proposes applying the following reforms:

- The PC of a purchased test be subject to an anti-markup provision;
- The anti-markup provision for the TC and PC apply to all arrangements not involving a reassignment from a full-time employee of the billing entity;
- The performing physician's or other supplier's net charge be calculated exclusive of any charge that reflects the cost of space or equipment leased to the performing physician or other supplier by the billing entity; and
- The anti-markup provision not apply to independent labs that have not ordered the TC.

CMS proposes to impose an anti-markup provision of the technical component (TC) and professional component (PC) of diagnostic services. This prohibition would apply irregardless of whether the billing physician or medical group outright purchases the PC or TC, or whether the physician or other supplier performing the TC or PC reassigns his or her billing rights to the billing physician or medical group. ASCP strongly supports this proposal. The only exception that should be allowed under the CMS proposed framework is if the performing supplier of the services is a full-time employee of the billing entity.

ASCP concurs with CMS about the possibility to "game" net charges, and thus we support the agency's proposal to define "net charge" as exclusive of any amount that is inflated to take into consideration the cost of equipment or space leased to the performing physician or other supplier.

We share CMS' concern that overutilization of diagnostic tests could occur in situations where the TC is performed by a part-time or leased employee. We urge the agency to apply the anti-markup provision to the TC performed in a centralized building when the TC is performed by a part-time or leased employee.

ASCP is concerned that the proposed anti-mark-up rule will not eliminate the profit and self referral incentives for a practice principally comprised of physicians ordering pathology tests (e.g., GI practices, Urology practices and Dermatology practices). The proposed language of Section 424.80 is limited to a reassignment. A GI practice, for example, that maintains its own CLIA-certified pathology laboratory staffed by part-time independent contractor histotechnologists or histotechnicians does not typically need a re-assignment of the right of the histotechnologist or histotechnician to bill Medicare, because the histotechnologist or histotechnician cannot bill Medicare for the technical component. Rather, the technical component is billed by the entity that holds the CLIA Certificate for the technical component laboratory.

ASCP suggests that CMS consider an anti-markup provision that would apply to any group practice where at least 90% of the practice is comprised of a single specialty other than pathology that orders the pathology tests billed by the practice. The anti-markup provision should prohibit any mark-up of the direct costs actually incurred by the practice (i.e., compensation paid to histotechnologists, histotechnicians, and pathologists, equipment and supplies utilized).

Moreover, for TCs performed by a "technician" in a "centralized building" we believe it would be useful to clarify that the employee is a bona fide full-time employee of the billing entity. Since there appears to be no definition of what is meant by a "full time," ASCP suggests CMS should define a full-time employee as an individual who works at least 35 hours per week. This is consistent with the agency's 2007 Physician Fee Schedule Proposed Rule. We do not concur with the agency in its proposal not to make changes to the definition of a centralized building. Moreover, we believe entities seeking to take advantage of the centralized building exemption should not be located in other states, unless they are located no farther than 20 miles from the referring office.

ASCP agrees with the need to except the anti-markup provisions for PCs ordered by independent laboratories because these entities pose little risk of program abuse. Independent labs are not ordering the TC.

Moreover, we believe it would be useful to restate that the requirements of subsection 414.50 apply, even if the physician or group billing is acting under the contractual arrangement exception to the rule. Additionally, CMS should require that, for both the reassignment rules in 424.80 and the purchased diagnostic test rules in 414.50, to bill for the TC, the billing physician or medical group must directly perform the PC. That said, we foresee the need to exempt independent labs, because of states where the corporate practice of medicine doctrine is in effect. An exemption for dermatologists that directly perform the interpretation may also be necessary if this proposal is implemented.

We believe that the rule would benefit from application of the purchased test rules to reassignments. Regarding the agency's concern about how this affects multi-specialty group practices, we believe these concerns have merit for "true" multi-specialty groups. But we do not believe that it would be appropriate to allow a group practice to qualify as

a "multi-specialty" group by hiring one or more pathologists. (See aforementioned proposal on percentage composition.)

ASCP believes first and foremost that these proposed physician self-referral provisions must be applied to pathology/laboratory medicine. We believe that application of the anti-markup and reassignment rules to other medical specialties is a concern best addressed by the organizations representing those specialties. Thus ASCP declines to express an opinion whether these proposals should be applied beyond pathology and laboratory medicine. Lastly, ASCP supports CMS's proposals and urges the agency to implement these reforms without delay or grace period.

II. CLINICAL LABORATORY ISSUES

Reconsideration Process
In its proposed rule, CMS proposes to establish a reconsideration process to re-examine the reimbursement of laboratory tests not adequately reimbursed via the "crosswalk" or "gap-filled" process.

CMS' proposal allows for reconsideration under the following circumstances:

- If it determines that the payment amount for a cross-walked code is not appropriate, it may seek public comments on a more suitable reimbursement level. The new payment rate would take effect the following year.

- If after the first year of gap-filling the Agency determines that the carrier-specific gap-filled amounts do not sufficiently pay for the test, it may crosswalk the test during the second year in order to establish a more accurate fee. The new payment rate would take effect the next year.

ASCP supports these recommendations. We believe these changes will start to address a number of the flaws in the current payment process, particularly in regards to gap-filling.

We also encourage CMS to take a more proactive approach in preventing the problems that may result in the need to utilize the above mentioned scenarios. Here ASCP believes that the Agency should require that local contractors develop a transparent, formal process for making gap-fill decisions, including a formal appeals process. Utilizing such a process may help prevent disputes from escalating to the federal level.

III. TRHCA – Section 104: Physician Pathology Services
CMS states in its Proposed Rule that it intends to implement the "grandfather" provision for the TC of pathology services furnished to hospital patients. Currently, an independent laboratory can bill Medicare for the TC of a service furnished to hospital patients if the hospital has a prior relationship with the independent laboratory for this service. CMS states that this will expire at the end of the year.

As Congress has routinely extended this provision each year in the past, ASCP suggests that CMS implement the grandfather on a permanent basis. Even if CMS does not choose to do so, however, we believe that it would be useful for CMS not to implement its proposal for at least six months after the end of the year. In the past, laboratories prepared for the Department's proposed termination of billing rights, and then Congress acted, often just before the year's end, or even thereafter, to extend the provision. This creates difficult billing issues, because laboratories must be poised to implement the new requirements and inform customers of the change. Then if Congress acts, they must go back to customers and explain that the change is not going to occur, after all. CMS has similar issues, as it must inform carriers to implement, only to revoke that instruction shortly thereafter.

As a result, because Congress is again considering extending this provision, we believe it would be useful if CMS stated that, if Congress does not act and extend the provision, it intends to delay enforcement until at least July 1, 2008. That would permit laboratories and hospitals (and CMS) time to determine if Congress was going to act again with regard to the provision and take the necessary action to inform hospitals.

ASCP appreciates this opportunity to provide comment on the proposed rule and looks forward to working with you on corrections to the Clinical Laboratory Technology Practice Act. If ASCP can be of further assistance, please do not hesitate to contact me or Matthew Schulze, ASCP's Senior Manager for Federal and State Affairs, at (202) 347-4450.

Sincerely,

John S.J. Brooks, MD, FASCP
President, ASCP

Submitter : Dr. Michael Perconti **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15356-Attach-1.PDF

15356

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Michael Perconti, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : **Mr. Paul Valentine** **Date: 08/31/2007**

Organization : **Sleep HealthCenters LLC**

Category : **Other Health Care Provider**

Issue Areas/Comments

IDTF Issues

IDTF Issues

2. One Enrollment per Practice Location
CMS is proposing that IDTFs must separately enroll each of their practice locations (with the exception of locations that are used solely as warehouses or repair facilities). This means that each enrolling IDTF can only have one practice location on its CMS-855B enrollment application; thus, if an IDTF is adding a practice location to its existing enrollment, it must submit a new, complete CMS-855B application for that location and have that location undergo a separate site visit.
Application Process:
For those IDTFs that have multiple locations within a certain pay locality, it seems unnecessary to require additional paperwork with much of the same information that has already been filed with CMS. To have to complete an intensive application and undergo a site visit for each location seems like more of an administrative burden then something that would promote higher quality and ease of patient access. We understand that there would be a need to complete some paperwork to inform CMS of the addition, but to require individual provider numbers for locations that will all fall under the same tax identification number for the provider seems excessive. Also in terms of timeliness, it is doubtful that CMS will be able to review the paperwork in a timely fashion, thus possibly delaying the participation of the new facility and ultimately access to patients in need of services.

Site Visit:
In terms of a required site visit, CMS might want to consider the record of the IDTF applying for the provider number and/or whether it has other credentials such as accreditation by another organization. CMS will be inundated with requests and will need to do an undetermined amount of additional site visits. Again, this has the potential to cause enormous delays in the issuing of provider numbers if the site visit needs to occur prior to enrollment. We understand the intention to ensure that quality services are being provided to patients, but it seems unnecessary to add additional administrative costs and potentially unnecessary site visits which will only delay access to care.

Effective Date:
An IDTF that is enrolled in Medicare at one location, and is otherwise in good standing with the Medicare program, should have the ability to enroll new sites retroactively to the first date of service at the new location.

Deemed Status:
We suggest that CMS consider granting deemed status to IDTFs that are accredited by recognized accrediting bodies, allowing them to enroll new locations more easily so long as their accreditation is in place.

Submitter : **Dr. Gregg Farrell** **Date: 08/31/2007**

Organization : **Spectrum Medical Group**

Category : **Physician**

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Dear Ms. Norwalk,

As an anesthesiologist in northern Maine I have almost half of my patients being insured by Medicare. In addition to our ever increasing population percentage of retirees we suffer from a lower Medicare reimbursement than most other states. As a result my group finds itself at a significant disadvantage in recruiting physicians to our area. Over 40% of our recent hires have had to be J-1 FMGs. Please consider the proposed fee increase so that we may be able to retain physicians for our underserved area.

Thyank You,

Gregg Farrell, M.D.

Submitter : **Mrs. Joan Taylor-Webb** **Date: 08/31/2007**

Organization : **REHAB to Life, Inc.**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

REHAB to Life, Inc.
Inside of Gold s Gym
4310 Shipyard Boulevard
Wilmington, NC 28403
(910) 392-5463
Fax: (910) 392-0067

To: CMS

From: Joan Taylor-Webb, PT
Owner/Operator, President

Subject: Stark Referral for Profit

This is a request to remove physical therapy from the in-office ancillary services exception to the federal physician self-referral laws.

In the past 4 years, I have observed three large orthopedic groups in Wilmington start providing in-office therapy. It has been communicated to me through some of their patients that even though the patient is being given a list of physical therapy providers, they are being encouraged to go to the Orthopedic owned facility.

I also have found it interesting that since these 3 groups have built these new facilities just down the street from where my office is located, that they have removed my facility from this physical therapy list. I can only surmise that is because I would be a conflict of interest. I was also refused the opportunity to rent an office as it was owned by a MD that was planning on adding PT to his family practice within the year and considered it a conflict of interest to allow me to rent space down the street from his office.

My referrals from these facilities have virtually ceased which has affected my revenues greatly. I am an orthopedic therapist that now seldom gets to see orthopedic cases except when I have a patient referred by another previous patient or from another specialty or family practice MD.

I discussed this issue with one of the Orthopedic MD s that I previously received a great number of referrals and he just commented that he had to feed his own therapists.

I would like to see Medicare follow the ruling in South Carolina that does not allow MD owned physical therapy practices. I also don t think a corporation that is owned by MDs should be exempt which seems to be the new loophole.

Sincerely,
Joan Taylor-Webb

Submitter : Mr. Aaron Madsen **Date:** 08/31/2007

Organization : Concordia University--Nebraska; Sports Medicine

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am currently a Certified Athletic Trainer working at Concordia University--Nebraska's (CUNE) Sports Medicine Department. I obtained Exercise Science and Athletic Training degrees at the University of Nebraska at Kearney in 2001. I am one of two health care professionals at CUNE that provide overall health care for 400+ athletes, 18 Varsity, and 16 Junior Varsity sports. I am also a Nationally Registered and State Licensed Emergency Medical Technician.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Aaron Madsen, ATC, LAT, NREMT

Submitter : Dr. Oscar Mangini **Date:** 08/31/2007

Organization : MLD Pathology

Category : Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018
Attention: CMS-1385-P

To Whom It May Concern:

Thank you for the opportunity to submit comments on the Physician Self-Referral Provisions of CMS-1385-P entitled Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008. I am a board-certified pathologist and a member of the College of American Pathologists. I practice in Houston, Texas as part of a 7 member pathology group working both in a hospital setting and through our independent laboratory.

I applaud CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. I am aware of arrangements in my practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group s patients. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services.

Specifically I support the expansion of the anti-markup rule to purchased pathology interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. These revisions to the Medicare reassignment rule and physician self-referral provisions are necessary to eliminate financial self-interest in clinical decision-making. I believe that physicians should not be able to profit from the provision of pathology services unless the physician is capable of personally performing or supervising the service.

Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. I agree that the Medicare program should ensure that providers furnish care in the best interests of their patients, and, restrictions on physician self-referrals are an imperative program safeguard to ensure that clinical decisions are determined solely on the basis of quality. The proposed changes do not impact the availability or delivery of pathology services and are designed only to remove the financial conflict of interest that compromises the integrity of the Medicare program.

Sincerely,

Oscar R. Mangini, M.D

Submitter : Dr. Eward Yang **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1385-P-15362-Attach-1.PDF

15362

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Edward Yang, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : **Ms. Carey MacDonald** **Date: 08/31/2007**

Organization : **Salem State College**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer for Salem State College.
I am writing today to voice my opposition to the therapy standards and
requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy.
My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is
widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and
any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Carey L.MacDonald, ATC, MBA, BS

Submitter : **Date: 08/31/2007**

Organization :

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a Certified Athletic Trainer working in the secondary school setting.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Sincerely,

Nancy E. Craft,MS,ATC,CSCS

Submitter : Dr. Noel Zweig **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15365-Attach-1.PDF

15365

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Noel Zweig, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : **Mr. Tim Thorsen** **Date: 08/31/2007**

Organization : **Spine**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Tim P. Thorsen P.T., M.T.C.
CEO-Spine & Sport
586 Shepard Street
Rhinelander, WI 54501

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Medicare Program;
Proposed Revisions to Payment Policies under the Physician Fee Schedule,
and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Kerry,

I wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the in-office ancillary services exception. I would like to highlight the abusive nature of physician-owned physical therapy services and support PT services removal from permitted services under the in-office ancillary exception.

I am a Physical Therapist (PT) practicing in a relatively rural area of Northern Wisconsin in a Physical Therapist owned practice for over 13 years. We are Neuromusculoskeletal experts in outpatient orthopedics, and add value to the quality of life for many folks in our three clinic sites. One of the biggest threats to our business in Wisconsin continues to be a local physician group that would chose to open a PT practice they would own. We already have more than enough competition in our small service area including a Non-profit health system that has monopolistic behavioral patterns.

In many areas of the country (firsthand stories in FL and IL) my PT colleagues in practice state they are barely surviving the impact of physician groups (including orthopedists) opening PT practices and referring directly to themselves. In our local area a hospital system tries to dominate the local market and control physician referrals; but our relationships with the local physicians, grass roots marketing efforts, local community involvement and our quality of care allows us to survive. If our independent orthopedists (who currently display excellent ethical, legal, and community minded behavior) decided to employ their own PT s or rehabilitation services, as has happened in so many other areas, I do not know if we could survive.

2-

Please remove the temptation of physicians in unethical referral for profit by removing Physical Therapy as a Designated Health Service (DHS) permissible under the in-office ancillary exception of the federal physician self-refcrral laws. I know this is supported by the majority of physicians who practice ethically, and would not cross that line. That certainly would include Dr. Marc Durette, a local Physical Medicine Physician, whom I have worked with for over seventeen years. He is available at 715-365-5256, and he would share his perspective, which he and I have discussed.

In addition, as you probably know, physician direct supervision is not needed to administer physical therapy services. However, I recently learned that an increasing number of physician-owned physical therapy clinics are using the reassignment of benefits laws to collect payment in order to circumvent incident-to requirements.

Please put an end to the above ethical temptations by clearly stating that referral for profit is illegal, and be sure to maintain Physical Therapy Services are to be provided for consumers by Physical Therapists and Physical Therapist Assistants only, to protect the safety of the public, and to be sure that they are truly receiving Physical Therapy!

Please feel free to contact me for any additional information, and thank-you for taking action in this critical area of potential fraud and abuse.

Sincercly,

Tim P. Thorsen P.T., M.T.C.
(Physical Therapist WI Lic. #3896-024, Certified Manual Therapist)

Submitter : **Jennifer Smoyak** **Date: 08/31/2007**

Organization : **Florida International University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Jennifer Smoyak and I am a certified athletic trainer. I am an assistant athletic trainer for Florida International University. I am licensed in the state of Florida and have a Masters of Science degree in physical education.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Jennifer Smoyak MS ATC LAT

Submitter : **Mr. Kevin Axtman** **Date: 08/31/2007**

Organization : **North Dakota Board of Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. Pat Fry **Date:** 08/31/2007

Organization : Sutter Health

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15369-Attach-1.DOC

15369

Sutter Health
With You. For Life.

2200 River Plaza Drive
Sacramento, CA 95833
(916) 286-6840
(916) 286-6841 Fax

August 30, 2007

Honorable Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1385-P

RE: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Polices of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.

Dear Mr. Kuhn:

Sutter Health is pleased to submit the following comments on the above proposed rule, which was published in the *Federal Register* on July 12, 2007 (Volume 72, Number 133).

Sutter Health, one of the country's leading not-for-profit networks of community health care services, serves more than 20 Northern California counties. Sutter Health provides care for more inpatients than any other network in Northern California, and is the region's largest provider of maternity services, orthopedics, pediatrics and cancer care services. Sutter Health has care centers in more than 100 Northern California communities; more than two dozen acute care hospitals; graduate medical education programs, medical research facilities, region-wide home health, hospice and occupational health networks, and long term care centers. This experience provides us with unique insights into the practical impact of Medicare's physician fee schedule.

We want to focus on your invitation for comments regarding the proposed options for addressing the shifts in relative demographics and economic conditions among a number of counties within the current California payment locality structure.

Sutter Health has raised this concern in earlier correspondence and meetings with the Centers for Medicare and Medicaid Services (CMS) officials. We expressed particular anxiety as regard the cost disparities between Santa Cruz and Sonoma counties and the Rest of California payment locality to which these two counties are assigned. We have repeatedly argued that removal of these two counties from the Rest of California payment locality would effectively address the two largest inequities of the current payment locality policies.

Geographic Practice Cost Indices (GPCIs)

Sutter Health strongly supports and endorses Option 3 in the proposed rule, which would use a methodology similar to that used in the 1997 locality revisions, but would be applied at the county level rather than the "existing locality" level.

Sutter Health endorses the adoption of Option 3, which CMS described as applying a five percent floor for a given locality based upon the highest geographic adjustment factor (GAF) of a county within that locality, for several reasons.

- First, such a methodology is very similar to the approached used by CMS (then the Health Care Financing Administration (HCFA)) when the payment localities were last revised effective January 1, 1997. This approach would reduce the number of payment localities in California from nine to six and would create a structure where areas with similar costs would be grouped together. This option, as CMS noted, alleviates the greatest variations in cost between counties in California.
- Second, Option 3 is the only option in the proposed rule that reflects the recommendations of the Government Accountability Office (GAO).[1] According to the GAO, this option would:
    - Compared to the current localities, reduce the average payment difference by about 35 percent.
    - Eliminate relative underpayments to physicians, which, in turn, would reduce the number of counties that could potentially experience difficulty attracting and retaining physicians.
    - Reduce by about 29 percent payments to physicians who were overpaid relative to their county-specific GAF.
    - Not impose on physicians additional administrative burdens; allowing physicians to complete the same paperwork as they do now.
- Third, Option 3 while not only addressing the current economic inequities confronting physicians in Santa Cruz and Sonoma counties, would also effectively address the economically disadvantaged physicians in other California counties, e.g., San Diego, Santa Barbara, Monterey, Marin, and a number of other California counties.

[1] Government Accountability Office, "Medicare: Geographic Areas Used to Adjust Physician Payments for Variation in Practice Costs Should Be Revised," Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, June 2007.

Due to the projected adverse impact of Option 3, if adopted, on a majority of California counties, particularly rural counties, Sutter Health urges CMS to consider a transition period of at least two years to phase-in Option 3's payment locality changes.

As noted, we are mindful that Option 3, if adopted, would result in payment decreases for a majority of California counties. According to CMS, such reductions would range from -0.2 percent to -7.3 percent. While we understand current law requires that that any payment locality changes must be applied in a budget neutral manner, the size of the adverse impact on a majority of California counties, most particularly rural counties is troublesome. Many of these rural counties are in Northern California, which we consider our service area.

If, however, CMS determines that such a transition is not viable, Sutter Health, given the gross economic disparities under existing policies, continues to support the adoption of Option 3.

We are aware that there is a certain GAF inconsistency for Santa Cruz County and we believe that CMS may have miscalculated the designation of the new payment localities in California. We assume these apparent text and methodological errors will be corrected in the final rule.

In closing, we want to commend CMS for its sensitivity to this issue and the reasonableness of its proposals. If Option 3 is adopted in the final rule it should arrest any diminution in the availability and accessibility of physicians services to Medicare beneficiaries.

Sincerely,

Patrick E. Fry
President and CEO

Submitter : **Ms. Kate Romanow** **Date: 08/31/2007**

Organization : **The Orthotic and Prosthetic Alliance**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15370-Attach-1.DOC

#15370

The Orthotic and Prosthetic Alliance

August 31, 2007

Submitted Electronically To:
http://www.cms.hhs.gov/eRulemaking

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS 1385-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Comments on Physician Self-Referral Provisions in 2008 Medicare Physician Fee Schedule Rule: CMS-1385-P

Dear Acting Deputy Administrator Kuhn:

The Orthotic and Prosthetic Alliance (the "O&P Alliance") appreciates this opportunity to submit comments on the 2008 Physician Fee Schedule Rule concerning the physician self-referral provisions, in particular the in-office ancillary services exception.

The O&P Alliance is a coalition of four of the primary organizations representing the field of orthotics and prosthetics. The four organizations include the American Academy of Orthotists and Prosthetists ("AAOP"), the National Association for the Advancement of Orthotics and Prosthetics ("NAAOP"), the American Orthotic & Prosthetic Association ("AOPA"), and the American Board for Certification in Orthotics and Prosthetics, ("ABC"). The O&P Alliance represents the professional, scientific, research, business, and quality improvement aspects within the fields of orthotics and prosthetics (i.e., orthopedic braces and artificial limbs).

The O&P Alliance supports CMS's efforts to prevent fraud and abuse, and we feel that some current practices may result in over-utilization of Medicare services and may lessen the quality of care. Each organization in the O&P Alliance is interested in ensuring that Medicare beneficiaries receive orthotic and prosthetic care from qualified practitioners, providers, and suppliers. Consequently, the O&P Alliance is offering the following comments and recommendations in an effort to work with CMS to decrease fraud and abuse and increase the quality of care provided to Medicare beneficiaries.

I. Background

Orthotics and prosthetics ("O&P") have been subject to physician self-referral prohibitions since the Stark law was first implemented. The Stark law prohibits physicians from making referrals for Medicare or Medicaid paid designated health services ("DHS") to an entity that furnishes DHS and in which the physician has a financial relationship, unless an exception exists. A financial relationship may consist of an ownership interest or compensation arrangement. An exception to the referral prohibition for ownership interests and compensation arrangements is the "in-office ancillary services" exception. This exception allows physicians to refer patients for certain DHS that are then provided by the physician's practice if specific requirements are met.

On July 2, 2007, the Centers for Medicare and Medicaid Services ("CMS") released proposed revisions to the Medicare Physician Fee Schedule ("MPFS") for 2008, as published in the July 12, 2007 Federal Register at 72 Fed. Reg. 38122 (the "Proposed Rule"). Within the Proposed Rule, CMS included changes to the Stark law.

Because of concerns that some in-office ancillary services are not closely connected to the physician practice, CMS is soliciting comments on whether the in-office ancillary services exception should be revised and, if so, what changes should be made to prevent abusive arrangements. Among other issues, CMS is requesting comments on:

> "[W]hether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services)."

72 Fed. Reg. at 38181.

II. O&P Profession Comments

The Stark law's in-office ancillary services exception allows a physician to furnish (and financially benefit from referrals for) many ancillary services. There are conditions that must be met, however, such as supervision, location, and billing requirements that, in effect, seek to ensure that the ancillary services are furnished as an integral part of the physician's medical practice.

In the Proposed Rule, CMS expresses concern that this exception is being used to allow referring physicians to benefit financially from referrals for ancillary services that are "often not as closely connected to the physician practice." 72 Fed. Reg. at 38181. According to CMS, this exception is intended to allow group practices to provide their patients with ancillary services required for "the diagnosis or treatment of the medical condition that brought the patient to the physician's office." Id.

We believe the original intent of the Stark Law exception is applicable in a situation such as where a patient sees a physician and has a new fracture. In this example, we fully acknowledge that a patient seeing an orthopedic specialist for treatment may be best served by being fit with a fracture brace while in the physician's office. The diagnosis and need for treatment is immediate, and the fracture brace is used temporarily. This situation fits within what we believe to be the original intent of the Stark Law exception: to allow for a physician to provide certain items and services incident to an office visit, when medically necessary for the immediate diagnosis and care of the patient's condition. As stated by CMS in the final rule for "Phase I" of the Stark Law, Congress created the exception "to protect some in-office ancillary services provided that were truly ancillary to the medical services being provided by the physician or group . . ." 66 Fed. Reg. 856, 881 (Jan. 4, 2001).

However, we share CMS's concern that many "ancillary services" that fall under the definition of orthotics and prosthetics that are provided in physicians' offices are not closely tied to the diagnosis or treatment of the condition for which the patient is seeking care. There are situations where the patient's diagnosis, condition and needs are such that little or no immediacy exists, and the services are not truly ancillary to the medical services being provided. ***These situations should be defined and placed outside the ancillary services exception.*** We encourage CMS to use this opportunity to review the types of services and devices that fall under the definition of "orthotics" and "prosthetics" and identify those that should remain appropriately placed under the in-office ancillary services exemption and those that should be considered outside the exception. We suggest that three questions should be asked as each service/device type is considered:

1. Is there an immediate medical need and compelling urgency for the orthotic or prosthetic service or item to be provided while the patient is in the physician's office?

2. Is the service or item temporary in nature and being used to treat an acute condition?

3. Is the device prefabricated and can it be safely applied in the physician's office, with little or no fitting or modification?

If all three of these questions can be answered "yes", we believe the in-office ancillary services exemption should be applied as long as the physician meets all orthotic or prosthetic supplier accreditation standards. If the answer to any one of these three questions is "no", we encourage CMS to prohibit physicians from providing the service or device in office, or otherwise making a self-referral for provision of the service or device.

We thank you for the opportunity to comment on this important issue. As always, the members of the O&P Alliance are available to provide further information or input or to answer questions. If you have any questions or comments, please contact our counsel, Peter W. Thomas, Esq. at 202-466-6550.

Sincerely,

Thomas Guth

Thomas Guth, CP
President
National Association for the
Advancement of Orthotics and Prosthetics

Stephen Fletcher CPO.

Stephen B. Fletcher, CPO
President
American Board for Certification in
Orthotics and Prosthetics

Wendy Beattie

Wendy Beattie, CPO, FAAOP
President
American Academy of
Orthotists and Prosthetists

Ronald Ted Snell, CP
President
American Orthotic & Prosthetic Association

Submitter : Dr. Robert Zwolak **Date: 08/31/2007**

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Continuing Codes from the Five-Year Review: Six open Vascular Surgery Codes
SVS would again like to thank CMS for meeting with us on May 16, 2007 regarding the six interim valued vascular surgery procedures, some of our most complex and labor-intensive open aortic aneurysm and bypass operations (CPT codes 35102, 35081, 35556, 35566, 35583, 35585), procedures that are performed to save life and limb. We felt the meeting was very productive and allowed us to present new, additional regression analysis data in addition to information from our July, 2006 comments on the 2007 proposed Medicare Physician Payment rule and our December 30, 2006 comments on the final rule for 2007.
Despite of the opinion held by CMS regarding use of NSQIP data during the five-year review process SVS used multiple other methods besides NSQIP data to arrive at our work RVU recommendations for these codes. As we discussed at the CMS meeting on 16 May, we believe the Refinement Panel did not have time to fully consider all the huge amount of data supporting the conclusion that values above the median survey results were the most appropriate for these 6 very complex open surgical procedures. With due respect for the RUC process, SVS has processed nearly 100% of the vascular surgery codes to RUC survey and analysis, and we ALMOST NEVER asked for more than the median survey value. Nevertheless, for these six very large open surgery procedures, we believe the weight of evidence developed to validate our recommendations, i.e. building blocks, crosswalk comparisons intensity analyses, and finally the regression analyses, all serve to indicate that work RVUs greater than median survey are truly indicated to fairly value the work and to avoid rank order anomalies both within vascular surgery and across the entire relativity spectrum of all surgical procedures. We strongly urge CMS to reconsider the work RVUs of these 6 codes.
For example, regarding CPT code 35102 Open repair of abdominal aortic aneurysm requiring bifurcated graft an intensity/IWPUT analysis conducted by SVS determined that the appropriate IWPUT vale is 0.096, the mid-point range for all aneurysms and aortic surgery that maintains the relativity within the families of vascular surgery codes. The 2007 and proposed 2008 work RVUs instead establish a totally inappropriate IWPUT of 0.074, multiples of relative steps below appropriate intensity for open aortic surgery.
SVS used four additional analyses of physician work all of which indicated valuation higher than the CMS value. As we mentioned in our previous December 30, 2006 comments, SVS is very concerned that the Refinement Panel did not have adequate opportunity to review and discuss with SVS representatives the large body of data that SVS prepared and shared with them for all six of the open, vascular surgery codes that were part of the five-year review.

Again, we felt that our meeting on May 16th was a very productive exchange of information regarding the six CPT codes in question and these various methods and outputs that we have used to construct and verify SVS recommendations that we part of the five-year review. We look forward to some positive level of resolution when the 2008 Final Rule is published in November. As noted below, we are sending the data analysis under separate cover for reconsideration. The following are SVS recommendations for these six codes. The work RVUs have been adjusted from our 2005 RUC recommendations to reflect the changes in EM work RVUs.

	2008 NPRM	SVS Recommendation
35081 Open AAA repair	33.37	36.80
35102 Open AAA repair	36.37	42.20
35556 Open fem-pop bypass graft	26.62	33.20
35566 Open fem-tibial bypass graft	32.22	40.20
35583 Open fem-pop insitu bypass	27.62	33.70
35585 Open fem-tib insitu bypass	32.22	41.00

SVS is sending under separate cover the large compendium of data we used to arrive at these work RVU recs.

GENERAL

GENERAL

Dear Mr. Kuhn:

On behalf of the 2,300 members of the Society for Vascular Surgery (SVS), we offer the following comments on the Proposed Rule published in the Federal Register on July 12, 2007. We will address multiple provisions under this proposal.

For 2007, our specialty endured a 6% pay-cut due to the impact of the Deficit Reduction Act (DRA) on Noninvasive vascular laboratory studies plus negative changes in physician work payments due to the budget neutrality adjustor, plus additional reductions in the PE RVUs. Yet, again for CY 2008 our specialty is facing a reduction that is double in size to what we have lost in 2007, 12 percent. This simply can not continue. For many vascular surgeons, over 50% of their patients are Medicare beneficiaries, due the nature of the diseases and conditions we treat. We can not sustain reductions of this magnitude year after year and not at some point be forced to reduce access to Medicare beneficiaries. We are extremely concerned that 2008 will be the year that this happens.

These decisions regarding our practices are extremely difficult and not made lightly. SVS members are deeply committed to caring for our nation s seniors, but this combination of negative impacts may simply make it impossible for us to continue to offer all services to all Medicare beneficiaries.

The SVS comments will follow in this order:
1. Continuing Codes from the Five-Year Review Open Vascular Surgery Procedures
2. DRA Proposals Section 5102 Proposed Adjustments for Payments for Imaging Services
3. TRHCA Section 101(b) PQRI general comments

4. TRHCA Section 101(b) PQRI SVS ESRD quality measure
5. TRHCA Section 101(b) PQRI diabetic podiatry measures
6. Budget Neutrality Adjustor for Work RVUs & other work RVU issues
7. Resourced-Based PE-RVUs
a. Equipment Use Rate
b. CPT Codes 37205 and 37206 Direct PE Inputs for Non-facility Setting
8. Medicare Payment Policy

Resource-Based PE RVUs

Resource-Based PE RVUs

Equipment Use Rate

SVS agrees with CMS that the 50 percent utilization rate for medical equipment is appropriate for equipment used as part of office-based procedures. For surgical specialties, procedure specific equipment used in the office may only be in use approximately one two days a week, depending on the service mix of a specific office.

SVS is currently participating in two different surveys that are asking questions regarding equipment use rate. In both instances, the surveys are asking there questions in such a way to be both specialty and type of equipment specific. SVS believes that these types of specialty specific surveys are important and the type of data that CMS should be considering when making code specific decisions, regarding practice expense inputs. We believe that the data coming from these two efforts will be more instructive to CMS versus generalizing the higher utilization rates found by MedPAC in their six site survey for CT and MRI imaging equipment to even all types of imaging equipment i.e. ultrasound - or for other types of equipment. Instead, SVS hopes that CMS uses specialty and type of equipment specific data to work through this question going forward.

CPT Codes 37205 and 37206 Direct PE Inputs for Non-facility Setting

The SVS appreciates CMS reviewing clinical literature regarding transcatheter stent placement and what is considered standard practice regarding the number of stents placed per patient, per vessel. While we agree with CMS that it is not typical, i.e. greater than 50 percent of the time that two stents would be used to maintain the vascular integrity of an initial vessel, there are instances where a patient does need two stents. Since most of these stents cost more than $1,000 each, we ask that CMS provide some guidance to the Medicare contractors regarding how the cost of a second stent, when used, may be separately billable using a HCPCS code.

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

4. TRHCA Section 101(b) End-Stage Renal Disease Fistula Quality Measure
Not knowing exactly when CMS received the measures listed in Table 21, SVS wishes to inform CMS that it has submitted a measure to the NQF that we believe will be endorsed prior to November 15, 2007. This measure is relevant to the Medicare population and will allow vascular surgeons to report on their role and activities as providers of native hemodialysis access for Medicare beneficiaries that are in CKD 4,5 or End Stage Renal Disease. The goal of this measure is to provide a tool by which individual surgeon effort can be gauged in terms of creating native fistulas in those CKD and ESRD patients who are appropriate candidates. The details of this measure, which is currently under final review by the NQF, are provided here. We look forward to this measure being part of the 2008 set of PQRI measures.

NQF Number: 45

Focus: Vascular Access

Measure Title: Hemodialysis Vascular Access Surgical Decision-making to Maximize Placement of Autogenous Arterial Venous Fistula

Developer: SVS

Type Reclassified: Outcome

Setting: Ambulatory Care Hospital

Level of Analysis: Individual Clinician

Description: Percentage of patients with advanced chronic disease (CKD4 or 5) or end-stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arteriovenous fistula (AVF).

Numerator: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons OR Fistula not Performed for Patient Reasons. NOTE: This measure will be reported as the total of the three categories of numerators and also as the three numerators reported separately.

Numerator Data Collection: G8081: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons: Append modifier (1P) to G8081 to report documented circumstances that appropriately exclude patients from an autogenous fistula. A typical medical exclusion would include clinician documented that CKD4, CKD5 or ESRD patient requiring

hemodialysis vascular access was not eligible for autogenous AV fistula based on results of vein mapping. OR Fistula not Performed for Patient Reasons: Append modifier (2P) to G8081 to report documented circumstances that exclude patients for patient related reasons. For instance, clinician documented that CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access refused autogenous AV fistula following recommendation for same by provider. Autogenous is defined as the patient s own native tissue. Fistula is defined as a surgical connection established between and artery and a vein.

Case Finding: Patients eligible for inclusion are those with KDOQI Stage 4 and 5 CKD and ESRD.

Denominator: Patients with CKD4, CKD5 or End-stage renal disease who undergo open surgical placement of permanent hemodialysis access
Denominator Data Collection: ICD-9 585.3, 585.4, 585.5, 585.6 or 996.73 AND CPT 36818, 36819, 36820, 36821, 36825, or 36830

Exclusions: None

Risk Adjustment: This measure is recommended only for first-time vascular access patients, that is, all patients who have not previously undergone placement of a permanent upper extremity indwelling fistula or graft. The justification for this limitation to first-time access patients is that insufficient scientific data exists to know the target threshold for placement of native AVFs in patients who have previously undergone AVF surgery.

Data Source / Collection Instrument: Administrative and medical record data, provider data

Release / Revision Date: 2007

In Use: no

Testing: no

Conditions: Use term "autogenous" AV fistula.

Submitter : Mrs. Beth Wild-Shiring **Date:** 08/31/2007

Organization : UPMC Cancer Centers

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Dear MS. Norwalk:

Please See attached

CMS-1385-P-15372-Attach-1.DOC

CMS-1385-P-15372-Attach-2.DOC

15372

UPMC Cancer Centers

August 30, 2007

The Honorable Leslie V. Norwalk
Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn.: CMS-1385-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
http://www.cms.hhs.gov/eRulemaking

Dear MS. Norwalk:

UPMC Cancer Centers welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule CMS-1385-P, "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008."

UPMC Cancer Centers encompasses 180 cancer specialists at approximately 40 hospital-based and office-based locations throughout western Pennsylvania and serves a population of more than 6 million. Treating approximately 40,000 new patients per year, UPMC Cancer Centers is one of the largest cancer care networks in the nation. Our vast network represents the full spectrum of cancer care delivery including: physicians operating sole practices in rural areas; free-standing medical and radiation oncology facilities in rural and suburban areas; and a large group of academic physicians providing hospital-based outpatient care at the flagship Hillman Cancer Center and Magee Women's Hospital in Pittsburgh.

Since our region has one of the highest concentrations of individuals age 65 and over, the age group most at risk of being diagnosed with cancer, we rely heavily on CMS to provide fair and adequate reimbursement for us to care for these patients. We commend CMS for its increased research and analysis into the costs of providing cancer care; however, we do have some concerns regarding the proposed rule that we outline below.

ASP Issues

In CY 2005, CMS adopted the physician fee schedule the methodology of ASP+6% for drug reimbursement. There are several problems with the ASP calculation. Some issues include:

- ASP is based on the price that manufacturers charge to distributors, including any prompt pay discounts. These prices and discounts often are not passed along to providers but are included in the calculation of ASP.
- ASP is based on sales to all entities, including group purchasing organizations and large hospital systems on one end of the spectrum and one-physician oncology practices on the other. It means that many physician practices, particularly the smaller ones without purchasing power, will purchase drugs above ASP.
- There currently is a two-quarter lag in the calculation of ASP, meaning that reimbursement is based on prices that are six-months old. Since manufacturers typically raise prices two to three times per year, there is potential for physicians to suffer losses each time they administer drugs. Even as a large volume buyer, UPMC currently pays greater than ASP for many of our most highly utilized drugs and, in some cases, pay greater than ASP + 6%.
- ASP also does not make allowances for the inevitable bad debt that is associated with many Medicare claims. Despite aggressive collection efforts, UPMC Cancer Centers' bad debt percent associated with Medicare claims is approximately 4.5%. This coupled with the aforementioned issues with ASP creates an unsustainable reimbursement methodology for oncology drugs.

IDTF Issues

In the 2008 "Proposed Revisions to the Payment Policies Under the Physician Fee Schedule..." CMS proposes several new requirements for IDTFs including standards on insurance verification, complaint documentation, physician supervision, and sharing at a fixed location. We believe the standard which states "Dose not share space, equipment, or staff or sublease its operations to another individual or organization" is problematic and would like to make the following comments.

While we appreciate CMS' concern for insuring compliance of diagnostic services, the proposed standard to eliminate "sharing" and "sub-leasing" arrangements would destroy beneficial synergies of many current IDTF models. It is UPMC Cancer Centers opinion that this standard should be removed in its entirety due to several issues. First, the standard does not appear to be equitable with regard to other business models in the healthcare industry. For example, in many medical office buildings, hospitals, and other facilities, it is an accepted practice to share or sublease space, including waiting rooms, restrooms, exam rooms, etc. and equipment with other providers in an effort to manage expense. In IDTFs, this is also a common occurrence which would be prohibited under the new standard. It is not cost effective to require duplicative space that does not add to the provision of health services and IDTFs should not be prohibited from participating in these standard arrangements. Further, this regulation also prohibits the sharing or subleasing of staff, again a common business practice throughout the healthcare industry. Medical and clerical staff members are often employed part-time at other facilities or are sub-leased to or from other providers to accommodate overflow. It is UPMC Cancer Centers position that CMS should not be able to influence or limit employment opportunities unless a concern for patient safety exists.

Given the above, at a minimum, the proposed rules should be targeted at the entities that may pose highest compliance risk. For example, these rules should not apply to hospitals and radiology groups as they are not in a position to refer directly to the IDTF therefore concerns about self-referral do not apply.

It also is important to note that imposing this standard on mobile IDTFs would likely eliminate the mobile services model altogether. This model has been successfully developed to meet the needs of patients in many different markets. For example, UPMC Cancer Centers utilizes mobile IDTF arrangements for rural locations where the patient volume may make investing in the high fixed costs associated with a PET/CT cost prohibitive. When administered properly, patients benefit from an increased level of service without a negative impact to CMS. We ask that mobile services remain unhampered by this standard.

TRHAC-Section 110: Anemia Quality Indicators

The requirement that "Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit for the individual" is an inconvenience to patients, particularly those receiving weekly therapy. In many offices, lab work must be sent to an outside lab which in all likelihood would not have a sufficient turn-around time for the patient to be treated on the same day that the hemoglobin or hematocrit was drawn. This would cause an additional trip to the office for the administration of the drug, causing additional hardship to both patient and caregiver. Again, requiring hemoglobin or hematocrit results on the same day of growth factor administration poses additional hardships on our patients and their caregivers.

UPMC Cancer Centers would like to thank you for the opportunity to offer our formal comments for your consideration. As always, we are committed to serving the senior citizen population through the Medicare program. We stand ready to work with you to improve that program so that seniors can continue to access the highest quality care.

Sincerely,

Beth Wild Shiring
Chief Operating Officer
UPMC Cancer Centers

Submitter : Mr. Robert Baumgartner **Date:** 08/31/2007

Organization : Center for Diagnostic Imaging

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15373-Attach-1.PDF

CMS-1385-P-15373-Attach-2.PDF

CMS-1385-P-15373-Attach-3.PDF

CMS-1385-P-15373-Attach-4.PDF

CMS-1385-P-15373-Attach-5.PDF

5373

CENTER FOR
DIAGNOSTIC IMAGING

August 31, 2007

VIA ELECTRONIC DELIVERY

Mr. Herb Kuhn
Acting Deputy Administrator
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Kuhn:

The Center for Diagnostic Imaging ("CDI") thanks you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007.[1] As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

CDI and its radiologists[2] are deeply concerned that the Center for Medicare and Medicaid Services' ("CMS") proposed regulatory language set forth in §410.33(g)(15) will prohibit radiologists and radiology groups from continuing to practice medicine in our advanced diagnostic imaging centers (which are enrolled as independent diagnostic testing facilities ("IDTFs")) and impair our ability to continue to provide safe and quality diagnostic imaging services to Medicare beneficiaries. The intent of the proposed regulatory language is to curb arrangements that promote over-utilization of imaging services and fraud and abuse. In its efforts to achieve its goal of shutting down suspect arrangements, CMS would also prohibit legitimate, non-self-referral arrangements that exist between our centers and radiologists/radiology groups and sharing arrangements among affiliated companies that do not have any non-radiologist physician ownership and which promote clinical and economic efficiencies. Should CMS implement its proposed sharing and subleasing prohibition, we strongly recommend that CMS:

[1] 72 *Fed. Reg.* 38120 (July 12, 2007).
[2] Attached as Appendix A are copies of comment letters prepared by our medical directors and radiologists.

www.CDIradiology.com
5775 Wayzata Boulevard, Suite 400 Minneapolis, MN 55416 tel 952.543.6500 toll free 877.566.6500 fax 952.847.1152

1. Specifically exclude "radiologists and radiology groups" from the definition of "individual or organization" in the proposed regulatory language at §410.33(g)(15) so that imaging IDTFs can share space, equipment, and staff with radiologists and radiology groups.
    - Revise §410.33(g)(15) to read as follows:
        - "Does not share space, equipment, or staff or sublease its operations to another individual or organization, except for radiologists and radiology groups"
2. Clarify in the Preamble to the final rule that the prohibition does not preclude affiliated companies (which do not have any referring non-radiologist physicians as owners) that provide services integrally related to the operations of an imaging IDTF (such as an interoperable information system, centralized credentialing, staff and billing) from sharing space, equipment, and staff.
3. Clarify in the Preamble to the final rule that ownership or investment interests held by radiologists/radiology groups in an imaging IDTF does not constitute "sharing" for purposes of the proposed regulatory language at §410.33(g)(15).

Without these revisions, CDI's arrangements with radiologists and radiology groups in all of our 41 centers, none of which are suspect from the point of view of inducing inappropriate utilization, would be forced to disband or unwind and restructure.

IDTF ISSUES

I. CDI Is a Reputable Advanced Diagnostic Imaging Services Provider that Efficiently Delivers High Quality Services to Medicare Beneficiaries

CDI is a nationally and locally recognized leader in delivering high-quality advanced diagnostic imaging services headquartered in Minneapolis, Minnesota. CDI was founded 26 years ago by CDI's national medical director, Dr. Kenneth Heithoff. In 1981, the idea of an outpatient imaging center that specialized in one body part – spine – was radical. As a prominent hospital staff radiologist at that time, Dr. Heithoff passionately believed he could provide a more consumer-focused experience, while increasing quality by creating an imaging facility that exclusively focused on spine imaging. CDI was the second outpatient imaging facility in the nation and, from the day the first center opened, the radiologists, the technologists and the equipment have all been "subspecialized". Now at 41 centers in eight states,[3] CDI continues to provide fellowship-trained, sub-specialized radiologists along with high field, accredited equipment and specially-trained and nationally certified technologists to perform diagnostic imaging services in all subspecialty areas. CDI's center locations have been chosen to: (a) fit the local community's needs; (b) assure safety; and (c) focus on the customers' access and convenience. Hence, the majority of CDI's centers are in areas convenient to and safe for our

[3] We have diagnostic imaging centers in Minnesota, Wisconsin, Illinois, Kansas, Missouri, Indiana, Washington and Florida. We also have plans to expand and develop centers in other states.

patients, including rural and underserved communities. From July 2006 – June, 2007, CDI provided diagnostic imaging services to more than 52,000 Medicare beneficiaries.

We have developed an efficient model of delivering high quality diagnostic imaging services because of our collaboration with radiologists and radiology groups. Our IDTFs are usually organized as limited liability companies which may have multiple practice locations. Each center is enrolled as a separate IDTF (except for a few provider-based centers) as required by Medicare carriers and meet the performance standards set forth in §410.33. In many of the communities that we serve, we are a part of an integrated health system because we have subspecialized radiologists,[4] community-based hospitals and/or hospital health systems as our owner partners. *None of our centers are directly or indirectly owned by referring non-radiologist physicians.* With radiologists as our owner partners in many of the centers, we remain focused on clinical quality and delivering patient care in a manner that is consistent with ever-evolving best practice, clinical protocols. We have extensive quality assurance and compliance programs where our radiologist partners actively participate in a continuous quality improvement program that is indisputably the industry standard for peer review and clinical mentoring and which significantly reduces geographic practice pattern disparities. Commercial health plans and vendors of equipment/software frequently seek CDI's assistance in defining standards or as a beta tester, again because of our consistent standards.

Our IDTFs contract with radiologists/radiology groups for general and direct supervision as well as professional interpretation. In addition to professional services, our professional services agreements provide for sharing space, equipment, technology, and staff in our centers, a paperless work environment with Radiology Information Systems ('RIS") and Picture Archiving and Communication Solutions ("PACS") electronic connectivity, technologist monitoring, peer review and other quality improvement activities. These radiologists do not maintain separate office space outside of the center. Radiologists are on-site every day in our centers providing radiology services because our centers are their radiology offices. The radiologists share office space and our information systems so they can also provide professional interpretations for tests billed by the IDTF. The diagnostic imaging services performed by our centers are interpreted by our radiologist partners. These are not the type of suspect arrangements about which CMS is so concerned. These sharing arrangements can be easily distinguished from turn-key arrangements where an IDTF subleases space and equipment to one or more referring non-radiology physicians (who may also contract with the supervising radiologist for interpretation services) so that the referring non-radiologist physicians can bill and profit from their referrals.

Our IDTFs also contract with CDI Management Inc. ("CDI Management") for technologists, staff, and management services including information systems which increases efficiencies and provides significant value. CDI Management provides equipment financing, construction and purchasing management, a national equipment services and equipment

[4] The radiologists who provide services at our center are almost all fellowship-trained subspecialty radiologists. Many of them hold prominent professional society leadership positions and have published extensively in the area of radiology. CDI's peer review program, coordinated by the CDI Institute, is designed so that reviews are also sub-specialized. Over a dozen radiology groups in several states are actively participating in the peer review process.

maintenance contract, human resources and benefits management, electronic billing, collections, coding and payor relations, RIS and IT infrastructure support, centralized credentialing expertise and transcription services and assists with radiologist and technologist training and maintenance of sub-specialty certification.

We have developed a sophisticated interoperative information management system that improves quality. When an imaging order arrives from a referring physician, our electronic "decision support tool" evaluates whether the test is appropriate or indicated, which minimizes the need for additional tests and provides for cost savings. Because all of our centers are inter-connected, a sub-specialist radiologist can accurately and quickly review imaging protocols with the technologist (even if the subspecialist is at a different center that day). Associated images (including prior studies) are launched in PACS so that the patient medical record is readily available to the radiologist (rather than chasing down files when time is so critical). Interpretative reports are distributed to the referring physician, often via a secured, electronic portal, which improves patient care and medical decision-making because the patient's treating physician has the interpretative report without delay. The interoperable information system helps reduce medical errors, supports the delivery of appropriate, evidence-based care, and lowers costs.

These three organizations co-exist in our centers—the IDTF, the radiology group, and the management company. These affiliated companies share space, equipment, technology and staff to efficiently share resources, reduce costs of delivering health care services and enhance quality. Our collaborative model has been, and continues to be, recognized nationally and locally for delivering high-quality, low-cost diagnostic imaging service.[5] Through the quality improvement arm of CDI (known as the CDI Institute), we have developed a quality measurement tool (called the Advanced Imaging Services Provider Components of Quality Measurement Survey) used by third party payors to rate imaging providers and ensure that patients receive appropriate and high quality imaging services.[6]

Many health providers have looked to CDI because of our management, clinical expertise, and imaging data management systems infrastructure. When other imaging providers were closing their facilities due to financial losses associated with providing advanced imaging services in rural and underserved locations, CDI stepped in to keep the facilities open. In some rural and other underserved communities, we are the only provider of advanced imaging

[5] In 2006, CDI was named the number one outpatient imaging provider in the U.S. by its industry peers. Third party payors have consistently given CDI "Tier 1" status and "A" ratings for its low cost and high quality services. See Appendix B. Researchers, such as the American Lung Association, also look to CDI because we offer consistency in complex, high quality imaging testing across multiple centers and states

[6] "Advanced Imaging Services Provider Components of Quality Measurement Survey" utilizes established quality measurement and best practices indicators, including quality of professional services, quality assurance activities, quality and safety of imaging facility, and patient-centered services. Preferred One Health Plan uses this survey to evaluate its imaging providers for preferred provider status. Provider must maintain a quality rating of 80 total points or higher and meet certain cost expectations to be considered as a preferred provider status. See Appendix C for a copy of the Advanced Imaging Services Provider Survey.

services. Unlike stand-alone radiology practices, we are able to spread the financial costs associated with maintaining a center in a rural community across all of our center operations. We are committed to serving Medicare beneficiaries in underserved locations because we are all too aware of the fact that patient conditions can be missed or misdiagnosed if low-strength imaging equipment is used or can be unsafe if the equipment is not properly calibrated or the equipment operators are inadequately trained. The following are two examples of where we have ensured that Medicare patients continue to have access to high quality imaging services:

- In the rural regional center of Alexandria, Minnesota, we provide the in- and outpatient imaging services for Douglas County Hospital. This partnership was developed after a group of physicians in the community approached CDI because of their concern that their patients had to drive 60 miles for Advanced Imaging Services.
- In St. Louis, Missouri, where we have a partnership with St. Luke's Hospital and the radiologists who staff that hospital, CDI also recently took over the management of the St. Louis Cancer and Breast Center one of the largest in the country, when the center was in danger of closing.

We share CMS' concern about turn-key leasing and similar arrangements with referring non-radiologist physicians. These arrangements are in contrast to CDI's arrangements with radiologists and radiology groups. While the proposed language is meant to discourage these suspect relationships, it is too broad and will prohibit legitimate relationships with radiologists that pose little to no potential for fraud and abuse. Should the CMS proposal go into effect, CDI will be forced to disband its collaborative arrangements with radiologists and radiology groups and, subsequently, co-partner hospitals. In many communities, this means that Medicare patients will have reduced access to safe and high quality imaging services.

II. We Urge CMS To Narrowly Tailor its Proposed Sharing Prohibition To Ensure that There Is No Harm to Patient Care and so that Legitimate Relationships between Radiologists and our Centers Can Continue to Exist

A. Significant Clinical Benefits and Efficiencies Exist Because the Radiologists Use Space, Equipment, and Staff in our Centers as their Radiology Office

CMS' proposal will fundamentally change how radiologists practice medicine in our centers. Radiologists are on-site every day at our centers because our centers also serve as their radiology office. Radiologists who provide professional services to our centers do not maintain a separate medical office location outside of the center. Rather, the radiologists maintain their radiology office within the center without any visible distinctions or designated office space (*e.g.*, no separate office or exam rooms and no separate reception area). Not only are the radiologists on-site providing supervision, they are also on-site performing professional interpretations of the diagnostic tests performed and billed by the IDTF. The radiologists share the RIS and PACS stations and other office equipment in the center to perform their professional interpretation of the diagnostic imaging tests. (See Appendix D for RIS integrated workflow). Furthermore, both the U.S. Department of Health and Human Services ("HHS") and President George W. Bush have made it very clear that provider efforts to integrate electronically is a high

priority.[7] The proposed sharing ban, if finalized, is not consistent with the broader integration goal.

This close integration between the radiology practice and the center results in an efficient delivery of quality diagnostic imaging and interventional services. This allows a radiologist who is on-site at a center providing direct supervision of diagnostic imaging tests to also perform professional interpretations of those same tests. It also enables radiologists to confer with sub-specialist radiologist colleagues, who are in other centers, on difficult diagnostic imaging tests in real-time. For example, a radiologist who is interpreting a difficult MRI of the brain can consult with her colleague who is a fellowship-trained, sub fellowship trained, board-certified neuroradiologist who is providing supervision at another location.[8] The integrated RIS allows the radiologists to simultaneously view the same images even when a radiologist is consulting with a colleague who may be located many miles away. Our integrated network reduces the risk that a patient's condition may go undetected and improves the turn-around time on interpretative reports that are critical to the treating physician's determination of an appropriate treatment plan for the patient.

Additionally, CDI radiologists are on-site at the center to satisfy the direct supervision requirements for certain diagnostic tests and to perform professional interpretations. Our certified technologists have immediate access to a radiologist on-site and off-site (*e.g.*, when a subspecialists is at a different center) to ask questions about a particular patient and review imaging protocols. Our staff is able to immediately contact a radiologist on-site should a patient experience an adverse reaction after receiving contrast. Radiologists are readily accessible to confer with a referring physician and her staff to ensure that the appropriate diagnostic test is performed given the specific circumstances. This reduces the likelihood that additional diagnostic tests will be required and/or ordered for a patient resulting in overall cost savings to the Medicare system.

B. Interventional Radiologists Can Also Perform Interventional Radiology Procedures Under *Imaging* Guidance Using Imaging Equipment Located in our Centers Resulting in Improved Care

CMS' proposal would make it difficult for our radiologists who also perform interventional procedures to provide therapeutic procedures to patients in a convenient manner. The proposed prohibition, if finalized, would require our radiologists to perform interventional radiology procedures in a different location. Some of our diagnostic sub-specialized radiologists

[7] In 2004, President George W. Bush set a goal: nationwide adoption of electronic medical record ("EMR")—to include all medical practices—within a decade. President George W. Bush, State of Union Address, January 24, 2004 available at http://www.whitehouse.gov/stateoftheunion. Subsequently, HHS established the Office of the National Coordinator for Health Information Technology and the American Health Information Community. Also, many Senators have introduced legislation regarding electronic medical record and health technology such as the Health Technology to Enhance Quality Act (S.1262) which established a interoperable health information technology infrastructure, available at http://thomas.loc.gov/cgibin/bdquery/z?d109:SN01262:@@@D&summ2=m&.

[8] These consultations as part of our quality improvement program and Medicare is billed only once for the interpretation.

also sub-specialize in specific diagnostic and therapeutic injections (*e.g.*, epidurals, discograms, myelograms, and joint injections). These procedures are performed under imaging guidance using imaging equipment located in the IDTF. In general, the interventional radiologists do not become the patient's treating physician on an on-going basis when they perform the diagnostic injections and pain management procedures. Rather, these procedures are provided to the patient pursuant to a referral from the patient's treating physician. The patient presents to the interventional radiologist either (i) directly pursuant to the treating physician's referral or (ii) subsequent to a diagnostic imaging test where the referring physician determined that a therapeutic injection is appropriate to treat the patient's condition.

Below is a typical example of how our radiologists perform interventional procedure pursuant to the treating physician's order.[9] A patient presents for a screening mammography. The patient will know the results in a matter of minutes because our on-site radiologist will perform the interpretation. In accordance with Medicare requirements, the radiologist orders a diagnostic mammogram because she noted abnormal tissue.[10] The patient has the diagnostic mammogram immediately and if it detects abnormal tissue the radiologist can perform a breast biopsy if requested by the treating physician. This coordinated delivery of care is invaluable to the patient because it reduces patient anxiety, time off work and travel.

This is an example of how CDI and its radiologists can deliver coordinated care through sharing without increasing the potential for inappropriate utilization. No referral to the center occurs for the therapeutic services because the IDTF is not permitted to, and does not, bill for these services as they are not diagnostic imaging services. Rather, the radiologists bill for these therapeutic services as a physician practice and personally perform the services.[11] At all times, the radiologist is providing services in close consultation with the treating physician and the radiologist rarely, if ever, orders a follow-up diagnostic test.

We urge CMS to continue to permit radiologists to practice medicine within our centers so that patients can receive the best care possible without long waiting periods, multiple office visits, additional copayments, and unnecessary travel. Patient access and convenience should not be hampered when there is little risk that these arrangements will result in inappropriate utilization.

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[9] Another example is where a patient presents for a MRI to evaluate low back and leg pain. Our center performs the MRI scan and an radiologist with whom the center contracts for professional services performs the interpretation. After the interpretation of the MRI, the treating physician is notified of the findings. The treating physician orders an epidural steroid injection for pain control, which can be performed by our interventional radiologist at the same location on the same day. If performed, the patient receives pain relief without having to travel to another office to have the injection performed and without an additional visit to the treating physician.

[10] 42 CFR §410.32(a)(2) specifically provides that an interpreting physician may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

[11] Our centers receive a fee from the radiologists to reimburse the center for the use of the space, equipment and staff.

C. The Proposed Prohibition on Sharing Should Only Apply to Suspect Arrangements, Not Arrangements with Radiologists, Which Is Consistent with Stark Regulations and the OIG Guidance

CMS properly intends to prohibit the type of sharing arrangements with non-radiologist physicians that present fraud and abuse risks. We share CMS' concern regarding turn-key and leasing arrangements where an IDTF subleases space, staff, and equipment to one or more referring non-radiologist physicians so that they can bill and profit from their referrals.

Our sharing arrangements can be easily distinguished from those suspect arrangements. Clinical decisions to order the diagnostic services are made by physicians who do not have any financial relationship with CDI, the IDTF or its radiologists. Per Medicare regulations, all services must have an outside order from the patient's treating physician. Our centers are enrolled as individual IDTFs as required by carriers. The diagnostic imaging tests performed at the IDTF are billed by the IDTF and are interpreted by radiologists (not the referring physician). Unfortunately, the proposed regulatory language also would ban arrangements with radiologists that present little to no risk of inappropriate utilization.

We believe that CMS should apply the Stark statutory and regulatory standards to sharing arrangements. Congress specifically chose not to include radiologists in the definition of "referral" when it enacted the physician self-referral prohibitions at Social Security Act § 1877.[12] Congress regarded most radiologists as " . . . not instigating a referral for services but merely implementing the request of another physician who has already determined that the patient is likely in need of radiology services."[13] Congress believed "that, in general, a radiologist in this situation would not likely overutilize services"[14]

CMS has continued to recognize that a radiologist rarely orders the diagnostic tests that she interprets and only in limited circumstances orders diagnostic tests pursuant to a bona fide consultation.[15] The new Phase III regulations do not change the definition of referral and CMS' treatment of radiologists.[16] CMS specifically notes in the Preamble to the new Phase III

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[12] ". . . [A] request by a radiologist for diagnostic radiology services . . . if such services are furnished by (or under the supervision of) such . . . radiologist . . . pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician". Section 1877(h)(5)(C) of the Social Security Act.

[13] 66 *Fed. Reg.* 856, 874 (Jan. 4, 2001).

[14] *Id.* Indeed, in practicality, CDI's data, which can be confirmed with some of our knowledgeable commercial payers, indicates that CDI's model *reduces* the number and extent of the tests ordered through active consultation with the referring provider, including through the use of an electronic decision support tool. To date, the most dramatic reduction is in the use of a contrast agent for complex brain and spine exams.

[15] Referral "[d]oes not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy, if— (i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and (ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist. 42 CFR §411.351.

[16] "As we noted in Phase I (66 FR 874), the Congress regarded the specialists excepted under the definition of "consultation" as physicians who were not initiating a referral for services, but merely implementing the request of

regulations issued this year that the "the additional protection against overutilization of diagnostic radiology . . . services implicit when a radiologist, pathologist, or radiation oncologist merely implements a determination made by another physician . . ."[17]

Even in situations where a radiologist recommends additional testing, that is medically necessary, to the treating physician, which could generate some additional business for the radiologist, these additional tests do not constitute a "referral". The radiologist does not take over the responsibility for the care of the patient. Rather, in the vast majority of cases, the patient's treating physician continues to retain responsibility for the patient and must order any tests, whether or not they are recommended by the radiologist. Our imaging studies and procedures are ordered by clinicians who have no financial incentive or economic relationship with CDI's imaging centers. Furthermore, CMS' own policy treats radiology practices differently from other physician practices because a radiologist usually does not treat a patient's medical condition on an on-going basis.[18]

The OIG also agrees that radiologists are rarely in a position to make referrals for diagnostic services as they rely on other physicians and providers for access to patients. In two OIG advisory opinions, the OIG noted that radiologists are not likely to generate a significant number of referrals because they do not frequently order the tests that they interpret. [19]

Therefore, sharing arrangements between a radiologist and an IDTF are not suspect because generally neither the radiologist nor the center can order a diagnostic imaging test and both are dependent on referrals from a patient's treating physician. CMS' own regulations require the treating physician to order the diagnostic tests, except for diagnostic mammograms that are ordered by an interpreting radiologist based on her findings of a screening mammogram.[20] Diagnostic tests that are not ordered by the physician who is treating the beneficiary are not reasonable and necessary.[21] Consistent with CMS' own policy, CMS should

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another physician who has already determined that the patient is likely to need the specialist's services. In these situations, the Congress indicated its belief that overutilization would not be likely. As we noted in Phase II (69 FR 16064), the statutory consultation exception "creates a narrow exception for a small subset of services provided or ordered by certain specialists in accordance with a consultation requested by another physician." See Phase III regulations which are expected to be officially published in the Federal Register on September 5, 2007.

[17] Id.

[18] Program Integrity Manual 4.19 (stating that radiology offices are different from other physician practices and therefore may not necessarily need to enroll as an IDTF).

[19] "In general, radiologists do not order the radiological tests they perform; instead, such tests are ordered by a patient's treating physician. Although there may be situations in which a radiologist can recommend additional testing during the course of a consultation and, as a practical matter, indirectly generate some additional business, those tests must be approved by the patient's treating physician, except in very limited, well-defined circumstances. " See OIG Advisory Opinion No. 03-12 (May 22, 2003) available at OIG's website at http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2003/ao0312.pdf. See also OIG Advisory Opinion No. 97-5 (Oct. 6, 1997) http://www.oig.hhs.gov/fraud/docs/advisoryopinions/1997/ao97_5.pdf (noting that radiologists are not likely to generate an appreciable number of referrals because they do not order the diagnostic imaging tests that they perform.). See also 64 *Fed. Reg.* 63518, 63524 (Nov. 19, 1999) (stating that radiologists who occasionally recommend a specific diagnostic test to a referring physician with whom the radiologist has no financial arrangements and pursuant to a bona fide medical consultation is not prohibited under the anti-kickback statute).

[20] 42 CFR Section 410.32(a) and (a)(2).

[21] 42 CFR Section 410.32(a).

exclude radiologists and radiology practices from the proposed sharing and subleasing prohibition because they are not generally in the position to generate referrals.

We believe that our recommendations balance the interests of the agency in curbing suspect arrangements while minimizing any risk of harm to patient care and clinical quality that would occur should the prohibition be finalized as proposed.

D. The Proposed Prohibition Is an Unreasonable Restriction on the Practice of Medicine

The proposed sharing prohibition unfairly limits radiologists' ability to provide radiology services in an IDTF setting. This prohibition constitutes a Federal restriction on the practice of medicine, which is an area that is historically regulated by the states under state licensure laws. This restriction could result in radiologists establishing two different offices—one to receive Medicare patients and the other to see non-Medicare patients—without any demonstrative benefit to Medicare patients and may even limit access and quality.

E. Patient Care, Quality and Access Will be Harmed Should CMS Finalize its Proposed Prohibition (without Excluding Radiologists/Radiology Groups)

CDI's model for delivering efficient, high quality services would be lost if CMS finalizes its sharing prohibition as currently proposed. The proposed prohibition could significantly compromise patient care and quality and could have several unintended consequences including:

- Creation of two offices—a physician office that serves Medicare Beneficiaries and an IDTF that serves non-Medicare Beneficiaries. The office serving non-Medicare Beneficiaries would have higher imaging quality than the office serving Medicare Beneficiaries because the IDTF could continue to have the economic and clinical efficiencies and benefits (*e.g.*, integrated delivery of health care between the radiologists and the IDTF, interoperative information systems, high strength imaging equipment, certified technologists, and sub-specialist radiologists).

- Reduced quality for Medicare Beneficiaries. Physician offices have less stringent enrollment and quality standards (*e.g.*, technologist credentialing). Physicians likely would offer fewer modalities and have older field equipment because they lack the financial resources to make these significant capital expenditures. Less consistency among practice locations and more practice pattern disparities likely would occur.

- Less sub-specialization. Radiologists would spend more time outside of their sub-specialty.

- Less convenient/delayed discussions among radiologists regarding difficult cases. Radiologists could not confer with their radiologists in real-time because the physician office likely will not have an interoperative information systems.

- Inferior and duplicative information technology. A physician office likely could not incur the significant cost of developing an interoperative information system. This could lead to inconvenience and delayed reports to the patient's treating physician and unnecessary delay in treating the patient.

- Higher costs/less efficient use of resources. A physician office would purchase/lease duplicate imaging equipment and could not share certified technologists and administrative staff across all locations. No centralized credentialing services and human resource functions, operations, and administrative support would exist that promote consistency in patient care.

- Patients would have fewer provider options and reduced access to advanced diagnostic imaging procedures, especially in rural and underserved locations. Physicians cannot afford to operate in these locations because of the significant capital expenditures and IT infrastructure and operations support.

- Fewer centers could result in longer waiting times for Medicare beneficiaries and separate office visits for each procedure.

- An increased risk of fraud and abuse and over-utilization. Referring non-radiologist physicians could purchase their own equipment because they can not wait while CDI and our radiologists disband and restructure.

We strongly recommend that CMS specifically exclude "radiologists and radiology groups" from the definition of "individual or organization" in the proposed regulatory language §410.33(g)(15) so Medicare beneficiaries continue to have access to high quality imaging services in the IDTF setting. We recommend that §410.33(g)(15) be revised to read as follows:

> "Does not share space, equipment, or staff or sublease its operations to another individual or organization, except for radiologists and radiology groups"

Furthermore, we recommend that CMS implement our recommendation by amending the CMS Form 855B to require disclosure of sharing arrangements at the time an IDTF applies for enrollment and to report any changes in sharing arrangements to CMS within 30 days.

III. CMS Should Clarify that the Proposed Prohibition on Sharing Does Not Preclude Ownership in the IDTF

It is unclear whether CMS' proposal is intended to prohibit radiologists and/or radiology groups from having an ownership or investment interest in an IDTF because the word "sharing" is not defined in the proposed regulatory language. We jointly own many of our centers with radiologists and/or radiology groups. Unlike joint ventures involving referring physicians which CMS intends to prohibit, all of our physician investors are non-referring radiologists and radiology groups. Neither the center nor the co-owner radiologists can independently generate referrals to the center.

The OIG has consistently viewed outpatient imaging centers co-owned by radiologists/ radiology groups and hospitals unlikely to result in fraud and abuse.[22] Similar to the Stark Law, the OIG treats radiologists differently than non-radiologist physicians. In 1997, an OIG advisory opinion affirmed that hospitals and radiologists are rarely in a position to make referrals as they rely on other providers for access to patients. The OIG concluded that, although a joint venture between a hospital system and a radiology group to operate an outpatient radiology imaging center did not fall within the small entity safe harbor, it would not violate the Federal Anti-Kickback Statute because neither the hospital system nor the radiology group would be in a position to generate referrals to the joint venture. [23] The OIG concluded that the radiologist's recommendation for additional testing to the patient's treating physician with whom the radiologist has no financial arrangements and pursuant to a bona fide medical consultation is not prohibited under the Federal Anti-Kickback Statute.[24] In 2003, the OIG reached the same conclusion in another advisory opinion regarding a medical center and a radiology group's ownership in a joint venture entity that owns and operates an outpatient MRI facility.[25]

Similar to the hospital and radiology joint ventures discussed in two OIG advisory opinions, radiologists/radiology groups and/or non-physician investors (like CDI) joint ventures should not be viewed as violating the Anti-Kickback Statute because no illegal remuneration for referrals existed between the radiologists/radiology group and CDI. In fact, there is even less risk of fraud and abuse compared to the outpatient joint ventures discussed in the OIG advisory opinions because CDI, unlike a hospital, does not have a medical staff or does not employ non-radiologist physicians who could direct patients to the center. Neither the radiologists/radiology group nor CDI can independently generate referrals.

CMS should clarify in the preamble to the final rule that ownership or investment interests held by radiologists/radiology groups in an imaging IDTF does not constitute "sharing" for purposes of the proposed regulatory language at §410.33(g)(15).

IV. CMS Should Clarify that the Proposed Prohibition on Sharing does not Preclude Affiliated Companies that Provide Services Integrally Related to the Operations of an Imaging IDTF From Sharing Space, Equipment and Staff

CDI achieves economic and clinical efficiencies by sharing space, staff, information systems and equipment across all of our locations. We are concerned that CMS' proposed regulatory language set forth in §410.33(g)(15) will prohibit an IDTF from sharing with affiliated companies that provide staffing, information systems, and management services related to the operations of an imaging IDTF. The intent of the proposed regulatory language is to curb arrangements that promote inappropriate utilization of diagnostic services as well as fraud and

[22] See OIG Advisory Opinion No. 03-12 (May 22, 2003) available at OIG's website at http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2003/ao0312.pdf. See also OIG Advisory Opinion No. 97-5 (Oct. 6, 1997) http://www.oig.hhs.gov/fraud/docs/advisoryopinions/1997/ao97_5.pdf .
[23] See OIG Advisory Opinion No. 97-5 (Oct. 6, 1997) http://www.oig.hhs.gov/fraud/docs/advisoryopinions/1997/ao97_5.pdf .
[24] Id.
[25] See OIG Advisory Opinion No. 03-12 (May 22, 2003) available at OIG's website at http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2003/ao0312.pdf.

abuse. Our sharing of resources has nothing to do with creating incentives or opportunities for physicians to profit from their own referrals and thereby promote inappropriate utilization. In its efforts to achieve its goal of shutting down suspect arrangements, the CMS proposal would also prohibit corporate subsidiaries and affiliated companies from sharing staff, space and equipment so that they can efficiently share resources and reduce the costs of providing imaging services.

We recommend that CMS clarify in the Preamble to the final rule that the prohibition does not preclude affiliated companies (which do not have any referring non-radiologist physicians as owners) that provide services integrally related to the operations of an imaging IDTF (such as an interoperable information system, centralized credentialing, staff and billing) from sharing space, equipment, and staff. Without this exception, IDTFs would be forced to purchase/lease separate office space, purchase duplicate diagnostic equipment, information technology, office equipment and maintain duplicate staff. This would significantly reduce efficient use of resources and increase costs.

V. If CMS Rejects our Recommendations, CMS Should Delay the Effective Date of Any Sharing or Subleasing Prohibition for at Least Four Years

If CMS rejects our recommendations and finalizes the proposed prohibition on sharing, we urge CMS to delay implementation of its proposed prohibition for at least four years given the magnitude of the proposed changes. The proposed prohibition will drastically affect how CDI and its radiologists provide diagnostic imaging services to our patients and increases the overall cost of providing safe and high quality services. We will find it extremely difficult to comply with this requirement because of existing coordinated delivery of care models and arrangements that exist for the patients that we and our radiologists serve. We urge CMS to delay the effective date for at least four years to ensure that patient access will not be compromised while we and our radiologists unwind and restructure our companies and current arrangements, renegotiate with lenders and raise necessary capital for new office locations, find and lease or purchase new medical office space for radiologists, purchase additional diagnostic imaging equipment, and dismantle our information system and invest in RIS and PACS systems in separate office locations. We and our affiliated radiologists simply cannot adapt our integrated health care delivery system in less than four years.

When CMS has implemented significant changes to other policies that drastically affect how healthcare providers provide services and corporate arrangements, it has provided ample time for providers to comply with its new requirements. Similar to when CMS included nuclear medicine as a designated health service ("DHS") for purposes of the Stark Law, CMS should provide the imaging community time to revise and unwind existing arrangements so that there is as little interruption as possible to patient care. Unwinding the IDTF model is more complex than what was required to comply with CMS' inclusion of nuclear medicine as DHS. We are not a stand alone arrangement or center. Rather, we are sophisticated integrated health care delivery system consisting of many partnerships across over eight states. The IDTF model simply cannot be disbanded or restructured in a short period of time without a significant disruption to patient care.

Should CMS choose to implement its proposal within a shorter period of time to curb fraud and abuse resulting from sharing and subleasing arrangements with referring physicians, we ask that CMS provide an exception for sharing and subleasing arrangements with radiologists and radiology groups. We believe that there is little risk of fraud and abuse in delaying the effective date for radiologists and radiology groups.

V. Conclusion

While we support CMS' effort to reduce overutilization of imaging services and self-referral arrangements, the proposed regulation language would also prohibit legitimate sharing arrangements among IDTF, radiologists/radiology groups, and affiliated companies that promote quality and efficient use of resources. Should CMS implement its proposed sharing and subleasing prohibition, we strongly recommend that CMS:

1. Specifically exclude "radiologists and radiology groups" from the definition of "individual or organization" in the proposed regulatory language at §410.33(g)(15) so that imaging IDTFs can share space, equipment, and staff with radiologists and radiology groups.
    - Revise §410.33(g)(15) to read as follows:
        - "Does not share space, equipment, or staff or sublease its operations to another individual or organization, except for radiologists and radiology groups"
2. Clarify in the Preamble to the final rule that the prohibition does not preclude affiliated companies (which do not have any referring non-radiologist physicians as owners) that provide services integrally related to the operations of an imaging IDTF (such as an interoperable information system, centralized credentialing, staff and billing) from sharing space, equipment, and staff.
3. Clarify in the Preamble to the final rule that ownership or investment interests held by radiologists/radiology groups in an imaging IDTF does not constitute "sharing" for purposes of the proposed regulatory language at §410.33(g)(15).

* * *

Thank you for your consideration of these comments. We extend an invitation to you and your staff to visit one or our centers which shares space, equipment, and sometimes ownership with non-referring radiologists. If you have any questions, please do not hesitate to contact one of us.

Respectfully submitted,

Kenneth B. Heithoff, M.D.
Chairman and National Medical Director

Robert V. Baumgartner
Chief Executive Officer

Elisabeth Quam Berne
Director, CDI Institute

APPENDIX A

MEDICAL DIRECTORS COUNCIL

August 31, 2007

HAND DELIVERED

Mr. Herb Kuhn
Acting Deputy Administrator
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Kuhn:

As radiologists and the medical directors for the Center for Diagnostic Imaging ("CDI"), we are writing to urge the Centers for Medicare and Medicaid Services ("CMS") to take steps to ensure that we and our radiologist colleagues are able to continue our radiology practice in an independent diagnostic testing facility ("IDTF") setting.

CMS' proposed prohibition on IDTFs from sharing space, equipment or staff will fundamentally change how we practice radiology with no benefit to the patients whom we serve. We and our radiologist colleagues practice radiology in an IDTF-based setting and we do not maintain separate radiology office locations outside of CDI's centers, with the exception of limited space some of our radiologist practices have at the hospitals we serve. For the vast majority of us, the IDTF centers are our radiology offices. *The legitimate purpose of sharing space, equipment and staff in the center is to ensure the efficient delivery of safe, sophisticated diagnostic imaging services to patients.* If we are not allowed to share space, we will have to move our offices to a different location. This means that we will not be on-site every day at the centers like we are currently but only when required to provide supervision. Because our radiology office will be in a different location, we will not be as readily available to consult with referring physicians about the appropriateness of certain diagnostic imaging tests for a particular patient or answer patient questions and concerns, or be able to work closely with the technologists to prepare imaging protocols for specific patients and generally monitor the quality and safety of the diagnostic imaging services provided at the centers on a daily basis.

In addition to our diagnostic imaging services, many of us also perform interventional radiology and therapeutic procedures at the same IDTF locations but bill for them under our physician NPI (not under the IDTF number). This gives the attending physician and his or her patient the option of having a biopsy of a potentially malignant tumor (if ordered by the patient's attending physician) at the same location the diagnostic mammogram was performed. These biopsies are performed under imaging guidance using imaging equipment located in the IDTF.

c/o CDI Institute • 5775 Wayzata Blvd., Suite 400, St. Louis Park, MN 55416 • *tel:*952-543-6500 *fax:* 952-847-1152

Should the sharing prohibition go into effect, we would have to purchase duplicate imaging equipment in a separate medical office to perform these biopsies (or other urgent interventional procedures as ordered by the referring physician). The patient would have to schedule another appointment at another location on a different day. This would be a disservice to Medicare beneficiaries who want the procedure performed at the same location on the same day as the diagnostic imaging service. The benefits to the patient include reduced anxiety, less time off work for themselves or their escort and no need to arrange transportation.

We also use CDI's sophisticated Picture Archiving and Communication Solutions ("PACS") and Radiology Information Systems ("RIS") located in the centers to interpret diagnostic imaging services. The proposed sharing prohibition appears to only permit us to supervise a diagnostic imaging test but not perform the professional interpretation of the test. This would be a significant waste of our professional time and greatly reduce our efficiency.

In our radiology practice, we frequently consult with each other. For example, a radiologist interpreting a difficult MRI scan of the brain at our Douglas County, Minnesota location may want to consult with his/her fellowship trained, board-certified neuroradiologist who is practicing or providing supervision at our St. Louis Park, Minnesota location. (These consultations are performed among our practice as a professional courtesy and we only bill Medicare once for the interpretation.) The integrated RIS allows us to simultaneously view the same images even when we are consulting with our colleague who may be located 80 miles or more away. We believe that this sharing improves patient care because it reduces the risk that a patient's condition could go undetected and improves our turn-around time on interpretative reports. Without any prolonged delay, we can provide a high quality interpretative report to the patient's attending physician (and even have the images in the operating room) which is critically important to that physician's evaluation of the patient's condition and is needed before starting the patient's course of treatment.

Should CMS adopt its proposed prohibition, it would be extremely difficult for radiology practices to offer sub-specialized imaging services in rural locations or other underserved locations without collaborating with CDI. We simply could not bear the financial commitment to purchase high field/cutting edge diagnostic imaging equipment, invest in an interconnected information technology system, hire certified, sub-specialized technologists to staff a location, and provide a sub-specialist radiologist to perform the supervision and interpretation of the tests. The productivity and quality losses associated with having a radiologist supervise and interpret tests in a rural community, without the connectivity to a company such as CDI, is easily assessed in terms of equipment strength and accreditation, level of technologist training and radiologist specialization. Should the proposed prohibition go into effect, we would have to disband our collaborative arrangements with CDI and would be forced to make painful choices about not serving Medicare beneficiaries in rural and other underserved locations. As a result, many Medicare beneficiaries will have fewer provider options and reduced access to high quality imaging services.

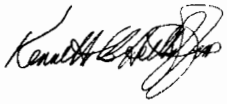
This proposal unfairly limits our ability to provide radiology services in an IDTF setting. This constitutes a Federal restriction on the practice of medicine, which is an area that is historically regulated by the states under state licensing laws. This restriction would appear to require us to establish two different offices—one to receive Medicare patients and the other to see non-Medicare patients—with no identifiable public policy rationale or benefit to patients.

We believe that no other medical specialty is as dramatically affected by the proposed prohibition. This proposal, if finalized, would make it impossible for us and our radiologist colleagues to continue our practices as we currently operate and to provide safe, sub-specialized, high strength imaging services and care to patients.

We urge you to address this issue by specifically excluding radiologists and radiology groups, who are not self-referring, from the proposed ban on sharing arrangements in IDTFs.

Thank you for your consideration of our concerns.

Sincerely yours,



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Michael Sullivan, M.D.
Medical Director
CDI Provena, Geneva, ILL

Aaron Guajardo, M.D.
Medical Director
CDI Provena, Bourbannais, ILL

Thomas Vahey, M.D.
Medical Director
CDI Indiana

CENTER FOR
DIAGNOSTIC IMAGING

August 15, 2007

Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

To whom it may concern:

I am writing this letter to supplement a comment letter being submitted by the Center of Diagnostic Imaging with respect to the Proposed Rule CMS-1385-P, Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008. I am a sub-specialized spine and musculoskeletal radiologist. My job has three major components. These are deeply integrated and performance of one job both enhances and supports the performance of the other tasks.

First, I interpret MRI and CT scans of the spine and joints. I am responsible for the protocols, for monitoring the examinations, and for rendering an interpretation. As you know we call any major or emergent findings directly to the physician. After the completion of the dication, we are responsible for reviewing the reports for accuracy.

Second, I perform diagnostic and therapeutic injections into the spine and joints. In general we will be injecting a mixture of cortisone and local anesthetic into the epidural space, along the nerve roots, or into various joints in order to determine whether the pain is coming from that source. These procedures are also performed to control pain, and to enhance and extend the course of conservative therapy. In order to perform injections, we need to review prior cross sectional imaging examinations in order to select the safest and most direct route. The objective of the injection technique is to deliver the dose of cortisone as close to the pain generator as possible. This may be a disc herniation or an area of stenosis.

Third, I provide consultation to the referring physicians. In many cases the referring physician will call and describe the patient's symptoms to us in order to determine the most appropriate imaging test. Physicians also frequently call with imaging results and would like to know what the most appropriate injection would be in patients who have failed a course conservative therapy with oral medications, physical therapy or chiropractic adjustment. A physician might also call with respect to the possibility of underling malignancy and may ask me to biopsy a suspected tumor.

www.CDIradiology.com
5775 Wayzata Boulevard, Suite 190 St. Louis Park, MN 55416 *tel* 952.541.1840 *toll free* 800.422.0948 *fax* 952.543.6524

ST. LOUIS PARK COON RAPIDS MAPLEWOOD MENDOTA HEIGHTS BURNSVILLE WOODBURY EDEN PRAIRIE MAPLE GROVE
OWATONNA SARTELL ST. CLOUD DULUTH

Each of these tasks is intricately weaved through the course of the day. It would be very difficult to separate to the imaging from the diagnostic and therapeutic injections. My ability to interpret images greatly enhances my choice of my injection sites and also enhances my ability to deliver useful consultative advice to referring physicians.

I hope this information is useful. If you need any further information, please do not hesitate to contact me.

Sincerely,

Thomas J. Gilbert, M.D., M.P.P.
Director of Spine Imaging
Center for Diagnostic Imaging

CENTER FOR
DIAGNOSTIC IMAGING

BLAKE A. JOHNSON, M.D.
Director of Neuroimaging

August 16, 2007

Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

To whom it may concern:

I am a neuroradiologist at the Center for Diagnostic Imaging, where we practice subspecialty radiology as fellowship trained radiologists. As a neuroradiologist, I interpret MR and CT studies of the brain, head, neck and spine, which are performed at our imaging centers. In addition, as an interventional spine radiologist, I perform image-guided diagnostic and therapeutic spinal injection procedures for evaluation and management of spine related pain pursuant to a consultation with the patient's attending physician.

The imaging studies, as well as the image-guided injections, are performed at outpatient radiology centers. Our technologists are trained to perform both imaging studies and assist with the image-guided injection procedures. The imaging studies and procedures are ordered by clinicians who have no financial incentive or economic relationship with the imaging center. They order these studies and procedures based on medical indications only.

The performance of these radiology services by independent diagnostic testing facilities, which are staffed by radiologists and do not have an economic relationship with the clinicians who are ordering the studies, minimizes overuse and the performance of radiology services primarily for economic gain. It is critical that the CMS recognize the difference between radiologist-staffed IDTF's and those staffed by non-radiologists, where the decision to order imaging studies or image-guided procedures is made by owners of the equipment.

I am available for further comment on this matter, and would be happy to discuss this with the CMS staff. I may be reached at (952) 525-6304.

Sincerely,

Blake A. Johnson, M.D.
Director of Neuroimaging

BAJ:bjb

www.cdiradiology.com
5775 Wayzata Boulevard, Suite 190 Minneapolis, MN 55416
tel 952.525.6304 *toll free* 800.422.0948 *fax* 952.543.6524 *email* bjohnson@cdirad.com

APPENDIX B

AIM American Imaging Management

OptiNet

Assessment Report Card for:
CENTER FOR DIAGNOSTIC IMAGING

Address 10206 LANTERN RD
FISHERS , IN 46037
County HAMILTON
Registration # 1095

Site Score (base score)

Factor Name	Factor Description	Score Weight	Raw Score	Weighted Score
Site Hours	Sum of total hours open for services	10%	100	10
Site accessibility	Wheelchair and pediatric availability	5%	100	5
Site Policies & Procedures	Quality measures for sites not accredited	20%	100	20
Site QA	Quality measures for sites not accredited	20%	100	20
Site Accreditation	JCAHO accreditation	10%	100	10
Site Tech staffing	Quality measures for sites not accredited	20%	100	20
Site CAQs	Additional physician radiology certifications	10%	100	10
Site Number of Modalities	A count of high-tech modalities offered	5%	50	2.5
	Section total calculated:	**100%**	**750**	**97**
	Site Score			97.5

CT Modality Scoring

Modality Factor	Modality Factor Description	Score Weight	Raw Score	Weighted Score
Equipment Age	Age in years of machine(s)	10%	100	10
Equipment Quality	Number of Channels	10%	50	5
Modality Accreditation	Machine/modality accreditation	20%	100	20
Modality Policies & Procedures	Modality QA for non-accredited sites	10%	100	10
Schedule Lead Times	Modality-specific scheduling lead time	5%	100	5
Modality Technologists	Modality-specific technologist certification	20%	100	20
Modality MD Certification	Physician staffing with radiology, neurology or neurosurgery board certification	25%	100	25
	Section sub-total:	**100%**	**650**	**95**
	Modality total (based on Site and Modality)		96.25	
	Average Modality Cost		351	

MR Modality Scoring

Modality Factor	Modality Factor Description	Score Weight	Raw Score	Weighted Score
Equipment age	Age in years of machine(s)	10%	50	5
Equipment Quality	CT channels, MRI field strength, etc.	10%	75	7.5
Modality accreditation	Machine/modality accreditation	20%	100	20
Modality Policies & Procedures	Modality QA for non-accredited sites	10%	100	10
Schedule lead times	Modality-specific scheduling lead time	5%	100	5
Modality Technologists	Modality-specific technologist certification	20%	100	20
Modality MD Certification	Physician staffing with radiology, neurology or neurosurgery board certification	25%	100	25
	Section sub-total:	**100%**	**625**	**93**
	Modality total (based on Site and Modality)		95	
	Average Modality Cost		598	

Score Legend

Site Scoring:

What is a Report Card?

The Report Card displays t service and modality quality scores for this site. The calculations of these scores are based on the site registration information ent into OptiNet. Averaged exa costs, displayed as the projected sum of all the exa costs ordered for each case each modality, are also displayed.

How are the Quality Grad for each modality derived

The Quality Grade for each modality is determined by t following weighted score ranges:
A: 88 to 100
B: 76 to 88
C: < 76

Anthem.

PRINT THIS PAGE X Close Window

View Treatment Costs

Topic: Stomach - CT Scan Abdomen - Diagnostic Tests - Outpatient

Services typically included in the cost of this treatment:

- X-ray pictures of the stomach, intestines or liver

View Description of Treatment

CT Scan (computerized tomography), commonly known as a "cat" scan, of the Abdomen is X-ray pictures of structures such as in the stomach, intestines or liver created by a computer that turns the images into pictures on a screen.

Facility Name	Minimum Agreed Price		Maximum Agreed Price	Annual # of Svcs Performed
Center for Diagnostic Imaging	$333	-	$517	759
Blackford Community Hospital	$333	-	$517	*
Northwest Radiology Network	$333	-	$517	840
Howard Regional Health System	$333	-	$517	*
Columbus Diagnostic Imaging	$333	-	$517	868
Premier Diagnostic Imaging LLC	$333	-	$517	*
St Vincent Northwest Radiology	$333	-	$517	270
Advanced Medical Imaging	$333	-	$517	639
Greene County General Hospital	$333	-	$517	*
Indiana University Radiology Associates	$333	-	$517	*
The Imaging Cntr	$333	-	$517	*
Muncie Open Sided MRI	$333	-	$517	*
Whitewater Valley Imaging Center	$333	-	$517	*
Indiana Mri Of Terre Haute	$333	-	$517	*
SIRA Imaging Center LLC	$333	-	$517	*
Memorial Hospital Of Logansport	$518	-	$665	*
Community Hospital Of Anderson	$518	-	$665	*
Ball Memorial Hospital	$518	-	$665	*
Decatur County Memorial Hospital	$666	-	$813	*
Johnson Memorial Hospital	$666	-	$813	*
Community Hospitals Indiana Inc	$666	-	$813	*
Dunn Memorial Hospital	$666	-	$813	*
Community Hospital South	$666	-	$813	*
The Indiana Heart Hospital	$666	-	$813	*
St Francis Hospital	$666	-	$813	11492
Westview Hospital	$666	-	$813	*
Columbus Regional Hospital	$814	-	$961	*

Union Hospital	$814	-	$961	*
Morgan Hospital and Medical Center	$814	-	$961	1318
St Vincent Carmel Hospitals x HHC	$814	-	$961	*
St Vincent Hospital and HCC	$814	-	$961	*
Wm S Major Hospital	$814	-	$961	2011
Hancock Regional Hospital	$814	-	$961	2826
West Central Community Hospital	$814	-	$961	*
Sullivan County Community Hospital	$814	-	$961	*
Indiana Orthopaedic Hospital LLC	$814	-	$961	14
Dukes Memorial Hospital	$814	-	$961	501
Rush Memorial Hospital	$814	-	$961	593
Riverview Hospital	$962	-	$1,109	3416
Putnam County Hospital	$962	-	$1,109	*
St Vincent Frankfort Hospital	$962	-	$1,109	*
Schneck Medical Center	$962	-	$1,109	*
St Joseph Hospital And Health Center	$962	-	$1,109	*
Hendricks Regional Health	$962	-	$1,109	4057
Terre Haute Regional Hospital	$962	-	$1,109	*
Witham Memorial Hospital	$962	-	$1,109	*
Wishard Memorial Hospital	$962	-	$1,109	*
Henry County Memorial Hospital	$962	-	$1,109	*
St Vincent Heart Center of Indiana LLC	$962	-	$1,109	*
ST Johns Health System	$1,110	-	$1,257	*
St Vincent Randolph Hospital	$1,110	-	$1,257	*
ST Vincent Clay Hospital Inc	$1,110	-	$1,257	*
St Vincent Jennings Hospital	$1,110	-	$1,257	*
Jay County Hospital	$1,110	-	$1,257	*
St Vincent Mercy Hospital	$1,110	-	$1,257	*
Fayette Memorial Hospital	$1,258	-	$1,479	*
Tipton County Mem Hospital	$1,258	-	$1,479	494
Reid Hospital and Health Care Services	$1,258	-	$1,479	18032

What The Results Tell You
Minimum Cost -> Maximum Cost
Most procedures involve a particular bundle of related services, tests and visits. Based on our members' history, we've listed a standard bundle that's typical for this procedure (see list above). Each facility's price range tells you the agreed-upon price for this procedure's bundle of related services, including physician services. So you can see the total price of having a procedure done, not just the surgery itself. Where your actual price falls within the range depends on which of these related services your doctor recommends or prescribes for your treatment.

Where The Prices Come From
At Anthem Blue Cross and Blue Shield we negotiate standard prices with each facility on behalf of our members to lock in the best rates possible for you. Listed below are the agreed-upon prices for Anthem members - no matter what the hospital would normally bill. Use this range as a baseline to figure your actual out-of-pocket costs based on your plan's benefit levels. See APPLYING CO-PAY AND CO-INSURANCE for examples. Since these facilities are in Anthem's network, the ranges are based on in-network pricing (it's a good idea to remind your doctor to schedule your procedure or test in a facility that is part of our network).

AIM American Imaging Management

OptiNet

Click here to better understand the report card

Assessment Report Card for:
MILWAUKEE CTR DIAG IMAGING

Address **2445 N MAYFAIR RD**
WAUWATOSA , WI 53226
County **MILWAUKEE**
Registration # **1844**

Site Score (base score)

Factor Name	Factor Description	Score Weight	Raw Score	Weighted Score
Site Hours	Sum of total hours open for services	10%	100	10
Site accessibility	Wheelchair and pediatric availability	5%	50	2.5
Site Policies & Procedures	Quality measures for sites not accredited	20%	100	20
Site QA	Quality measures for sites not accredited	20%	100	20
Site Accreditation	JCAHO accreditation	10%	100	10
Site Tech staffing	Quality measures for sites not accredited	20%	100	20
Site CAQs	Additional physician radiology certifications	10%	100	10
Site Number of Modalities	A count of high-tech modalities offered	5%	50	2.5
	Section total calculated:	**100%**	**700**	**94**
	Site Score			95

CT Modality Scoring

Modality Factor	Modality Factor Description	Score Weight	Raw Score	Weighted Score
Equipment Age	Age in years of machine(s)	10%	100	10
Equipment Quality	Number of Channels	10%	50	5
Modality Accreditation	Machine/modality accreditation	20%	100	20
Modality Policies & Procedures	Modality QA for non-accredited sites	10%	100	10
Schedule Lead Times	Modality-specific scheduling lead time	5%	100	5
Modality Technologists	Modality-specific technologist certification	20%	100	20
Modality MD Certification	Physician staffing with radiology, neurology or neurosurgery board certification	25%	100	25
	Section sub-total:	**100%**	**650**	**95**
	Modality total (based on Site and Modality)		95	
	Average Modality Cost		129	

MR Modality Scoring

Modality Factor	Modality Factor Description	Score Weight	Raw Score	Weighted Score
Equipment age	Age in years of machine(s)	10%	100	10
Equipment Quality	Magnet field strength and Dedicated coils	10%	100	10
Modality accreditation	Machine/modality accreditation	20%	100	20
Modality Policies & Procedures	Modality QA for non-accredited sites	10%	100	10
Schedule lead times	Modality-specific scheduling lead time	5%	100	5
Modality Technologists	Modality-specific technologist certification	20%	100	20
Modality MD Certification	Physician staffing with radiology, neurology or neurosurgery board certification	25%	100	25
	Section sub-total:	**100%**	**700**	**100**
	Modality total (based on Site and Modality)		97.5	
	Average Modality Cost		761	

Score Legend

Site Scoring:

What is a Report Card?

The Report Card displays service and modality qua scores for this site. The calculations of these sco are based on the site registration information e into OptiNet. Averaged e costs, displayed as the projected sum of all the e costs ordered for each ce each modality, are also displayed.

How are the Quality Gra for each modality deriv

The Quality Grade for ea modality is determined by following weighted score ranges:
A: 88 to 100
B: 76 to 88
C: < 76

How do I return to Optil

Click the **Back** button at bottom of the Report Car page to return to the Site Selection page of OptiNe

Note: The **Print this pag** button allows you to send Report Card to your print

APPENDIX C

Advanced Imaging Services Provider (AISP)

Components of Quality Measurement

SURVEY

I. Overall Purpose: Consumer Value and assurance of *"The Right Test, Done Right and at the Right Time"*

In an effort to provide significant value to its enrollees, Preferred One has established a network of advanced imaging providers based on measurable indicators of quality and cost. The cost measure includes assessment of both price and pricing simplification for the consumer.

The quality measurement is based on evidenced-based best practices that are measurable and comparable. Using the measures below, an imaging provider must demonstrate it maintains a quality rating of 80 total points or higher to be considered for the network and before negotiating reimbursement specifics. The rating scale is designed to be understandable to the purchaser and enrollee as well as avoiding burdensome administrative costs for the treating provider or health plan.

Each provider must therefore meet both quality and cost expectations prior to being designated a preferred provider of advanced imaging services for Preferred One.

II. Weighting the Quality Components

The general categories upon which a provider of advanced imaging services is rated are as follows:

- 40%forthequalityofphysician interpretive/diagnostic services;
- 30 % for the quality and safety of the facility; and
- 30 % for patient-centered service.

All individual measures are based on best practices as defined by published clinical data (i.e., evidence-based literature) or community standards established nationally and/or local standards of best practices and packaged so that they are understandable to consumers and other purchasers.

Name of Provider:

Please list or attach list of centers for which you are requesting preferred status.

Part I:
Professional Services (40% of overall rating)

NOTE: The following components should be reported for the provider-company level rather than at each, individual imaging facility.

1. *What percent of the total number of radiologists who sign reports for the Provider named above, have been fellowship trained in radiology?* _____%

   Please report the source used to calculate this percentage:*

   _____

[Rating is percentage of total number of radiologists, who sign reports for the imaging provider, who are fellowship-trained (10 points if at 100%; 9 points if at 90%, etc.) Evidence: A national and local standard: Fellowship programs have been recognized to add interpretation proficiency.]

2. *What percent of the total number of radiologists, who sign reports for the provider, have a report volume that is at least two-thirds in the area of their subspecialty?* _____%

   Please report the source used to calculate this percentage:*

   _____

[10 points if 100% of the provider's signing-radiologists meet the two-thirds standard; 9 points if 90% meet the standard, etc. *Evidence: A national and local standard: Sub-specialization by body part and/or modality has been recognized to add interpretation proficiency].*

*Source data must be available for review by Preferred One for verification.

3. *a) Do all the radiologists who sign reports for this provider, actively participate in a peer review program that is ongoing, with participation on a weekly basis and which includes some outside-of-practice reviewers?*

   ☐ Yes ☐ No

   b) Are all the physicians who supervise tests for this provider certified in Advanced Cardiac Life Support?

   ☐ Yes ☐ No

[5 points for each if answer is yes; 0 points if no. Evidence: Both are best practices standard of AMA and physician specialty professional associations.]

4. *a) What activities are underway by the provider that demonstrate a formal effort to identify and participate in community or national development of best practices such as collecting outcomes measures (e.g., clinical trials, data tracking analysis, community measurement activities, etc.)?*

   Please attach a one page or shorter description of each activity and identify the contact physician for that activity.

   b) Do you have a formal program for annually surveying or otherwise measuring referring physician satisfaction?

   If so, please attach survey instrument and results of last survey.

[a) Preferred One will designate 1 point (up to 5 total) for relevant activities. (b) 5 points if in place. Evidence: A local standard for collaboratively working to foster best practices throughout the health care delivery system.]

Part II:
Quality and Safety of Facility (30% of [illegible])

NOTE: The following components are measured at the individual imaging facility.

5. *What percentage of technicians, including "float" staff, who are assigned to MRI, CT and/or PET/CT services are certified by the American Registry of Radiologic Technologists?*

   _____%

   Please tell us the source used to calculate this percentage:* _____

[8 points if 100% of the facility's technologists are ARRT certified, including "float" technologists; 7 points if 90% or higher; 5 points if 80% or higher; 4 points if at 70% or higher; 3 points if at 60% or higher; 0 points if lower than 60%. Evidence: A national and local standard of best practice.]

6. *Is each of your MRI, CT and PET/CT scanners accredited by a nationally recognized body such as the American College of Radiology or Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories?*

☐ Yes ☐ No

If not, what percentage of your total advanced imaging equipment is accredited by ACR or ICANML?

_____%

[8 points if fully accredited; 3 points if accredited in two or more modalities. Evidence: A national standard based on evidence of consistent quality images because of better maintained/calibrated equipment; also some evidence of consistent, integrated safety processes.]

7. *Please list your advanced imaging equipment (MRI, CT and PET/CT) and give the age and strength of it:*

Please report the source used to tabulate the average number of tests by modality:*

_____

[1 point for each modality (up to 6) at the facility that is actively used. Evidence: A local standard in other parts of the nation and it other developed countries. Proponents of this standard point to the convenience for the patient if the type of scan originally ordered needs to be changed ("right test"); the efficiencies of the operations in terms of physician oversight and administration; and demonstration of imaging expertise by those operating multi-modality centers.]

*Source data must be available for review by Preferred One for verification.

[1 point, up to 5 points total, for each MRI, CT or PET/CT machine whose original bill of sale is 5 years or less or if there is evidence of retrofitting of the machine within the last 12 months; 1 point, up to 2, for each CT that is a 4-detector or more; 1 point, up to 2, for each MRI that is 1.0 Tesla or greater. Evidence: Unfortunately, there has been great resistance to upholding a national or local standard for equipment age and strength. Additionally, Preferred One does not desire to promote excessive expenditures of imaging equipment. However, there is peer-reviewed evidence that older machines cannot maintain calibration and may produce images of inconsistent quality unless appropriately upgraded to manufacturer's specifications. Further, there are safety concerns for the density of radiation for single slice CT scanners and evidence of poorer quality images on lower strength MRI scanners. Preferred One is maintaining the above standard to assure that the right test is done right the first time and that no enrollee is exposed to unnecessary radiation or experiences a mis-diagnosis because of the quality of the equipment used.]

8. *Please list the types of imaging equipment (i.e., modality/scanners) that are in use at this facility for at least 10 tests per week, on average, for the last calendar quarter:*

*Source data must be available for review by Preferred One for verification.

Part III:
Patient-Centered Service (30% of overall rating)

NOTE: The following components are measured at the provider-company level rather than at each, individual imaging facility.

9. *Has this provider measured the patient satisfaction of its services through a formal survey process?*

☐ Yes ☐ No

Please attach the survey instrument and most recent results.

[5 points if there has been at least 4 consecutive quarters (one year) of consumer satisfaction surveys undertaken by the imaging provider (note: Preferred One does not require a specific survey tool at this time but this measure may use the Clinical CAPP's survey when available). Evidence: Measuring patient satisfaction is a national standard, as evidenced by the continued work on an outpatient CAPP's survey; other evidence is found in the series of Institute of Medicine papers entitled "Crossing the Quality Chasm."]

10. *Measured by working day (i.e., days when facility is open), what is the turn around time (TAT) from when the patient presents for the test until the signed report is delivered to the treating physician?*

TAT Score: _____
Please report the source used to tabulate the average TAT:* _____

[5 points if 80% of reports have a TAT of one working day or less. Evidence: A delayed diagnosis is not best practice.]

11. *Are the electronic reports and images available and readily accessible to treating physicians?*

___*Diagnostic Reports*
___*Diagnostic Images*

[5 points if reports are available electronically; 5 points if images are available. Evidence: There is a definitive national and local standard that computerized images are superior to film. Additionally, making diagnostic reports and images readily accessible, electronically, for treating physicians offers more ***timely*** *and* ***efficient*** *service, as outlined by the IOM components of quality.]*

*Source data must be available for review by Preferred One for verification.

12. Do you have a formal and active safety program in place?

☐ Yes ☐ No

If yes, please describe:

13. *Are your safety records open for confidential audit by Preferred One?*

☐ Yes ☐ No

[10 points for JCAHO Accreditation (demonstrates a formal process in place); or 2 points for each consecutive year (limit 5 years) of formal records maintained, by the imaging provider, that verify safety audits, which included assessing and reporting to a governing board, of physical incidents or injuries such as falls; medical incidents; and contrast or injection incidents. Evidence: There is a definitive national and local standard for safety assessment and reporting as indicated by recent state disclosure legislation, Leapfrog initiatives and peer-reviewed literature.]

Part IV:
Indicators of interest for comparison, but not measurement

(please attach additional information, as appropriate):

14. *Do you employ an electronic decision support tool that is based on evidenced based ordering guidelines?*

☐ Yes ☐ No

15. *What was the average number of continuing medical education (CME) credits your radiologists acquired last year?*

_____

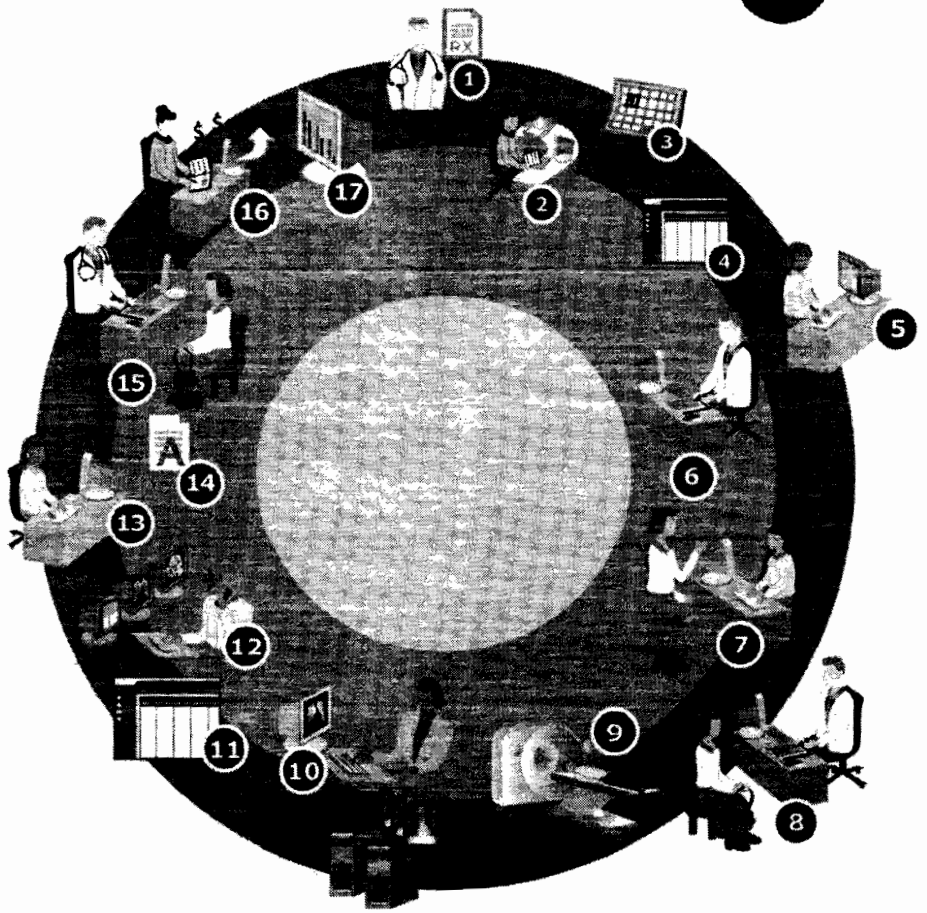
16. *How do you prepare your patients for their advanced diagnostic test (i.e., education; diet restrictions, allergy check, etc.)?*

APPENDIX D

CENTER FOR
DIAGNOSTIC IMAGING

CDI

Our solutions manage all critical workflow tools – RIS, PACS, Dictation, Document Management, Billing and Analysis to integrate, streamline, and automate workflow.

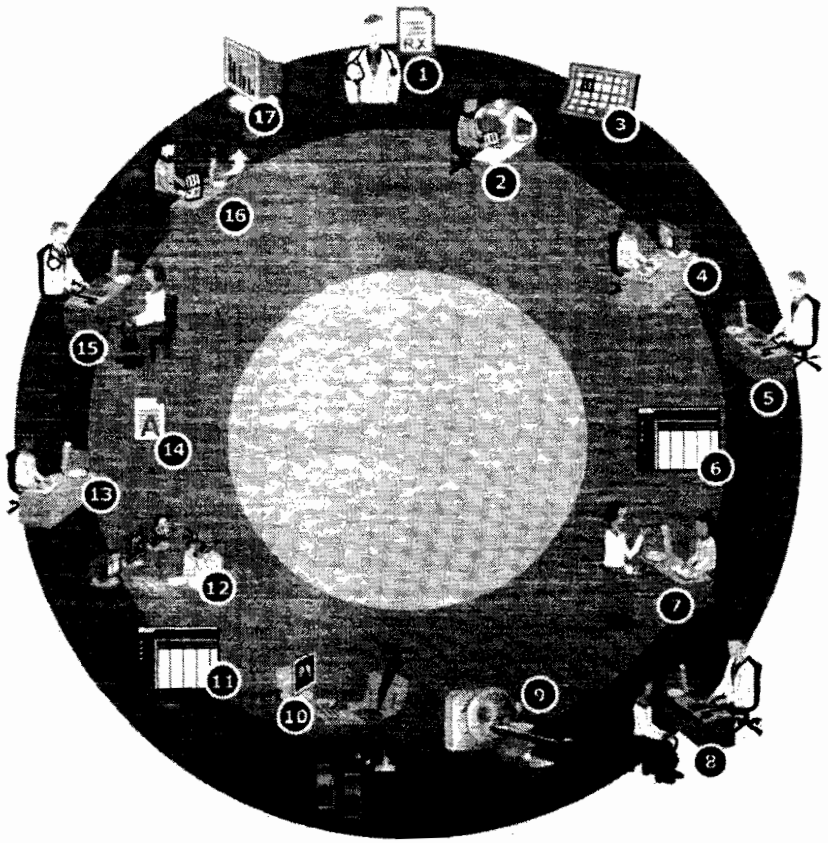


Electronic Business and Clinical Workflow of an IDTF/Radiologist Practice Center

CENTER FOR DIAGNOSTIC IMAGING

CDI

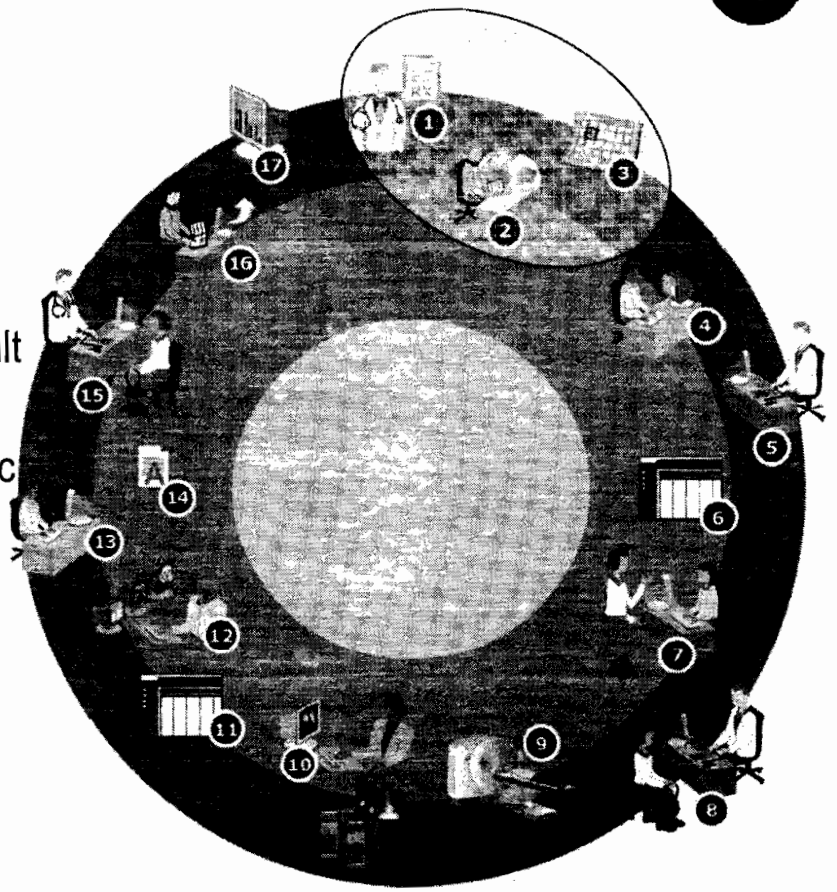
1. Imaging Order arrives from referring physician, sometimes using integrated, electronic "decision support tool" (or using designated 800# to call radiologist to consult on most appropriate test);
2. Request is registered within CDI's electronic system, with an electronic submission to health plan for prior authorization, as required;
3. Exam is scheduled and confirmed;
4. Technologist or nurse reviews upcoming appointments for special needs of specific patients. For many procedures, patients will be contacted by the nurse or technologist to assure compliance with pre-scan requirements or to obtain more clinical information, as appropriate.
5. Supervising radiologist reviews protocols to be used for each patient on next days' schedule. In about 5% of scheduled exams, this review will require contact with referring physician to clarify or obtain information or to recommend alternative testing or treatment protocol.
6. Patient name and clinical demographics are electronically integrated to modality to improve patient safety; the same information appears on technologist electronic worklist;
7. Patient arrives for exam or procedure and information in electronic system is verified.
8. Exam or procedure is explained again to patient, by the radiologist, nurse or technologist, depending on the specific service to be performed;
9. Exam or procedure is performed;
10. Images are viewed at modality on computerized screen;
11. Diagnostic Only: Images are distributed to radiologists' electronic worklist based on their sub-specialty;
12. Diagnostic Only: Associated images and priors are launched in PACS and images are interpreted and dictated by sub-specialized radiologist;
13. Report gets electronically transcribed then goes to radiologist's pending signature worklist;
14. Radiologist signs off on report via electronic signature;
15. Final report and diagnostic images are distributed to the referring physician, often via secured, electronic portal;
16. Exam is coded and billed by electronic transmittal when possible;
17. Practice Analysis takes place.



CENTER FOR
DIAGNOSTIC IMAGING

CDI

1. Imaging order arrives from referring physician, sometimes using integrated, electronic "decision support tool" (or using designated 800# to call radiologist to consult on most appropriate test);
2. Request is registered within CDI's electronic system, possibly with an electronic submission to health plan for prior authorization, as required
3. Exam is scheduled and confirmed;



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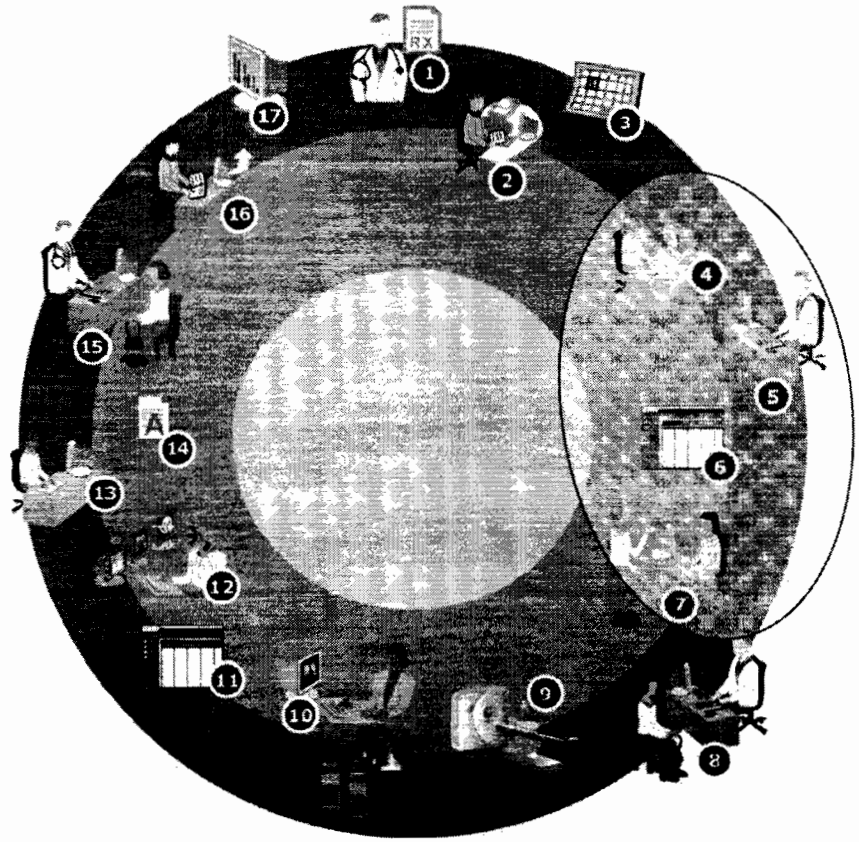
CDI

4. Technologist or nurse reviews upcoming appointments for special needs of specific patients. For many procedures, patients will be contacted by the nurse or technologist to assure compliance with pre-scan requirements or to obtain more clinical information, as appropriate.
5. Supervising radiologist reviews protocols to be used for each patient on next days' schedule. In about 5% of scheduled exams, this review will require contact with referring physician to clarify or obtain information or to recommend alternative testing or treatment protocol.
6. Patient name and clinical demographics are electronically integrated to modality to improve patient safety; the same information appears on technologist electronic worklist.
7. Patient arrives for exam or procedure and information in electronic system is verified.



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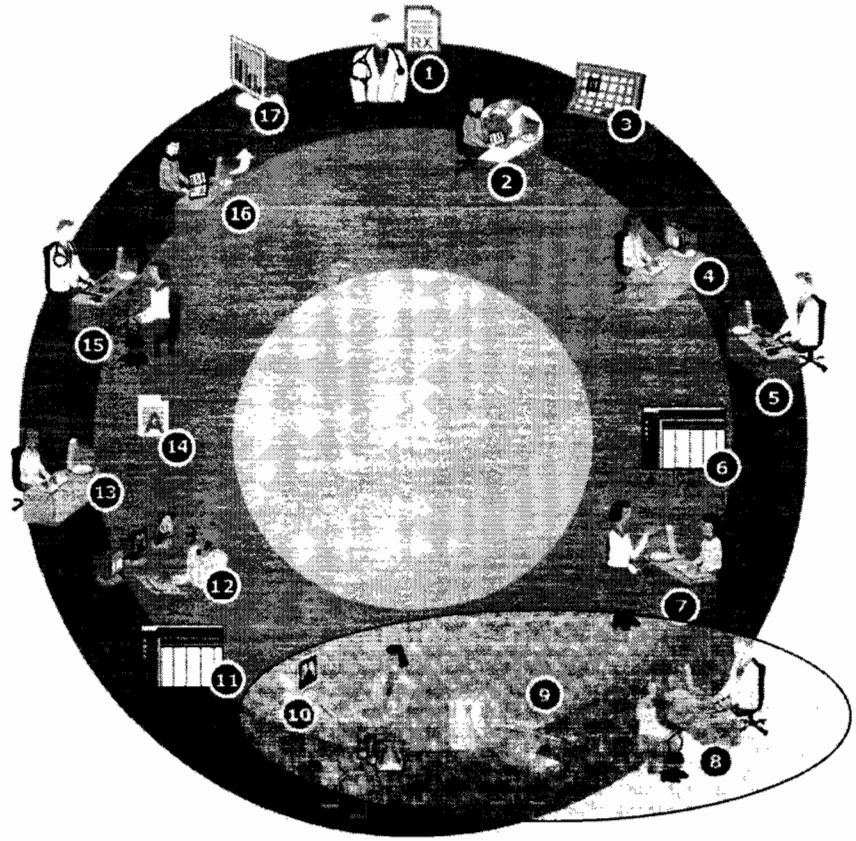
8. Exam or procedure is explained again to patient, by the radiologist, nurse or technologist, depending on the specific service to be performed;
9. Exam or procedure is performed;
10. Images are viewed at modality on computerized screen;



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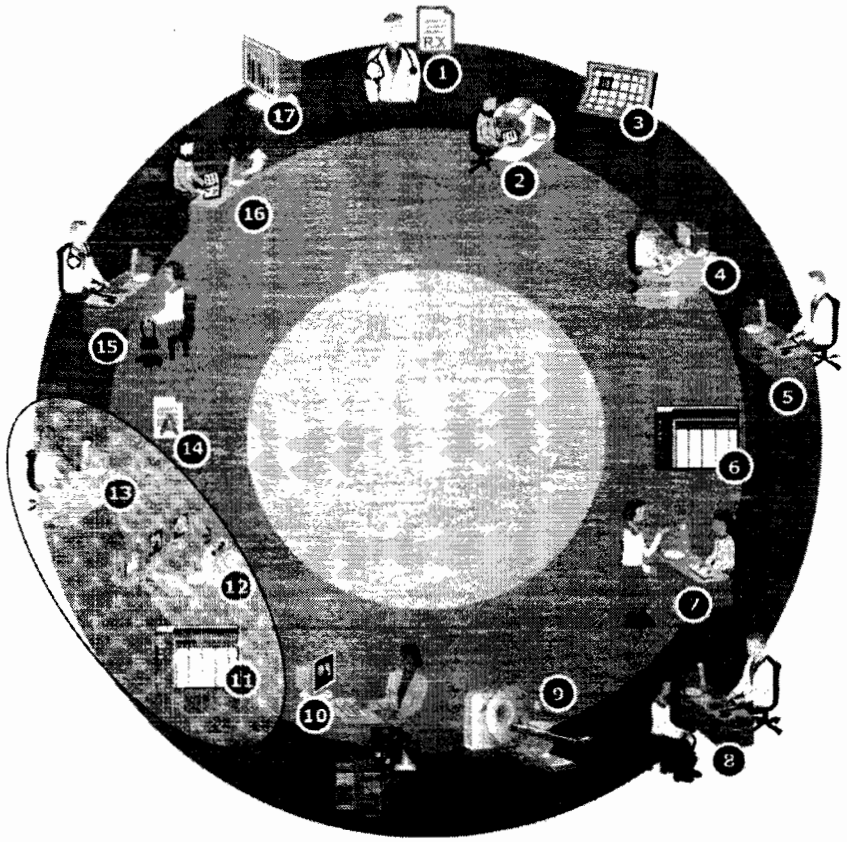
11. Diagnostic Only: images are distributed to radiologists' electronic worklist based on their sub-specialty;
12. Diagnostic Only: Associated images and priors are launched in PACS and images are interpreted and dictated by sub-specialized radiologist;
13. Report gets electronically transcribed then goes to radiologist's pending signature worklist;



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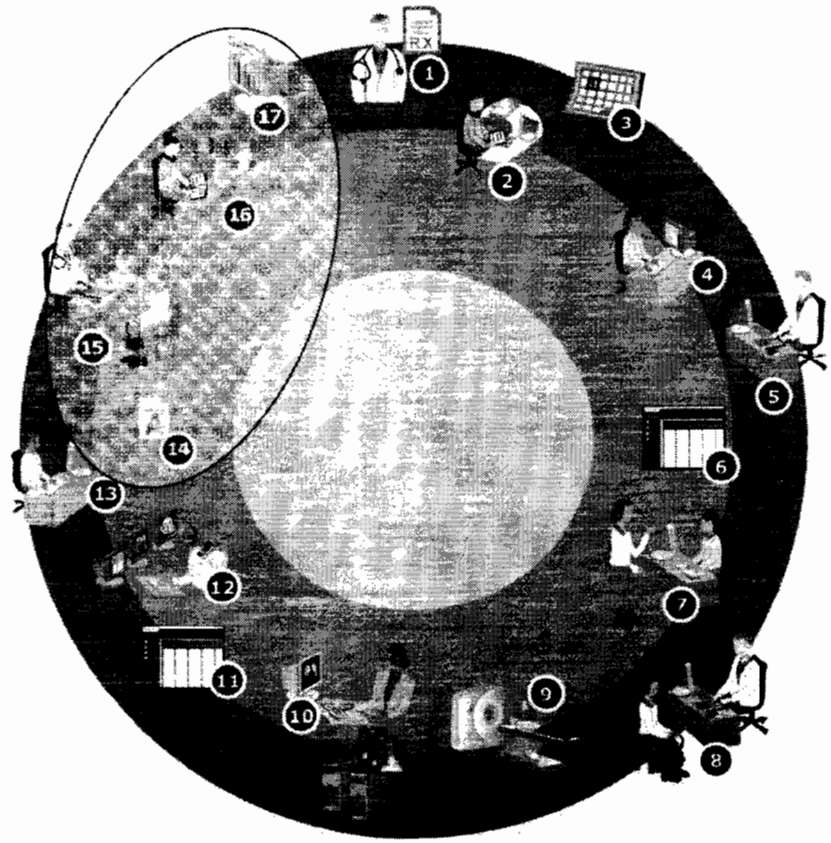
DIAGNOSTIC IMAGING

CDI

14. Radiologist signs off on report via electronic signature;
15. Final report and diagnostic images are distributed to the referring physician, often via secured, electronic portal;
16. Exam is coded and billed by electronic transmittal when possible;
17. Practice Analysis takes place.



Submitter : Mr. Seth Axelrad **Date:** 08/31/2007

Organization : Concerned Pathologists

Category : Health Care Professional or Association

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please see attachments

CMS-1385-P-15374-Attach-1.DOC

CMS-1385-P-15374-Attach-2.DOC

15674

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FOUNDED 1866

August 31, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

Dear CMS:

Concerned Pathologists appreciate this opportunity to comment on the Proposed Rule (CMS-1385-P) published in the Jul. 12, 2007 Federal Register (72 Fed. Reg. 38122). On behalf of Concerned Pathologists, please accept the following comments regarding physician self-referral issues.

Sincerely,

Seth A. Axelrad

CMS-1385-P
PHYSICIAN SELF-REFERRAL PROVISIONS

Concerned pathologists submit these comments in response to the amendments proposed by the Centers for Medicare & Medicaid Services ("CMS") to the reassignment and physician self-referral rules relating to diagnostic tests.[1] We commend CMS for addressing the problems associated with self-referral arrangements involving pathology services. We are concerned, however, that the proposed rule does not sufficiently distinguish between abusive arrangements involving referring physicians and non-abusive arrangements in which referring physicians are not involved.

In particular, CMS in its rules needs to walk a fine line that avoids imposing burdensome requirements on independent laboratories and pathology practices on the one hand, while prohibiting any "mark-up" or profiteering by certain practices that are attempting to capture the "profits" from pathology testing results ordered by members of the practice.

Protecting Non-Abusive Pathology Practices

With respect to regulatory language protecting non-abusive pathology arrangements, the proposed rule (42 C.F.R. § 484.80(d)(3)) purports to apply to physicians or medical groups that bill for the technical or professional component of a diagnostic test. It would appear that CMS used that language to distinguish between independent laboratories (to which the provision would not apply) and ordering physician practices (to which the rule would apply). However, the language of the rule would appear to cover a pathology practice that operates as a physician group providing both the professional and technical components of pathology services.

The issue raised by the potential application of the rule to a pathology practice is the nature of relationships between the pathology practice and histotechs. Depending on the nature of market conditions in various parts of the country, some pathology practices operate a CLIA-Certified Histolab that needs to obtain services from part-time histotechs (who are either employed or independent contractors). We do not think there is any reason to apply an anti-mark-up provision to pathology practices without regard to the arrangements the practice may have with its histotechs.

As you know, pathologists generally do not order the pathology tests that they and their histotechs perform. Thus, there is no reason to impose any limitations on the arrangements that a pathology practice may have with its histotechs or the manner in which it provides either the technical or the professional component of anatomic pathology services.

In order to eliminate potential confusion under the proposed rule, we recommend that CMS make clear that the limitations on charges to the Medicare program set forth in 42 C.F.R. § 424.80 not apply to either independent laboratories or pathology practices that may perform pathology tests. The exclusion applicable to pathology practices could

[1] 72 Fed. Reg. 38122 (July 12, 2007).

either expressly name pathology practices, or apply to any physician practice performing diagnostic tests which were not ordered by a member of the billing physician practice.

Addressing Abusive Self-Referral Arrangements

As CMS has recognized in its recent proposed rule-making, the real concern is to limit or eliminate abusive self-referral arrangements. In recent years, a number of specialties that order a significant number of pathology tests have attempted to set up creative ways to profit from their referrals. The specialties most active in this area include GIs, Urologists and Dermatologists. Initially, many of these arrangements involved pod labs and other abusive arrangements. The concern, however, is that whatever rules CMS may establish, creative practices motivated by the financial lure of profiting from self-referrals will find a way to structure an arrangement that fits a loophole in the rule.

We are concerned that CMS's most recent proposed rule still has a significant loophole. We agree that CMS's proposed approach of eliminating the "profit" element to ordering physicians is the correct way to address the issue. We also agree that limiting the ability of a practice to "mark-up" tests to arrangements where all of the services are performed by full-time employees of the billing practice is a promising way to address this issue. On the basis of CMS's discussion on pages 38179-38180 of the Preamble, it appears that CMS intends for its rule to prohibit any mark-up of the technical component by an ordering practice that purchases the technical component from part-time histotechs.

Unfortunately, however, we do not believe that the proposed rule will accomplish CMS's objective. In particular, the language of 42 C.F.R. § 424.80 applies to "re-assignments." However, if a GI practice maintains a CLIA-certified laboratory that is staffed by part-time independent contractor histotechs, it is not clear to us that there is any "re-assignment" necessary for the practice to bill for the technical component. The practice likely will bill under the CLIA number of its histotech lab, notwithstanding the fact that the lab is staffed by part-time independent contractor histotechs and headed by a part-time independent contractor medical director. It is not clear to us that the language will do anything to stop a practice with a CLIA number from marking-up and profiting from the technical component of pathology tests.

We suggest that CMS consider a two-pronged approach to addressing the problem. First, CMS should attempt to define the scope of the rule. At least initially, we propose limiting the scope to certain practices in specialties (GI, Dermatology and Urology) that order a significant number of pathology tests. While the problem could also exist with certain multi-specialty group practice, it is difficult to define which multi-specialty group practices are concerns. Thus, starting with single specialty practices in the areas of concern would be a good first step. CMS could subsequently broaden coverage to the extent that new abusive arrangements develop.

Another approach would seek to define practices to which the rule would apply on the basis of other objective criteria. For example, the rule could apply to a group practice

billing for pathology services where at least 75% of the members of the group practice are from a single non-pathology specialty and where at least 75% of the pathology services billed by the group practice were ordered by members of the group practice. Such a definition should cover most of the abusive arrangements that have developed in recent years.

After defining the practices to which the rules applied, we recommend imposing a broad prohibition on mark-up or profiting from pathology tests ordered by members of the group. The prohibition should apply without regard to whether the histotechs and pathologists performing the pathology services billed by the practice are full-time or part-time, employees or independent contractors. If a practice within the defined coverage billed for pathology services, the referring physicians should be prohibited from profiting from pathology services.

A prohibition on profiting could be accomplished by prohibiting any mark-up over the direct costs incurred by the group practice in providing such services. Direct costs would be defined to be limited to the compensation paid to the persons providing the services and the cost of equipment and supplies utilized in performing the services. If GIs, Dermatologists and Urologists could not profit from the pathology tests that they order, there should not be an economic incentive to over-utilize.

Another alternative is to amend the Stark regulations to preclude referring physicians from profiting from pathology tests. One option is to add a new prong to the definition of "group practice" set forth in 42 C.F.R. § 411.352(j). This new prong should ensure that referring physicians within a group practice cannot profit from Medicare payments for pathology services performed within the group practice. Possible language to accomplish this is as follows:

> (j) *Special rule for allocating profits derived from pathology services.* Notwithstanding § 411.352(i), in a group practice composed of (1) Gastroenterologists, Urologists and/or Dermatologists who comprise at least seventy-five percent of the physicians in the group and (2) one or more Pathologists in the group who provide pathology services for the other members of the group practice, all of the revenues derived from pathology services shall be used exclusively to pay for the direct costs of the professional and technical components of pathology services and compensation of the histotechs and physicians performing or supervising these services, except that pathology may be asked to make a contribution to the overhead of the practice that does not exceed, as a percentage of net revenues, the percentage contribution to overhead made from revenues of the other specialties.

The intent of the foregoing is to establish, as part of the regulatory requirements for a qualifying group practice, a prohibition on the referring specialties profiting from the services of pathology to which those physicians refer. Referring physicians should not be able to avoid a prohibition on profiting from referrals by hiring at cut-rate prices professionals to perform services ordered by members of the group practice. Note once again that we are proposing limiting the application of the rule to those specialties which have been most prominently identified as involved in pod labs and other similar financial

arrangements providing them with a financial incentive for their referrals of pathology specimens.

Conclusion

We appreciate this opportunity to comment on CMS's proposed rules. While we commend CMS for taking a strong first step towards addressing the problems of pathology self-referrals, we respectfully request that CMS refine its proposed rule to address the concerns expressed in these comments.

Submitter : **Alan Peterson** **Date: 08/31/2007**

Organization : **NASL**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

NASL Comments Attached

CMS-1385-P-15375-Attach-1.DOC

15375

NASL Insight • Advocacy • Action

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS — 1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

RE: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule (CMS-1385-P)

Dear Mr. Kuhn:

The National Association for the Support of Long Term Care (NASL) is a trade association representing providers of both ancillary services and products to the long-term care industry. Our member companies provide speech-language pathology; physical, occupational and respiratory therapy; portable x-ray/EKG and ultrasound; pharmacy; long term care (LTC) software systems; and other ancillary services. NASL members also provide products such as complex medical equipment; parenteral and enteral supplies, equipment and nutrients; and additional specialized supplies for post-acute care settings nationally.

NASL is pleased to submit comments on the proposed rule described above. Since these issues are all of critical importance to our members and the Medicare patients they serve, we presenting our comments to address the following provisions as they appear in the proposed rule:

- Independent Diagnostic Testing Facility (IDTF) Issues
- Update to Fee Schedules for Class III DME for 2007 and 2008
- Therapy Standards and Requirements
- Proposed Elimination of the Exemption for Computer-Generated Facsimile Transmission From the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard for Transmitting Prescription and Certain Prescription Related Information for Part D Eligible Individuals
- Physician Quality Reporting Initiative (PQRI)
- Extension of Therapy Cap Exception Program
- General comments regarding proposed reduction in CY PFS Update

NATIONAL ASSOCIATION FOR THE SUPPORT OF LONG TERM CARE
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WWW.NASL.ORG

IDTF ISSUES

CMS Should Revise Proposed Documentation Requirement on IDTF Performance Standards

NASL associates itself with and supports the comments by HealthTrac on the proposed IDTF provisions. We also offer the following comments on these provisions:

Section 410.33(g)(8) of the proposed rule would require Independent Diagnostic Testing Facilities (IDTFs) to document and maintain records of all beneficiary questions and complaints and responses to those complaints and inquiries. While the proposed rule suggests that this provision would simply correct an oversight in the performance standards, it would impose a significant new regulatory burden on IDTFs.

In the Paperwork Reduction Act (PRA) filing at the end of the proposed rule, the agency estimates that the adoption of this provision would impose an estimated annual reporting and recordkeeping burden of 1 million hours. This requirement would add new administrative costs without improving patient care. In fact, it could reduce patient care by forcing IDTFs to spend 1 million hours in staff resources summarizing and maintaining files of all patient questions rather than assisting those patients.

CMS states that this requirement is modeled after the standard imposed on DMEPOS. It is our understanding that DMEPOS are not required to documents billing questions. Since many of the beneficiary questions received by IDTFs relate to routine billing question, we recommend clarification to specifically state that this standard relates to the provision of service complaints. Clarification of this requirement would help avoid unnecessary regulatory burden on small business entities and further accountability could be achieved without imposing such a sweeping new recordkeeping requirement on IDTFs.

DME UPDATE

NASL Supports the Proposed Update for Class III DME

NASL supports the proposed update for Class III DME based upon the CPI-U.

THERAPY STANDARDS AND REQUIREMENTS

NASL Generally Supports Proposed Changes Although Clarification is Necessary

a. Revisions to Personnel Qualification Standards for Therapy Services

NASL generally supports the proposal to update the personnel qualifications in Sec 484.4 for occupational therapists (OTs), physical therapists (PTs), speech-language pathologists (SLPs), occupational therapy assistants (OTAs) and physical therapy assistants (PTAs). Current regulations contain outdated terminology relating to these health care professions. However, we wish to comment and seek clarification on several specific provisions within the proposed rule.

With respect to the proposed broadened use of grandfathering clauses, CMS states, "we propose to revise our requirements to recognize PTs, OTs, PTAs and OTAs who meet their respective State qualifications before January 1, 2008." However, in the paragraphs describing the proposed qualifications for OTs and OTAs we note a specific reference to a January 1, 2008 date, while there is no such reference for the paragraphs related to PTs or PTAs. NASL recommends that the reference dates be consistent.

In the section relating to qualifications for PTs, we note that CMS proposes that "the therapist must be licensed as a physical therapist by the State in which practicing and accredited by the Commission on Accreditation in Physical Therapy (CAPTE) based on American Physical Therapy Association (APTA) guidelines. When licensure requirement is not applicable (that is, for services furnished incident to the services of physicians and NPPs), we propose to require that PTs must have been accredited by the CAPTE." It is our understanding is that the CAPTE accredits educational programs rather than individuals, so there is some confusion regarding why CMS would propose to have individual therapists accredited by the CAPTE. The same comment would apply to proposed qualifications for PTAs with respect to the CAPTE.

There are very specific proposed qualifications for OTs and OTAs educated outside the United States or by the U.S. Military. There are no such proposed qualifications for PTs or PTAs, and we believe there should be similar proposals tailored for PTs and PTAs related to: 1) educational curriculum accreditation; 2) eligibility criteria; and 3) successful completion of a standardized certification examination.

b. Application of Consistent Therapy Standards

NASL agrees with the agency's intent to unify the therapy standards and policies across all settings. However, as CMS notes in the rule, this should be done *"to the extent possible"* and that *"many, but not all"* outpatient therapy standards are appropriate in inpatient settings. It is important to note that major differences exist among therapy settings due to regulations governing payment. Outpatient settings are paid under the Medicare Physician Fee Schedule while institutional settings are paid under DRGs or PPS, and many settings are burdened with consolidated billing requirements.

NASL requests the opportunity for stakeholder organizations to discuss the specific changes that CMS believes should apply across settings prior to implementation. Provider organizations can provide additional insight regarding the effect these proposed changes could have on patient care and access to services.

NASL supports the use of qualified personnel in the provision of physical therapy, occupational therapy, & speech-language pathology services. With that consideration, NASL also recognizes that implementation of many of the standards that apply to services provided to Medicare B beneficiaries could necessitate significant changes for providers. It is important to consider and address the impact of the changes on the different providers and the ability of patients to have access to quality care prior to implementation.

NASL also urges CMS to clarify supervision requirements as they relate to students. We recommend that student services provided under clinically appropriate supervision be considered for payment across all settings, including settings in which Medicare Part B beneficiaries receive care. This is critical to ensuring that future therapists will understand and effectively document treatment provided to Medicare beneficiaries.

c. Outpatient Therapy Certification Requirements

NASL supports the proposed changes regarding outpatient therapy certification requirements.

TRHCA—SECTION 101(b): PQRI

NASL Supports the Inclusion of SNF-Based Reporting Data

NASL has been disappointed with the agency's implementation of the Physician Quality Reporting Program (PQRI) in 2007 because it excluded eligible professionals providing covered therapy services to Medicare Part B beneficiaries in inpatient settings (i.e. SNFs, Rehab Agencies, outpatient HH) from participating in the program. The Tax Relief and Health Care Act of 2006 (TRHCA) specifically defined physical therapists, occupational therapists and qualified speech-language pathologists as eligible professionals, but those therapists providing care to some of the most medically complex Medicare patients are unable to report for two reasons: (1) the claims format does not allow providers in these settings to report the information to CMS – even though these professionals are providing interventions that currently qualify for PQRI (specifically the Falls screening), and (2) no measures have been approved for SLPs, which effectively blocks them out of the entire program.

Although NASL and others have recommended ways in which SNF-based quality reporting data could be collected, the PQRI program for 2008, as outlined in the proposed rule, would continue the exclusion of reporting from institutional settings. We believe that the restrictive means of quality reporting adopted by CMS undermines the validity of the therapy data that are being reported.

Nothing in either the TRHCA or supporting legislative history suggests that Congress intended for a significant segment of professional Medicare Part B therapy services to be excluded. In fact, the success of the CMS value-based purchasing enterprise initiative depends upon gathering meaningful data from the entire spectrum of eligible professionals practicing in all settings. Therefore, NASL recommends further implementation of the PQRI be delayed until CMS adopts a reporting mechanism that applies to all eligible professionals in all settings as outlined in the statute.

While NASL has serious concerns about the current state of the PQRI program, we are encouraged by the agency's proposal to evaluate and test mechanisms for registry-based reporting. We believe that the adoption of registry reporting could help alleviate the inequities that exist today. NASL also encourages CMS and its contractors (NQF & other consensus based groups) to adopt PQRI measures that are inclusive of all professionals outlined in the statute.

PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

NASL Supports Proposal with Two Exceptions

On November 7, 2005, CMS issued a final rule requiring the use of the NCPDP SCRIPT Standard transaction format among Medicare providers, suppliers, pharmacies, and Part D Plan Sponsors using an E-Prescribing system for filling Medicare Part D prescriptions.[1] This rule included an exemption for computer-generated faxes that is currently codified at 42 C.F.R. § 423.160(a)(3)(i).

On July 12, 2007, CMS proposed removing the computer-generated fax exemption from 42 C.F.R. § 423.160(a), requesting comments by August 31, 2007.[2]

As NASL understands it, the proposed rule would not require any entity to adopt an e-prescribing system. Rather, the proposed rule would prohibit prescribers who transmit prescriptions via "electronic media"[3]—which includes computer-generated faxes[4]— from transmitting prescriptions directly from a computer to a receiving party's facsimile (fax) machine, whether the receiving fax equipment is a dedicated machine that physically prints the prescription or is a computer or other system that receives it completely electronically.[5]

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[1] 70 Fed. Reg. 67568 (Nov. 7, 2005).
[2] 72 Fed. Reg. 38121, 38194–38196 (July 12, 2007).
[3] See 42 C.F.R. 423.159.
[4] 72 Fed. Reg. at 38195.
[5] See 72 Fed. Reg. at 38195.

Although the proposed rule and its predecessors discourage the use of paper faxes when e-prescribing systems are available,[6] removing the 423.160(a)(3)(i) exemption would not necessarily prohibit an entity currently using computer-generated faxes from typing a prescription on a computer, printing it, and then sending it via conventional fax machine to a recipient.[7] However, as the proposed rule noted, this would reduce, rather than increase, the efficiency of the prescription process as a result of wider implementation of e-prescribing standards.

As CMS has explained, the computer-generated fax exemption was designed to help providers and dispensers already using e-prescribing technology (or technology capable of being adapted to meet e-prescribing requirements) to transition from paper through computer-generated faxes to a true NCPDP SCRIPT-compliant e-prescribing system.[8]

NASL strongly supports the movement to e-prescribing systems due to the documented efficiencies, cost savings, reduced risk of adverse drug events, and fewer pharmacy "call backs" related to illegible or failed delivery of faxes. E-prescribing has the potential to significantly improve quality of care and already has provided tangible benefits to patients and providers. In the November 7, 2005 e-prescribing final rule, CMS recognized the differences between the long-term care and ambulatory settings and exempted the long-term care setting.

Our members are committed to facilitating the adoption of e-prescribing standards and practices in all health care settings, including long-term care. Our efforts are focused on ensuring that the SCRIPT standard is able to meet long-term care needs so that e-prescribing can be adopted and implemented in the long-term care setting by August 2009, the expected completion date of the final long-term care electronic health record certification by the Certification Commission for Health Information Technology (CCHIT). It is important for the long-term care industry to adopt e-prescribing following the CCHIT roadmap and not be hindered by regulations counter to the certification process.

Notwithstanding NASL's unwavering support for widespread implementation of e-prescribing, we recognize that there are two areas of pharmacy practice that render complete removal of the computer-generated fax exemption problematic. For this reason, NASL proposes the retention of the exemption in two narrow circumstances. NASL believes that its recommendations, as outlined below, would achieve CMS's goal of encouraging prescribers and dispensers to move toward the SCRIPT standard, while also preserving the ability of small independent pharmacies to continue to serve patients and allowing strict adherence to federal law regarding the prescribing of controlled substances.

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[6] See generally 70 Fed. Reg. 6256, 6260 (Feb. 4, 2005); 70 Fed. Reg. 67568, 67571 (Nov. 7, 2005); 72 Fed. Reg. at 38194–38196.

[7] See 70 Fed. Reg. at 67571, 67590.

[8] *See* 70 Fed. Reg. at 67571, 67584, 67592.

1) Computer-generated faxes should be permitted when transmitting to pharmacies and facilities without e-prescribing capabilities.

As CMS acknowledges, approximately 80 percent of independently owned pharmacies do not have an e-prescribing system in place because the perceived return on investment is so low for them.[9] Although the current exemption allows providers to send computer-generated faxes to these pharmacies, if the exemption were entirely removed, providers would be required to print and then manually fax the prescriptions to such pharmacies, fund such pharmacies' use and implementation of e-prescribing systems, or stop doing business with those pharmacies altogether. This could result in substantial losses for some pharmacies and is likely to cause disruptions in care delivery in areas where independent pharmacies are more prevalent than other kinds of pharmacies.

NASL respectfully suggests that CMS allow prescribers and facilities to transmit prescription orders via computer-generated fax to pharmacies that do not use systems that are able to, or are capable of being modified to, receive SCRIPT transactions especially the SCRIPT standard modified for the long-term care setting. This would strike a proper balance between increasing the utilization of available technology by entities that already use or plan to use it and recognizing the important role of independent pharmacies and long-term care facilities in delivering health care products and services. It would avoid penalizing providers and beneficiaries for choosing to do business with independent pharmacies or utilizing e-prescribing in the long-term care setting.

2) Computer-generated faxes must be permitted when prescribing controlled substances

It is currently not legal to issue written prescriptions for controlled substances using e-prescribing systems.[10] Schedule II prescriptions are required to be in writing and must be "manually signed" by the prescriber.[11]

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[9] 72 Fed. Reg. at 38195.

[10] See 21 C.F.R. §§ 1306.05, 1306.11, 1306.21. *See also* 71 Fed. Reg. 28052 (May 15, 2006) (announcing a public meeting of the Drug Enforcement Administration to discuss the possibility of modifying DEA regulations to allow e-prescribing of controlled substances).

[11] 21 C.F.R. §§ 1306.05(a), 1306.11(a).

Schedule II controlled substance prescriptions may be transmitted by fax, but the pharmacist must receive an original paper copy of the prescription before dispensing the drug.[12] However, the following exceptions to the original copy requirement are granted: if the Schedule II drug is "to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion"[13], is for a resident of a long-term care facility,[14] or is for a patient in a Medicare-covered hospice program,[15] a copy of the prescription may be transmitted entirely via fax without requiring the pharmacy to obtain an original manually signed copy of the prescription.[16]

Federal law generally allows the transmission by fax of written controlled substance prescriptions for Schedule III, IV, and V substances.[17] Although it is not clear from Drug Enforcement Administration (DEA) controlled substance prescription regulations or written guidance whether such prescriptions must be manually signed,[18] based upon sub-regulatory guidance and a discussion with DEA's Office of Diversion Control, it is assumed for the purposes of this comment that before such prescriptions are faxed, they must be manually signed.[19]

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[12] 21 C.F.R. § 1306.11(a).
[13] 21 C.F.R. § 1306.11(e).
[14] 21 C.F.R. § 1306.11(f).
[15] 21 C.F.R. § 1306.11(g).
[16] *See* 21 C.F.R. § 1306.11(a) (incorporating by reference the exemptions at § 1306.11(e), (f), and (g)).
[17] 21 C.F.R. § 1306.21(a). Although the regulations explicitly permit the exclusive fax transmission of a Schedule III, IV, or V prescription without the need to send an original, manually signed copy of the prescription, a representative of the Washington DC Field Office of the DEA's Office of Diversion Control indicated that DEA requires pharmacies to keep on file original, manually signed copies of all controlled substance prescriptions, regardless of their Schedule.
[18] 21 C.F.R. § 1306.21(a) reads: "A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in §1306.05, except for the signature of the practitioner." If there were a comma after "pharmacist", the inapplicability of the "manually signed" requirement would be more clear.
[19] *See* 21 C.F.R. § 1306.05(a) ("Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner."). Because an oral order for Schedule III, IV, and V substances is permitted by 21 C.F.R. § 1306.21(a), it is arguable that the "manually signed" requirement does not apply, however the prescription must still be signed in some form. See 21 C.F.R. § 1306.21(a). However, according to the DEA's notice of proposed rulemaking with respect to 21 C.F.R. § 1306.21, "All conditions specified under 21 CFR 1306.05 regarding the manner in which a prescription must be prepared shall apply to prescriptions generated via facsimile." 58 Fed. Reg. 49453, 49454 (Sep. 23, 1993). Therefore, it appears that although § 1306.21(a) is less than clear about the "manually signed" requirements as applicable to faxed Schedule III, IV, and V prescriptions, DEA's original intent was to require such prescriptions to be "manually signed" prior to being faxed.

DEA controlled substance prescription regulations do not specifically prohibit a computer-generated fax transmission of a "manually signed" prescription.[20] That is, under the current computer-generated fax exemption and DEA regulations, a prescription that must be "manually signed" could be transmitted via computer-generated fax in a three step process: the prescription is 1) printed from a computer, 2) "manually signed",[21] and 3) scanned back into the computer system, archived, and simultaneously faxed directly from that computer system to the receiving pharmacy.[22]

However, if the computer-generated fax exemption were removed completely, a prescriber or facility that wishes to move toward a paperless environment would be prevented from complying with DEA requirements in the most efficient way possible. Completely removing the exemption would require at least a fourth step to be added to the prescription process outlined above given CMS's current recognition of computer-generated faxes as "electronic media".[23]

That is, instead of 1) printing, 2) signing, and 3) simultaneously scanning and faxing, the prescription would need to be 1) printed, 2) signed, 3) faxed via a conventional fax machine, and then 4) scanned into the records system (if desired). Assuming that a conventional single page fax takes at least one minute to arrange, monitor, and complete, depending upon a prescriber's practice setting, completely removing the exemption could add tens—if not hundreds—of hours per year to a prescriber's prescription processing workflow if the prescriber (or the prescriber's facility) currently uses computer-generated faxes for its controlled substance prescriptions.

Thus, if the e-prescribing exemption were removed, prescribers that use computer-generated faxes to the extent possible for controlled substance prescriptions might, in effect, be penalized for having moved closer to e-prescribing.

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[20] *See* 21 C.F.R. § 1306.11(a) ("A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment"); 21 C.F.R. § 1306.21(a) ("A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V ... only pursuant to ... a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in §1306.05, except for the signature of the practitioner."); 68 Fed. Reg. 37405, 37407 (June 24, 2003) ("a prescription that is generated by a computer software application and subsequently printed is acceptable so long as it is manually signed by the practitioner and contains all required elements of a prescription."). Additionally, a representative of the Washington Field Office of DEA's Office of Diversion Control confirmed that a computer-generated fax of a manually signed prescription would be permissible.

[21] See 68 Fed. Reg. at 37407.

[22] The DEA regulations do not distinguish between a dedicated fax machine or "computer generated" faxes. See 21 C.F.R. §§ 1306.11, 1306.21.

[23] See 72 Fed. Reg. at 38195 ("faxes generated by one computer and electronically transmitted to another computer or fax machine would be included under the e-prescribing definition of electronic media.").

To continue to encourage prescribers to recognize the benefits of moving toward e-prescribing and maximizing the efficiency with which they may comply with DEA requirements, NASL suggests that controlled substance prescriptions should continue to be subject to the computer-generated fax exemption.

NASL respectfully recommends that 42 C.F.R. § 423.160(a)(3)(i) be modified to read as follows (proposed modifications are underlined):

(i) Entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information in cases where—

(A) one of the entities receiving the information is a pharmacy or other facility without the technical capability to receive written prescription-related information by means other than—

(I) facsimile-receiving equipment or services incapable of being used or modified to meet the SCRIPT Standard, or

(II) physical delivery of a paper prescription;

or

(B) State or federal law precludes the use of e-prescribing, other than computer-generated faxes, to transmit the particular prescription(s) or prescription-related information.

TRHCA—SECTION 201: THERAPY CAPS

An Arbitrary Cap on Therapy Services is a Particularly Harsh Policy for Nursing Home Residents

The proposed rule affirms the agency's intention to implement a cap on outpatient therapy services beginning January 1, 2008. We recognize that the agency must adhere to statutory requirements, but that does not change the hardships that would be imposed on Medicare patients if arbitrary caps on outpatient therapy services were put into place.

Provisions of the Tax Relief and Health Care Act of 2006 (TRHCA) extended the clinically-based exceptions process through 2007. If Congress does not act to extend the exceptions process, rehabilitative care for our nation's most frail citizens will be restricted severely with no regard for patient needs.

The therapy cap is a particularly harsh policy for nursing home residents. It only serves to deny access to services for those patients in greatest need. Patients with co-morbidities and medical complications that warrant more extensive treatment would find their care restricted.

For SNFs, Part B-covered therapy services are secondary to Part A coverage. A high percentage of facility admissions are Part A Medicare patients. Approximately three out of four new admissions are in RUG rehabilitation categories. About half of these individuals are discharged within 45 days; for those not discharged, a high proportion become eligible for Medicare Part B therapy services because the intensity of services decrease below the thresholds required for Part A coverage. It is critical to emphasize that for nursing facilities, the volume of Part B therapy services is dependent on the admission and discharge patterns and case mix of the facility. It is clinically difficult (and often impossible) and cost prohibitive for nursing facility residents to avail themselves to the therapy cap's safety valve of outpatient hospital services.

Paired with continual increases in edits from the Correct Coding Initiative (CCI), this makes provision of medically necessary care challenging for skilled nursing rehabilitation providers. Currently under the CCI edits, a Medicare Part B beneficiary in need of multiple therapy services cannot receive care because of mutually exclusive codes that cross the therapies (physical, occupational and speech-language pathology).

CMS should be aggressive in urging the Congress to intervene to alter the current law. To assure rehabilitation services for nursing home residents, CMS should separately address the therapy cap impact for these beneficiaries protecting their access to clinically necessary services.

NASL supports strongly the development of a condition-based payment system as a viable alternative to the arbitrary therapy cap. While that system is being developed, Congress should extend the exceptions process to the therapy caps.

GENERAL COMMENTS

CMS Should Assume Greater Leadership in Preventing a Conversion Factor Cut

If Congress does not pass legislation superseding the proposed rule, the conversion factor under the Physician Fee Schedule (PFS) will be negative 9.9 percent, with additional cuts projected for future years. We cannot emphasize enough the disruptive impact that would come from a reduction of this magnitude in the physician fee schedule.

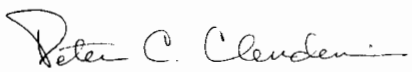
The severe cuts proposed by the rule for 2008 and projected forward are not sustainable, and they would cause irreparable damage to patient access to health care. CMS should assume greater leadership in urging Congress to enact corrective legislation before the end of this year.

Several of the issues outlined in our letter represent recurrent themes. NASL is concerned that many of the successful programs focusing on the most clinically complex and medically needy populations are again being threatened. NASL hopes that these comments will help stimulate CMS to reexamine the impact of its rule-making on special needs populations residing in skilled nursing facilities.

Thank you for your time in considering these comments and suggestions. NASL appreciates the agency's efforts to expand access to the regulatory process to providers and suppliers for the improvement of delivery of quality healthcare to the beneficiaries of the Medicare program.

We welcome the opportunity to work with CMS in resolving the issues contained in this document. Please feel free to contact me directly by telephone at (703) 549-8500, or by e-mail at clendenin@nasl.org with any questions that you may have regarding these comments.

Sincerely,



Peter C. Clendenin
Executive Vice President

Submitter : **Dr. david seamans** **Date: 08/31/2007**

Organization : **mayo clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
David Seamans, MD

Submitter : **Ms. Rebecca Snead** **Date: 08/31/2007**

Organization : **National Alliance of State Pharmacy Associations**

Category : **Other Health Care Professional**

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

attachment

CMS-1385-P-15377-Attach-1.DOC

15377

August 31, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS 1385-P
PO Box 8018
7500 Security Blvd
Baltimore, Maryland 21244-8018

Subject: Proposed Elimination of Exemption for Computer-Generated Facsimiles (Docket no. CMS-1385-P)

[Submitted electronically to www.cms.hss.gov/eRulemaking]

On behalf of the National Alliance of State Pharmacy Associations (NASPA), the national organization representing all fifty state pharmacy associations, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed regulations and revisions (published in the *Federal Register* notice on July 12, 2007 72FR.17559 38122, Docket NO. CMS-1385-P) to proposed elimination of the Exemption for Computer-Generated Facsimile Transmission from the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard for Transmitting Prescription and Certain Prescription Related Information.

Pharmacists are the medication use experts helping patients and communities safely make the best use of medicines to improve health, reduce overall healthcare costs, and prevent the unnecessary costs and suffering of chronic disease. In order to maximize pharmacists' potential as the medication expert, we recognize the importance of a more holistic approach to electronic medical records (EMR) and the role electronic prescribing plays in that evolution. Pharmacists' access to and active participation in the creation and support of the EMR is critical to assure optimal health outcomes.

NASPA is supportive of CMS' desire to facilitate and foster adoption of electronic prescribing and understands the proposed elimination of the Exemption for Computer-Generated Facsimile deadline as an effort to drive adoption. However, systematic and economic investments need to occur to be in compliance and safely implement true electronic prescribing. Given the magnitude of the transformation needed by both on the prescriber and pharmacy, we are concerned that some of the fine operational considerations may not have been thoroughly considered when drafting this proposed rule. As a result, patient care may be compromised which would be counterproductive to the efforts by the Administration to advance patient safety and increase efficiencies in the health care system.

Operational considerations that CMS should consider regarding implementation:

- The impact such exemption elimination would have patients of prescribers and pharmacies whose system capabilities do not meet the NCPDP SCRIPT standard, and recommend that the exemption continue to apply for these prescribers and pharmacies;
- Acknowledge the additional per transaction costs charged pharmacies for true electronic prescribing versus computer generated faxes;
- Acknowledge that a large number of pharmacies who are currently utilizing pharmacy systems that are "certified" to accept electronic prescribing have not yet invested the necessary funds to activate their systems;
- The Drug Enforcement Administration (DEA) needs to finalize regulations for the electronic prescribing of controlled substances;
- Address situations in which faxed prescriptions may be the preferred alternate method for transmitting a prescription electronically, such as computer system and software problems, technology failures, maintenance operations, etc.;
- Explore potential unintended outcomes that may limit adoption of true e-prescribing if computer-generated faxes are not allowed and prescribers revert to paper prescriptions as some entities use computer-generated faxes as an intermediate step towards true e-prescribing;
- Explore the impact on faxed prescribing practices within the long-term care industry;
- Understand the confusion created in pharmacy practice and prescriber practice in States that include computer generated faxed prescriptions within the definition of electronic prescriptions;
- Assess the impact of the inevitable transitional systematic errors that are unique to electronic prescribing and the resolution of those errors on pharmacists and prescribers workflow and time;
- Preserve patient choice to utilize their pharmacy of choice;
- And, provide consideration for rural areas where access to networks and services are currently limited.

Conclusion

In conclusion, NASPA strongly supports of CMS' efforts to facilitate and foster adoption of electronic prescribing. We recognize that pharmacy systems and prescribing processes have had substantial growth in electronic information exchange and we support their commitment to further advance the exchange of electronic information within the health care system. We stand ready to work with the agency to address the implementation and educational challenges during the adoption of new technologies including electronic prescribing by providers. We urge you to use us to address the above mentioned operational challenges.

The National Alliance of State Pharmacy Associations (NASPA) promotes leadership, sharing, learning, and policy exchange among pharmacy leaders in all 50 states and Washington, DC, and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health. NASPA was founded in 1927 as the National Council of State Pharmacy Association Executives (NCSPAE).

If you have any questions or need any additional information, please do not hesitate to contact Rebecca P. Snead, R.Ph., Executive Vice President and Chief Executive Officer NASPA, at (804) 285-4431 or via email at becky@naspa.us.

Sincerely,

/s/

Rebecca P. Snead, R.Ph
Executive Vice President and Chief Executive Officer
National Alliance of State Pharmacy Associations

Submitter : **Mr. Jeff Petersen** **Date: 08/31/2007**

Organization : **Iroquois Memorial Hospital**

Category : **Hospital**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P. I serve as the Director of Rehab Services, Sports Medicine, Home Health, Hospice, and as the General Manager of our DME company. I hold an MBA and am a Certified Athletic Trainer. Our hospital services five surrounding counties and over 50,000 people. These changes, along with the previous unrecognition of athletic trainers as health care professionals is very detrimental to our organization. All of our rehabilitation departmental staff (PT's, OT's, and ATC's) are very highly skilled and offer a unique aspect to our rehab services, completing a full team of care. Our program services multiple communities and multiple school systems. The outreach and outpatient care that is provided by our athletic trainers is a vital part to the services we provide. Our schools, our patients, and our communities need the skilled professional care that our athletic trainers provide. Under their state practice act and license, they provide quality physical medicine and rehabilitation to athletes (patients) in the local schools system, athletic venues, as well as our outpatient rehabilitation clinic; contributing to revenue for our organization and providing the care our community members need. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility, and begin recognizing athletic trainers as the health care professionals that they are.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jeff Petersen, MBA, ATC
Iroquois Memorial Hospital
Director of Rehab Services, Sports Medicine, Home Health, Hospice

Submitter : **Mr. Joseph Scarcella** **Date: 08/31/2007**

Organization : **college of marin**

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Joseph Scarcella, I work at the College of Marin in Kentfield , Ca. I am a Certified Athletic Trainer board certified by the National Athletic Trainers Association. My job at the College is injury treatment, evaluation, and rehabilitation to all student athletes, as well as faculty.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Joseph Scarcella, MS, ATC, CSCS
College of Marin sportsmedicine
835 college ave
Kentfield, ca 94904

Submitter : Dr. JAMES SCULLY, JR. **Date:** 08/31/2007

Organization : AMERICAN PSYCHIATRIC ASSN.

Category : Health Plan or Association

Issue Areas/Comments

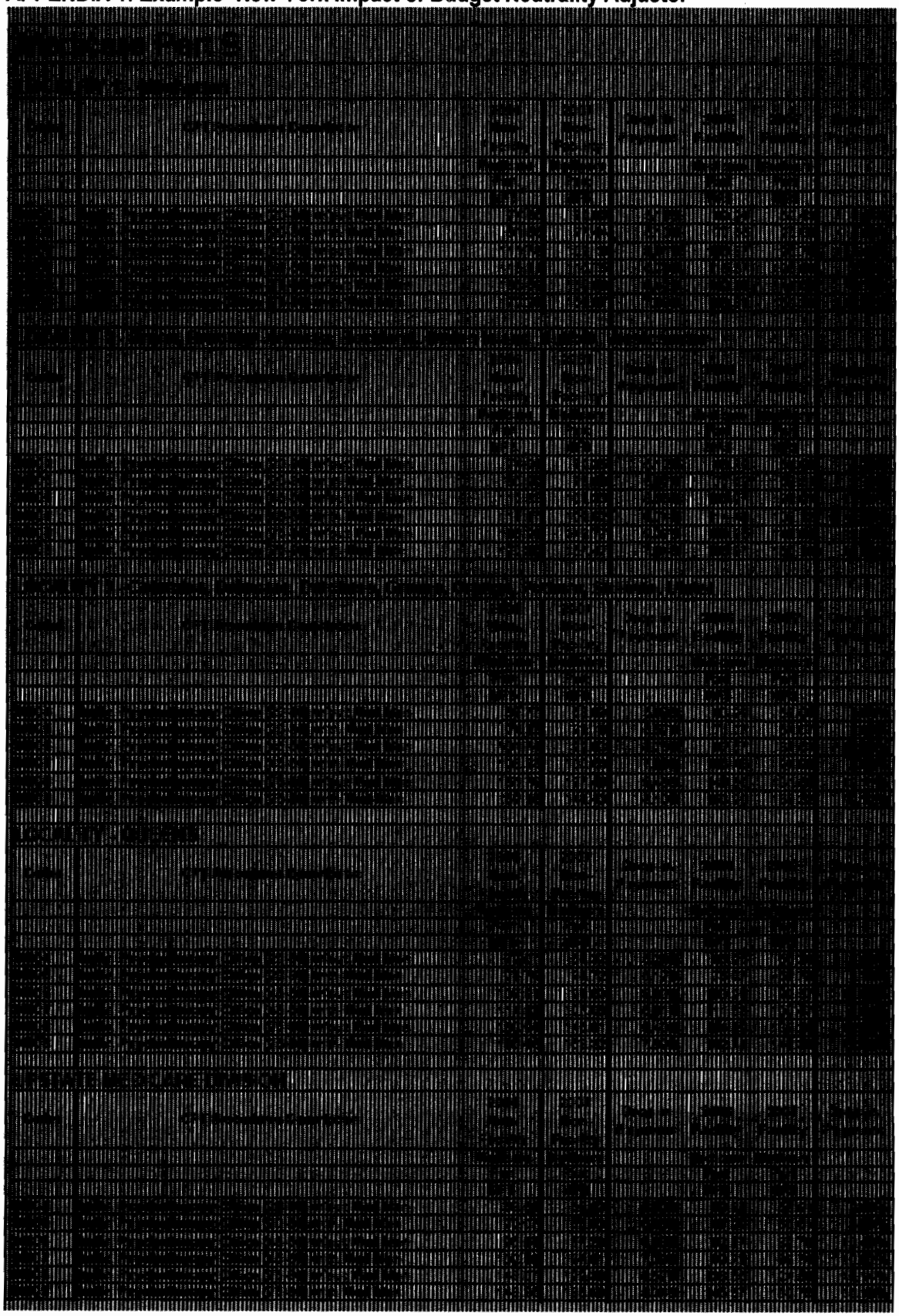
GENERAL

GENERAL

PLEASE SEE APPENDIX 1- THIS MS WORD FILE & ASSOCIATE WITH THE BODY OF COMMENTS SUBMITTED VIA THIS SITE A FEW MINUTES AGO. DUE TO ITS SIZE, I HAD TO BREAK THE FILE INTO THREE PARTS (BODY & TWO APPENDIX FILES, APPX. 1 AND APPXS. 2 + 3 IN ORDER TO TRANSMIT. THANK YOU. A.F.

CMS-1385-P-15380-Attach-1.DOC

APPENDIX 1: Example- New York Impact of Budget Neutrality Adjustor



CMS-1385-P-15451 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : Dr. JAMES SCULLY **Date & Time:** 08/31/2007

Organization : AMERICAN PSYCHIATRIC ASSN.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

PLEASE SEE APPENDIX 3-THIS MS WORD FILE & ASSOCIATE WITH THE BODY OF COMMENTS SUBMITTED VIA THIS SITE A FEW MINUTES AGO. DUE TO ITS SIZE, I HAD TO BREAK THE FILE INTO THREE PARTS (BODY & 3 APPENDIX FILES, APPX. 1, 2 + 3) IN ORDER TO TRANSMIT. TRIED MULTIPLE TIMES BEFORE 5 PM WHICH DID NOT GO THROUGH, SO BROKE INTO 3 APPX FILES. THANK YOU. A.F.

CMS-1385-P-15451-Attach-1.DOC

APPENDIX 3:
NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR AMBULATORY CARE JULY 2007
(pgs. 7-8)

Mental Health and Substance Use Disorders		
Major Depressive Disorder: Diagnostic Evaluation	Percentage of patients with a diagnosis of major depressive disorder who met the DSM–IV™ criteria during the visit in which the new diagnosis or recurrent episode was identified	AMA PCPI[2]
Major Depressive Disorder: Suicide Risk Assessment	Percentage of patients who had a suicide risk assessment completed at each visit	AMA PCPI[2]
New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management (b) Effective Acute Phase Treatment (c) Effective Continuation Phase Treatment	a. Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication, and who had at least three follow-up contacts with a practitioner during the 84-day (12-week) Acute Treatment Phase. b. Percentage of patients who were diagnosed with a new episode of depression, were treated with antidepressant medication and remained on an antidepressant drug during the entire 84-day Acute Treatment Phase. c. Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication and who remained on an antidepressant drug for at least 180 days.	NCQA

MEASURE TITLE MEASURE DESCRIPTION IP OWNER[1]

Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents	Percentage of patients newly diagnosed with attention deficit hyperactivity disorder (ADHD) whose medical record contains documentation of Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or Diagnostic and Statistical Manual for Primary Care (DSM-PC) criteria being addressed.	ICSI

Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents	Percentage of patients diagnosed with attention deficit hyperactivity disorder (ADHD) and on first-line medication whose medical record contains documentation of a follow-up visit twice a year.	ICSI
ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication.	a. *Initiation Phase:* Percentage of children 6 – 12 years of age as of the Index Prescription Episode Start Date with an ambulatory prescription dispensed for and ADHD medication and who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. *Continuation and Maintenance (C&M) Phase:* Percentage of children 6 – 12 years of age as of the Index Prescription Episode Start Date with an ambulatory prescription dispensed for ADHD medication who remained on the medication for at least 210 days and who in addition to the visit in the Initiation Phase had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ends.	NCQA
Bipolar Disorder and Major Depression: Assessment for Manic or hypomanic behaviors	Percentage of patients treated for depression who were assessed, prior to treatment, for the presence of current and/or prior manic or hypomanic behaviors.	STABLE
Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use	Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use	STABLE
Bipolar Disorder: Appraisal for risk of suicide	Percentage of patients with bipolar disorder with evidence of an initial assessment that includes an appraisal for risk of suicide.	STABLE
Bipolar Disorder: Level-of-function evaluation	Percentage of patients treated for bipolar disorder with evidence of level-of-function evaluation at the time of the initial assessment and again within 12 weeks of initiating treatment	STABLE
Bipolar Disorder: Assessment for diabetes	Percentage of patients treated for bipolar disorder who are assessed for diabetes within 16 weeks after initiating treatment with an atypical antipsychotic agent	STABLE

Initiation and Engagement of Alcohol and Other Drug Dependence Treatment a. Initiation b. Engagement	Percentage of adults aged 18 and over diagnosed with AOD abuse or dependence and receiving a related service who initiate treatment Assessment of the degree to which members engage in treatment with two additional AOD treatments within 30 days after initiating treatment.	NCQA/WC

Submitter : **Mr. Michael Landas** **Date: 08/31/2007**

Organization : **Mr. Michael Landas**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My Name is Michael J. Landas and I am a certified athletic trainer for Mount San Antonio College in Walnut, CA. I am certified in both athletic training and strength and conditioning. I receive my bachelors degree in Kinesiology from California Polytechnic University, Pomona and my masters degree from California State University, Long Beach.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Michael J. Landas, MA ATC CSCS

Submitter : **Mr. Jason Uhlenhake** **Date: 08/31/2007**

Organization : **Simpson College**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Jason Uhlenhake and I am the Head Athletic Trainer at Simpson College in Indianola, Ia. I am a nationally certified and state-licensed athletic trainer. I am writing to voice my strong opposition to the therapy standard and requirements for staffing provisions for rehabilitation and other facilities proposed in 1385-P.

The proposed changes will create a lack of access to certified athletic trainers, who are more than equipped to treat the physically active. An Athletic Trainer, or ATC, is fully qualified to perform physical medicine and rehabilitation services, which, is not of course the same thing as physical therapy. An ATC's education includes didactic coursework, extensive clincial experiences and national certification exam ensuring their patients recieve quality health care. Outcome studies have proven this on numerous occasions. The American Medical Association, recognition by many state laws, and other qualified medical professionals has deemed us qualified to perform such services. The proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jason Uhlenhake, LAT ATC
Head Athletic Trainer
Simpson College

Submitter : **Mr. Craig Carvaho** **Date: 08/31/2007**

Organization : **Mr. Craig Carvaho**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

Hello, my name is Craig J. Carvalho MS, ATC, ACI. I am currently the Head Athletic Trainer at John Jay High School, where I have been for the past 11 years. I attended North Adams State College in Massachusettes and The University of Albany. I responsibly for the health of appoximately 600 athletes while the participate in interscholastic athletics here at John Jay.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Craig J. Carvalho MS, ATC, ACI

Submitter : Dr. Randy Pilgrim **Date:** 08/31/2007

Organization : Emergency Department Practice Management Assoc.

Category : Health Care Provider/Association

Issue Areas/Comments

Background

Background

EDPMA is the organization that advocates for emergency physician groups and their partners to enhance quality patient care through operational excellence and financial stability. EDPMA members include emergency department medical groups and business partners who support emergency department groups. EDPMA members represent approximately one-third of all of the emergency department visits in the U.S. through direct patient care or support services to physicians and providers.

We greatly appreciate the opportunity to provide CMS with our comments on the Proposed Rule and its potential impact on Emergency Departments.

Americans trust that when they need urgent medical attention, the Emergency Departments will be there to help. EDPMA members are working day and night to ensure that quality health care is available to Americans whenever they need it. But the ever-increasing demands on the Emergency Department mean that our safety net is stretched to, and in some cases beyond, its limits.

Visits to the Emergency Department are on the rise while the number of facilities is declining. According to the Institute of Medicine (IOM), the number of emergency department visits increased by 27 percent from 1993 to 2003, although the population increased by only 12 percent. During the same period, 425 Emergency Departments closed, and the number of hospital beds decreased by 200,000. Proof of the stress on our nation s Emergency Departments is the IOM finding that an ambulance is diverted to a different hospital every minute due to overcrowding.

In addition to treating large numbers of Medicare beneficiaries in the Emergency Department, emergency physicians treat large numbers of uninsured and underinsured patients (including those with Medicaid and limited private insurance) in the Emergency Department every day. The Census Bureau very recently reported that the number of uninsured in America is on the rise. In 2005, 44.8 million people were without health insurance; in 2006, that number rose to 47 million. These figures represent 2.2 million Americans added to the ranks of the uninsured between 2005 and 2006. The Emergency Department is where millions of uninsured Americans receive urgent healthcare services regardless of their ability to pay - and cuts to the Medicare physician fee schedule place in jeopardy this important safety net.

According to recent survey data from the Centers for Disease Control and Prevention (CDC), emergency physicians provided health care services to more than 115 million patients in 2005, with 17 million visits from Medicare patients alone. Indeed, 51 percent of Medicare patients had at least one visit to an emergency department in 2005. In response to the cuts in the Medicare physician fee schedule, some physicians currently limit the number of Medicare beneficiaries they see. In contrast, Emergency Departments cannot under federal law turn away those in need of emergency services regardless of payment. As the number of available primary care and specialty physicians shrinks, even higher percentages and numbers of Medicare beneficiaries will turn to the emergency department for the treatment of acute and chronic conditions.

The 9.9 percent cut to the Medicare Physician Fee Schedule for 2008 has seen year-to-year reductions, freezes, and updates far below the rate of inflation for the past seven years. The current Sustainable Growth Rate (SGR) formula is anticipated to deliver more cuts in future years. Cutting physician payments year after year creates significant challenges for Emergency Departments and ED physician groups to attract and retain high quality physicians. We are very concerned about the impact of these cuts on the nation s ability to provide emergency medical care sufficient to meet the increasing demands of Medicare patients in this environment.

Resource-Based PE RVUs

Resource-Based PE RVUs

Budget Neutrality and Practice Expense

EDPMA strongly urges that CMS continue its long-standing policy of applying the budget neutrality adjustments to the conversion factor and not to the physician work relative values (RVUs). At a minimum, we would suggest that CMS apply budget neutrality to the global RVU and not specifically to the work RVUs. If the RVUs are reduced to accommodate budget neutrality, the recent improvements to valuation of primary care services and E/M services will be redueed as well and the full benefit of these improvements will not be achieved.

We continue to have concerns that the current practice expense formula does not take into account expenses associated with the provision of uncompensated care. For emergency physicians, providing uncompensated care, as is mandated by federal law, is a clear practice expense, but Medicare has yet to recognize it as such in the practice expense formula or Physician Fee Schedule. We strongly believe that federal policies should support the healthcare safety net by acknowledging the impact of providing uncompensated care and including that fiscal impact in the practice expense formula.

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

Physician Quality Reporting Initiative (PQRI) TRHCA Section 101(b)

Many EDPMA members are now participating in the 2007 Physician Quality Reporting Initiative (PQRI). EDPMA has encouraged our members to participate as a measure of our commitment to the delivery of quality care in the Emergency Department.

The Proposed Rule establishes the regulatory framework for PQRI in 2008. EDPMA believes that PQRI quality measures for physicians should be physician-developed. As such, we appreciate that the Proposed Rule will largely utilize measures developed by medical specialty societies in conjunction with the American Medical Association Physician Consortium for Performance Improvement (PCPI) and endorsed by the National Quality Forum (NQF). We also encourage CMS and others to harmonize physician measures with hospital quality measures where needed to ensure that physicians practicing in a hospital setting, including emergency physicians, can continue to work effectively with their hospital partners.

EDPMA urges CMS to finalize measure selection, measure specifications, and technical reporting requirements as far in advance as possible to the January 1, 2008 start of PQRI. Implementation of a revised and expanded PQRI framework for 2008 will require providers and their partners to implement changes in documentation protocols and billing and coding systems and to train physicians and staff regarding the new or revised measures and specifications. The Proposed Rule indicates that measure specifications will be finalized no later than December 31, 2007. We strongly urge CMS to complete their work and finalize the measure specifications far in advance of this date so that physicians and their partners will have the opportunity to implement the changes in a timely manner and begin effective participation on January 1, 2008.

EDPMA members participating in PQRI greatly appreciate that the program rewards reporting on quality measures. As physicians and their partners adjust to this new system of reporting on quality measures for Medicare, there is an inevitable learning curve that must be overcome. Providers must be educated on the reporting and documentation requirements associated with the measures and billing and coding staff must be trained on new extraction protocols. As such, we appreciate the use of the 8P-modifier in 2007 and hope that it will continue to be in use for 2008.

Submitter : Dr. Mark Stansberry **Date:** 08/31/2007

Organization : Mountain Town Rehab

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

15385

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Mark Murray **Date:** 08/31/2007

Organization : University Anesthesiologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15386-Attach-1.DOC

15386

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

As an assistant professor of anesthesia at the University of Tennessee Medical Center, I am writing to express my support of the RUC sponsored increase in anesthesia payments in the 2008 Physician Fee Schedule. I am grateful that the RUC and CMS have recognized the previous gross under valuation of anesthesia services, and that the Agency is taking steps to address this complicated issue. As a teaching institution, our residency and nurse anesthetist training programs are in jeopardy by because of the concomitant impacts of the under valuation of the conversion factor for anesthesia and the "teaching penalty" of 50% reduction in payments when anesthesia trainees are involved in the care of the Medicare patient.

When the RBRVS was instituted, a huge payment disparity for anesthesia care was created due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This conversion factor is actually lower than it was in 1990 and is less than 36% of the average commercial insurance conversion factor. In contrast, MedPAC reports that Medicare payments to other physician groups average 80% of commercial insurance payments. Furthermore, this amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work under valuation. This move would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services and help ameliorate the impact of the "teaching penalty".

Full and immediate implementation of the increase in the anesthesia conversion factor as recommended by the RUC is an imperative which cannot be ignored to ensure that our patients have access to needed anesthesiology medical care.

Thank you for your consideration of this serious matter.

Mark Murray, MD
Assistant Professor
Department of Anesthesiolgy
University of Tennessee Medical Center

Submitter : **Mr. Zafir Bludevich** **Date: 08/31/2007**

Organization : **Saint Michael's College**

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

Dear sir/Madam

I am a certified athletic trainier and a licenced physical therapist, I have been employed by Saint Micahael's College for over thirty years.

I am writing today to voice my opposition to the therapy standards and requirements in reguards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P

Thank you

Zafir Bludevich

Submitter : **Ms. Veronica Ampey** **Date: 08/31/2007**

Organization : **Georgetown Day School**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To whom it May Concern:
As an NATA Certified Athletic Trainer currently employed at Georgetown Day School - high School Campus, I am concerned about the potential ramifications of the propsed government regulations. Therefore, I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Veronica L. Ampey MS, ATC

Submitter : **Annemarie Francis** **Date: 08/31/2007**

Organization : **Annemarie Francis**

Category : **Other Practitioner**

Issue Areas/Comments

Impact

Impact

August 30, 2007Dear Sir or Madam:I am a state licensed and nationally certified athletic trainer. My professional experience over the past 12 years spans the work settings of collegiate, secondary school and now clinical environments. My current position is within a sports medicine program, associated with the outpatient physical therapy division of a large hospital network in Virginia. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P. While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients. As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards. The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available. Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility. Sincerely, Annemarie Francis, MS, ATC, VATL

Submitter : **Dr. Wes Robinson** **Date: 08/31/2007**

Organization : **ASA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Mr. Scott Piehl** **Date: 08/31/2007**

Organization : **AthletiCo LTD**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

Hello, my name is Scott Piehl, ATC, CSCS. I am a certified athletic trainer working in Illinois for AthletiCo. I have been a certified athletic trainer for 14 years. I am currently the facility manager at our Garfield Ridge location, in Chicago and oversee a staff of 25 that include physical therapists, occupational therapists, massage therapists, other athletic trainers and rehabilitation aides.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Scott Piehl,ATC,CSCS
Facility Manager - Garfield Ridge
AthleitCo Physical Therapy
6255 S. Archer Ave.
Chicago, IL 60638
spiehl@athletico.com

Submitter : Mrs. Nicolle Whalen **Date:** 08/31/2007

Organization : Simpson College

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am an exercise physiologist and a nationally certified and state-licensed athletic trainer at Simpson College in Indianola, Iowa. I am writing to voice my strong opposition to the therapy standards and requirements for staffing provisions for rehabilitation in hospitals and other facilities proposed in 1385-P.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Nicolle Whalen, MS LAT ATC HFI

Submitter : **Mr. Keith Berman** **Date: 08/31/2007**

Organization : **Health Research Associates**

Category : **Individual**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Please see comment letter attached.

CMS-1385-P-15393-Attach-1.DOC

15393

Health Research Associates

HRA

2500 E. Foothill Blvd., Suite 408
Pasadena, CA 91107-7125 USA
(626) 564-0456 fax: (626) 564-1010
e-mail: kberman@sbcglobal.net

August 30, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: **CMS-1385-P**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: RESOURCE-BASED PE RVUs – Photopheresis and Therapeutic Plasma Exchange

Extracorporeal photopheresis (CPT 36522) and therapeutic plasma exchange (TPE; CPT 36514) can be safely provided in a physician-directed clinic, and are each covered by Medicare for a number of serious hematological, neurological and/or autoimmune disorders in this setting.[1],[2]

Like many other procedures that began in the hospital setting and have moved to the physician office or clinic, benefits of doing so with photopheresis and TPE include an improved patient treatment experience, reduced nosocomial infection risk in these usually immunocompromised patients, and potentially significant overall cost savings to the Medicare Trust Fund.

Unfortunately, physicians interested in bringing these two historically hospital-based apheresis procedures into the office-based setting are being completely stymied by severe under-valuations of their proposed "fully implemented" practice expense RVUs (PE RVUs). The proposed valuations will yield payment rates that fall far short of actual direct and indirect costs of providing these unusually supply-intensive procedures.

The basis for this undervaluation is driven by CMS' application of a roughly 40% "direct PE budget neutrality adjustment" ("direct adjustment"),[3] which CMS applies equally to clinical labor, supplies and equipment expenses. The impact of this "direct adjuster" then

[1] Medicare Coverage Manual Sect. 110.14 (Coverage Issues Manual §35.60).
[2] *Fed Reg.* July 12, 2007; 72(133):38273.
[3] This direct adjuster appears likely to range between the 0.584 value published in the July 12 *Federal Register* and the 0.6186 value used in a sample PE RVU calculation for TPE which was provided to me by CMS.

ripples through the entire calculation of PE RVUs: the "adjusted direct RVUs," reduced by about 40%, are fed into the indirect RVU calculation: *Indirect Pct * (Adj. Direct RVU/Direct Pct.) + Work RVU*, which in turn is further sharply reduced by an "indirect adjustment."

Applying SMS and supplemental survey data across all physicians, a hypothetical procedure involving 5 physician work RVUs and $100 in direct practice expense is accompanied by roughly $200 in indirect practice expense, for a total of $300.[4] At the end of the sequence of adjustments that CMS uses to bring down payments to match available budget dollars, that presumptive $300 in non-physician practice expenses has been pared to an average payment rate of roughly $130.

One might ask how physician providers, for whom Medicare patients often constitute a large share if not the bulk of their caseload, can afford to accept and treat Medicare patients without losing huge amounts of money and quickly going out of business. That they *are* accepting Medicare patients and not going out of business all but dictates that there is a large and widespread overstatement of direct cost inputs for many or most of the 7,000-odd procedures and services, despite having passed through the AMA "refinement" process by its RUC and PEAC bodies.

Because the allocation of RVUs is a "zero-sum" game where more RVUs assigned for some procedures means less for others, there is unfortunately a powerful incentive for physician survey respondents and medical specialty societies to exaggerate cost inputs.

In the case of photopheresis and TPE, I will document that the direct cost inputs for these two services are *not* exaggerated and that proposed fully transitioned PE RVUs fall well short of actual costs. I will then address how these and likely certain other highly supply-intensive procedures are systematically undervalued using the proposed PE RVU development methodology, and finally I will suggest an methodological "fix" that will enable providers to cover their actual costs and provide this pair of important services.

For each procedure, below are:

1. Aggregated direct clinical labor, supply and equipment costs;
2. Total direct PE RVUs and "adjusted" total direct PE RVUs
3. Calculated indirect PE RVUs applying direct cost-adjusted PE RVUs;
4. Total direct costs restated in RVUs, applying the originally scheduled 2007 conversion factor (CF) of $35.9848 per RVU..

[4] *Fed Reg.* July 12, 2007; 72(133):38132. Table 2 (all physicians).

Some values presented below in Table 1 may not exactly agree with your calculated values, but I believe they are fair approximations for purposes of understanding the nature and rough magnitude of our underpayment issue.

Table 1. Unadjusted and adjusted direct and indirect PEs

Therapeutic Plasma Exchange (CPT 36514):

	Direct Costs (CPEP)	Direct PE RVUs	Total Direct RVUs Total Direct Adj. RVUs[5]
Clinical labor	$76.86	2.136	***9.13***
Supplies	$210.08	5.838	↓
Equipment	$41.67	1.158	**5.65**
Total direct costs:	**$328.61**	***9.13***	+
			Total Indirect Adj. RVUs[6]
			4.76

Proposed fully implemented non-facility PE RVUs: **10.41**

Photopheresis (CPT 36522):

	Direct Costs (CPEP)	Direct PE RVUs	Total Direct RVUs Total Direct RVUs (Adj.)[5]
Clinical labor	$92	2.56	***32.98***
Supplies[7]	$1,045	29.03	↓
Equipment[8]	$50	1.39	**20.40**
Total direct costs:	**$1,187**	***32.98***	+
			Total Indirect Adj. RVUs[9]
			16.64

Proposed fully implemented non-facility PE RVUs: **37.04**

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[5] Applying a "direct adjustment" factor of 0.60 to total direct RVUs; CMS applied 0.584 in 7/12/07 *Fed. Reg.*

[6] Applying an indirect adjustment factor of 0.362 to total indirect RVUs, followed by a 0.973 PCI adjustment

[7] Based on CPEP supply , updated with current average prices for photopheresis procedure kit ($976.39) and methoxsalen ($59.48) which have been submitted separately in a comment letter from the American Academy of Dermatology. NOTE: procedure kit price reflects discounts based on very high volume orders by large hospital users.

[8] Estimated from CPEP equipment , with addition of light source, photopheresis, whose average price is approximately $8.64 per procedure (source: Therakos Inc.).

[9] Applying an indirect adjustment factor of 0.362 to total indirect RVUs, followed by a 0.973 PCI adjustment

The mathematics of arriving at total PE RVUs that "fully implement" the CMS "bottom-up" methodology are no different for any of the other 7,000-odd procedures and services in the Physician Fee Schedule. However, one very important distinction sets these two services (and likely a small number of others) apart: disposable supplies account for most -- 64% and 88% -- of the direct practice expense for TPE and photopheresis, respectively.

CPEP database – direct supply costs

TPE procedure. The CPEP supply inputs accurately reflect both the types and quantities of supplies that are actually used for this procedure. Notably, the major disposable item, the tubing set used in tandem with the apheresis machine, accounts for about 83% of total supply costs, while the remaining 17% comprises mostly inexpensive items commonly used in IV injection and blood collection procedures.

The $173.33 price identified for the tubing set, entered into the CPEP file in 2004, reasonably approximates the average selling price (ASP) by the product's leading supplier, which serves approximately 85-90% of the U.S. market.[10] However, this ASP reflects the heavy influence of very large-volume purchase activity – in the thousands of units – by the small minority of its largest customers, whose pricing is well below $173. Approximately 80% of customers – individual hospitals and clinics – pay between $190 and $215 (the current list price) per tubing set, reflecting in part their higher transaction and customer service-related costs. Generally the smaller the customer, the higher the unit price; according to the leading manufacturer, the ASP for most physician-directed clinics will fall close to the list price.[10]

The price for the tubing set in the CPEP database is therefore roughly $20 to $40 below the actual cost that applies for relatively low-volume physician-directed offices. The total of $210.08 that CMS presumes to reflect actual supply costs therefore may underestimate actual costs by roughly 10% to 15%, more importantly, it certainly is not an overestimate.

Photopheresis procedure. While most supply items in the CPEP database are accurate, a few important corrections need to be made. I have collaborated with the American Academy of Dermatology on these issues, and you should receive comments from the Academy requesting specific item and pricing corrections. In particular, the price identified for the photopheresis procedure kit ($858) is about $118 lower than the year-to-date ASP supplied by the manufacturer ($976.39).

Like the circumstance with the TPE tubing set, the price of this item is tiered according to customer ordering volume. At one end of the pricing spectrum are very large hospital-based cancer centers, which pay marginally less than $976 per kit. At the other end are

[10] Personal communication: Dawson Smith, Director of Sales, Therapeutics Division, North America, Gambro BCT, Inc.

smaller programs, including the office-based photopheresis provider, which ordinarily purchase between 4 to 36 kits ($1,100 per kit) or 37 to 104 kits ($1,013.25 per kit). At an order quantity of more than 104 kits, the price drops to about $900 per kit.

Thus, the current CPEP price for the kit, which accounts for fully 93% of total procedural supply costs, is more accurately between $155 and $245 lower than the actual price now paid by the small office-based customer that is extremely unlikely to purchase more than $100,000 worth of inventory of this supply item.

Again, the supply component of direct costs for photopheresis are moderately understated, and certainly not overstated.

CPEP database – direct clinical labor costs

For both TPE and photopheresis, direct labor costs are a significant element of total costs, but are dwarfed by supply costs. It happens that these procedures are unusual, however, for the fact that a highly trained nurse specialist must work one-on-one through the set-up, intra-procedural phase and post-procedural phase. I understand that CMS officers have personally observed this procedure and are aware that there are no meaningful opportunities for staff "multi-tasking" during this complex procedure, which requires many steps and close monitoring of the patient's vital signs and overall health status.

Underpayment for TPE and photopheresis: a formula-driven problem

As noted earlier and presented in Table 1, supply costs account for about 64% and 83% of total direct costs in TPE and photopheresis procedures, respectively. According to data supplied by CMS at a February 15, 2006 Town Hall meeting[11] to address PE methodology options, supplies accounted for just 18% of total practice expense-related payments under the PFS.

In contrast, two other survey processes found that supplies account for

[11] Summary of CMS Town Hall Meeting on Practice Expense (PE) Methodology, Feb. 15, 2006. Prepared by the American Society of Nuclear Cardiology. File attached to this comment letter and available online at: http://www.asnc.org/imageuploads/HPM%206%20-%20Summary%20of%20CMS%20February%2015%20Town%20Hall%20meeting%20on%20PE.pdf

Table 2. Classification of direct PEs by SMS and SMS/supplemental surveys

Source	Clinical labor	Supplies	Equipment
SMS surveys[11]	57%	**28%**	16%
Fed Reg 7/12/07; 38132; Table 2	53.7% ($15.68/hr)	**32.3%** ($9.44/hr)	14.0% ($4.08/hr)

While random surveys of physicians imply that supplies account for roughly 30% of direct practice expenses, the contribution of supplies driven by CPEP inputs via the RUC/PEAC process is (or recently was) just 18% of the total.

This suggests that supplies are underrepresented as a proportion of overall direct practice expenses. I propose that the review and audit of procedural supply inputs is far more objective and readily auditable than is the case for either clinical labor or equipment. Both clinical labor time and equipment amortization demand very close and extensive investigation, of a nature that I believe was at best partly accomplished by the RUC/PEAC direct PE "refinement" process.

The most obvious means of clinical labor overstatement is assignment of more activity minutes by clinical staff persons than actually are devoted to the procedure or service. Equipment cost overstatement can be occur, for example, through overstatement of the cost of capital equipment items and/or useful life of those items. In the instance of the two procedures in consideration here, equipment-related costs account for a small contribution (13% and 4% for TPE and photopheresis, respectively).

Consequently, the dramatic formulaic reductions by CMS in direct PE across labor, supplies and equipment is – and must be – ameliorated for many or most services by significant overstatements of labor and equipment amortization costs.

In the case of TPE and photopheresis, where direct supply costs constitute most of direct cost burden, the "direct adjustment" factor of approximately 40% reduces very real costs that are actually paid before the procedure can even be initiated.

Consider the direct PEs for these two procedures and the proposed payment rate based on the currently published "fully implemented" PE RVUs:

Procedure	Direct procedural costs	Proposed PE RVUs	Proposed payment ($36/RVU)	Implied indirect RVUs and payment
TPE	$328.61	**10.41**	$374.76	**1.28** ($46.15)
Photophereresis	$1,187	**37.04**	$1,333	**4.05** ($146)

The effective indirect cost contribution of the proposed fully implemented PE RVUs is therefore 1.28/10.41 = 12.3% for TPE and 4.05/37.04 = 10.9% for photopheresis.

These contributions to indirect practice overhead are clearly far below what is financially feasible for office-based providers.

Recommendation

I recommend that CMS make a single modification to its direct PE RVU adjustment formula, to address procedures for which supply costs represent more than 40% to 50% of total direct costs.

Specifically, I recommend that, for procedures for which supply costs represent more than 40% to 50% of total direct costs, that all supply costs be passed through and the direct adjustment factor be applied as usual to direct labor and equipment costs sourced from the CPEP database.

I recognize that, to remain compliant with your budget neutrality imperative, this will necessitate a small adjustment in the direct adjustment factor to assure that total RVUs remain unchanged.

In all the jockeying by various interest groups to capture Medicare practice expense dollars, and CMS' sincere efforts to fairly allocate those dollars, are a relatively small number of procedures, provided by a small cadre of trained specialists, that do not have the good fortune to have a vocal or well-financed organization to aggressively advocate for them. For two of these procedures – photopheresis and TPE – the losers stand to be seriously ill patients with such diagnoses as cutaneous T-cell lymphoma, chronic graft-versus-host disease, myasthenia gravis and chronic relapsing polyneuropathy.

While I ask you to resolve the unfair and financially untenable impact of the "direct adjustment" on these two supply-intensive services, I would also like to commend the work of the CMS staff, who face the unenviable task of balancing the interests of U.S. taxpayers, providers and the Medicare beneficiaries they ultimately serve.

In a phone discussion recently about our particular concern, the CMS officer reassured me that "we want to get this right."

On behalf of office-based providers and Medicare beneficiaries who require photopheresis and therapeutic plasma exchange, I am confident that you will get this right.

Sincerely,

Keith E. Berman, MPH, MBA

Submitter : **Mr. Rodney Koehler** **Date: 08/31/2007**

Organization : **Physical Therapy Works**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Rodney Koehler. I own an outpatient physical therapy center located in Dodge City, Kansas.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Rodney A. Koehler, ATC

Submitter : Dr. JAMES SCULLY, JR **Date:** 08/31/2007

Organization : AMERICAN PSYCHIATRIC ASSN.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

PLEASE SEE APPENDICES 2 + 3- THIS MS WORD FILE & ASSOCIATE WITH THE BODY OF COMMENTS SUBMITTED VIA THIS SITE A FEW MINUTES AGO. DUE TO ITS SIZE, I HAD TO BREAK THE FILE INTO THREE PARTS (BODY & TWO APPENDIX FILES, APPX. 1 AND APPXS. 2 + 3 IN ORDER TO TRANSMIT. THANK YOU. A.F.

Submitter : Mr. James Wiehl **Date:** 08/31/2007

Organization : Fulbright and Jaworski, LLP

Category : Attorney/Law Firm

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Administrator Norwalk:
We welcome the opportunity to comment on the Physician Self-Referral Provisions of the CY 2008 Physician Fee Schedule proposed rule issued on July 12, 2007 (72 Fed. Reg. 38122) (the Proposed PFS). Our comment relates to the proposed definition of entity in the Proposed PFS.
The proposed revision as drafted would invalidate thousands of current arrangements which are not the subject of CMS concern. It would also require the unwinding of a number of developing models which are in fact improving the quality, accessibility, affordability and efficiency of health care.

The proposed revised definition is too broad in its scope and vague in its application, and would cause the following types hospital service providers around the country to be in violation of the Stark Law: providers of inpatient hospitalist services, providers of rehabilitation services, providers of radiology services, etc. CMS concern regarding abuse is already well protected by the law s current requirement that any such services be provided at fair market value. Changing the definition, as proposed, would cause significant disruption and would create additional substantial costs in connection with the delivery of health care.
In addition, significant gains have been made over the recent years through legitimate joint venture arrangements between physicians and hospitals focused on working together to improve the quality, accessibility, affordability and efficiency of health care to patients. These joint venture arrangements have developed in response to several deficiencies in the historical relationship between hospitals and physicians. First, many economists agree that the historical relationship between physicians and hospitals is fundamentally flawed -- a physician has a greater incentive to be efficient in his or her own office (a low cost center) than in a hospital (where the government clearly spends the most and where there is the best opportunity for substantial savings). Second, the current circumstances provide no incentive for physicians to work with hospital administrators in improving the quality, accessibility, affordability and efficiency of inpatient and outpatient hospital services. In response to these deficiencies, these recent joint ventures have bridged the gap in the hospital/physician relationship and are improving health care delivery.
The current Stark Law and regulations provide appropriate protection from the risk of abuse in connection with these models by requiring that the fees paid to the joint venture be at fair market value. Due to the significant concerns described above with the proposed revision to the definition, CMS should not change the definition of entity, but focus on ensuring that existing safeguards are enforced.

Respectively Submitted,

James G. Wiehl,
Fulbright & Jaworski L.L.P.

CMS-1385-P-15396-Attach-1.DOC

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August 31, 2007

ELECTRONIC SUBMISSION

Ms. Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018, Baltimore, MD 21244-8018

Re: CMS-1385-P; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008
PHYSICIAN SELF-REFERRAL PROVISIONS

Dear Administrator Norwalk:

We welcome the opportunity to comment on the Physician Self-Referral Provisions of the CY 2008 Physician Fee Schedule proposed rule issued on July 12, 2007 (72 Fed. Reg. 38122) (the "Proposed PFS"). Our comment relates to the proposed definition of entity in the Proposed PFS.

The proposed revision as drafted would invalidate thousands of current arrangements which are not the subject of CMS' concern. It would also require the unwinding of a number of developing models which are in fact improving the quality, accessibility, affordability and efficiency of health care.

The proposed revised definition is too broad in its scope and vague in its application, and would cause the following types hospital service providers around the country to be in violation of the Stark Law: providers of inpatient hospitalist services, providers of rehabilitation services, providers of radiology services, etc. CMS' concern regarding abuse is already well protected by the law's current requirement that any such services be provided at fair market value. Changing the definition, as proposed, would cause significant disruption and would create additional substantial costs in connection with the delivery of health care.

In addition, significant gains have been made over the recent years through legitimate joint venture arrangements between physicians and hospitals focused on working together to improve the quality, accessibility, affordability and efficiency of health care to patients. These joint venture arrangements have developed in response to several deficiencies in the historical

relationship between hospitals and physicians. First, many economists agree that the historical relationship between physicians and hospitals is fundamentally flawed -- a physician has a greater incentive to be efficient in his or her own office (a low cost center) than in a hospital (where the government clearly spends the most and where there is the best opportunity for substantial savings). Second, the current circumstances provide no incentive for physicians to work with hospital administrators in improving the quality, accessibility, affordability and efficiency of inpatient and outpatient hospital services. In response to these deficiencies, these recent joint ventures have bridged the gap in the hospital/physician relationship and are improving health care delivery.

The current Stark Law and regulations provide appropriate protection from the risk of abuse in connection with these models by requiring that the fees paid to the joint venture be at fair market value. Due to the significant concerns described above with the proposed revision to the definition, CMS should not change the definition of "entity," but focus on ensuring that existing safeguards are enforced.

Respectively Submitted,

James G. Wiehl,
Fulbright & Jaworski L.L.P.

Submitter : **Dr. Tamara Enfiedjian** **Date: 08/31/2007**

Organization : **Fortanasce**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To whom it may concern at the Centers of Medicare/Medicaid Services,

I am writing with concerns regarding physician self referral as it is harming the physical therapy profession in multiple ways.

Educational programs are preparing physical therapists to provide quality patient care including screening of medical diagnoses, thorough examination/evaluation processes, and proper therapeutic programs. With the growing rate of physician self-referrals, the education that physical therapists have strived to gain is being discounted. We have the abilities to excel but our education is not being respected.

Physician self-referral also is harmful to the physical therapy business market. When physicians establish their own clinics, it eliminates the competition for patients. Small physical therapist owned clinics are now struggling to maintain a business secondary to the lack of patients/clients. This suffering is intensified secondary to the fact that physical therapists in California rely on physicians to provide the business. As a result, multiple physical therapist-owned establishments are no longer able to survive in the market.

Likewise, the growth of the physical therapy profession is being inhibited as physicians refer to themselves. Autonomy is an idea that the profession has tried to gain and maintain; however, this is being hindered as physical therapists are having difficulty working in the struggling clinics. Those working in the physician-owned clinics may also be inhibited in autonomy as they may be forced to modify their treatment philosophies to be coinciding with the needs of the physician-owned practice.

As described physician self referral is detrimental to physical therapy, a field of health care that is whole-heartedly dedicated to serving the people, the community.

Thank you.
Respectfully,
Tamara Enfiedjian, PT, DPT

Submitter : Dr. Enrique Mendivil **Date:** 08/31/2007

Organization : West Central Anesthesiology Group, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1385-P-15398-Attach-1.PDF

15398

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Enrique Mendivil, M.D.
West Central Anesthesiology Group, Ltd
Department of Anesthesiology
Central DuPage Hospital
25 N. Winfield Road
Winfield, IL 60190

Submitter : Dr. Peggy Delahoussaye **Date:** 08/31/2007

Organization : MLD Pathology

Category : Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018
Attention: CMS-1385-P

To Whom It May Concern:

This letter serves to submit comments on the Physician Self-Referral Provisions of CMS-1385-P entitled Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008. I am a board-certified pathologist and a member of the College of American Pathologists. I practice in Houston, Texas as part of a 7 member pathology group working both in a hospital setting and through our independent laboratory.

I congratulate CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. Clearly, the risk of over-utilization and increased costs to CMS exist when a physician profits from the number of specimens sent to their own laboratory. I am aware of arrangements in my practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group s patients. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services.

Specifically I support the expansion of the anti-markup rule to purchased pathology interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. These revisions to the Medicare reassignment rule and physician self-referral provisions are necessary to eliminate financial self-interest in clinical decision-making. I believe that physicians should not be able to profit from the provision of pathology services unless the physician is capable of personally performing or supervising the service.

Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. I agree that the Medicare program should ensure that providers furnish care in the best interests of their patients, and, restrictions on physician self-referrals are an imperative program safeguard to ensure that clinical decisions are determined solely on the basis of quality. The proposed changes do not impact the availability or delivery of pathology services and are designed only to remove the financial conflict of interest that compromises the integrity of the Medicare program.

Sincerely,
Peggy M. Delahoussaye, M.D

Submitter : **Mr. Michael DeCarlo** **Date: 08/31/2007**

Organization : **Blue Cross Blue Shield Association**

Category : **Health Plan or Association**

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

RE: File Code CMS-1385-P - PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

Dear Sir / Madam:

The Blue Cross Blue Shield Association (BCBSA) made up of 39 independent, community-based and locally owned and operated Blue Cross and Blue Shield companies that collectively provide healthcare coverage for more than 99 million Americans is submitting these comments regarding the Centers for Medicare & Medicaid Services (CMS) proposed elimination of the exemption for computer generated facsimiles as published in connection with the proposed rule (NPRM) addressing proposed revisions to the Medicare physician fee schedule payment policies.

The proposed elimination of the exemption for computer-generated facsimile transmissions would affect compliance with the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for transmitting prescription and certain prescription-related information for Medicare Part D eligible individuals. See 72 Fed. Reg. 38122 (July 12, 2007.).

Support for eliminating the facsimile exemption

BCBSA supports CMS s goal of eliminating the facsimile exemption to encourage physicians and pharmacies to move to electronic prescribing using electronic transactions compliant with the mandated SCRIPT standards. Eliminating the facsimile exemption could hasten this change by requiring those approximately 127,500 identified prescribers with SCRIPT-capable software who are instead using a fax option in the software to begin using SCRIPT transactions simply by pushing a button. We understand the proposed change to affect both the prescriber generating the prescription and the pharmacy receiving it neither would be compliant if generating or receiving a facsimile as part of a transaction subject to the e-prescribing standards.

Moderating the impact of eliminating the exemption

While we support and applaud CMS s goal of advancing e-prescribing, we would recommend taking steps to moderate the impact of too aggressive an implementation timeline because of the following three issues.

1. Readiness of small prescribers

This group includes small prescribers, the 80% of non-SCRIPT using independent pharmacies CMS identified in the proposed rule, and any other dispensers who have not yet invested in SCRIPT based e-prescribing systems. For example, in one BCBS Plan s pharmacy network, 20% of pharmacies are capable only of receiving facsimile prescriptions. Eliminating the facsimile exemption could affect the capacity of such pharmacies to meet their contractual obligations with health plans.

2. Reliability of networks in emergencies

E-prescribing systems often use the facsimile prescription option as a failsafe back-up when there are information technology and internet connectivity problems that forestall electronic data transactions. This fail safe capability ensures that the physician continues to be able to write the prescription using the e-prescribing interface and capture the data. It also ensures that neither the patient nor the physician is inconvenienced by having to revert to paper-based prescriptions while the system is down. A blanket elimination of the fax exemption could inadvertently terminate this currently seamless failsafe option.

3. Integration into small physicians workflow

Eliminating the facsimile exemption may also impact physician workflow. With regard to the failsafe capability above which would require that the physician temporarily use a written prescription until the network connections are restored, there is ample industry experience showing that physician acceptance of the e-prescribing technology is lower where the technology is unreliable or lacks technical support.

The other negative influence is where the system application is inconsistent. Consider, for example, restricted class II drugs: federal law requires a written prescription signed by the physician. For these prescript

CMS-1385-P-15400-Attach-1.DOC

Submitter : **Dr. Thomas Bright** **Date: 08/31/2007**

Organization : **Urology Tyler, PA**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See attachment

15401

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : **Miss. Lisa Wojciechowski** **Date: 08/31/2007**

Organization : **Detroit Medican Center**

Category : **Hospital**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Lisa Wojciechowski and I am currently employed with Detroit Medical Center's Center for Spinal Cord Injury Recovery. I am a certified athletic trainer.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restriet their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Lisa M. Wojciechowski, ATC

Submitter : **Dr. Ragini Lakhia** **Date: 08/31/2007**

Organization : **MLD Pathology**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018
Attention: CMS-1385-P
To Whom It May Concern:
This letter serves to submit comments on the Physician Self-Referral Provisions of CMS-1385-P entitled Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008. I am a board-certified pathologist and a member of the College of American Pathologists. I practice in Houston, Texas as part of a 7 member pathology group working both in a hospital setting and through our independent laboratory.
I congratulate CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. Clearly, the risk of over-utilization and increased costs to CMS exist when a physician profits from the number of specimens sent to their own laboratory. I am aware of arrangements in my practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group s patients. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services.
Specifically I support the expansion of the anti-markup rule to purchased pathology interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. These revisions to the Medicare rcassignment rule and physician self-referral provisions are necessary to eliminate financial self-interest in clinical decision-making. I believe that physicians should not be able to profit from the provision of pathology services unless the physician is capable of pcrsonally performing or supervising the service.
Opponents to these proposed changes assert that their captive pathology arrangements enhance paticnt care. I agree that the Medicare program should ensure that providers furnish care in the best interests of their patients, and, restrictions on physician self-referrals are an imperative program safeguard to ensure that clinical decisions are determined solely on the basis of quality. The proposed changes do not impact the availability or delivery of pathology services and are designed only to remove the financial conflict of interest that compromises the integrity of the Medicare program.
Sincerely,
Ragini D. Lakhia, M.D

Submitter : **Mr. Rob Sundquist** **Date: 08/31/2007**

Organization : **Creekview High School**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Rob Sundquist. I am the Director of Sports Medicine and Head Athletic Trainer at Creekview High School in Carrollton, Texas. I have a Masters of Science degree in Exercise Physiology; I have been in my current job nine years and have been a certified athletic trainer for 14 years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Rob Sundquist, MS ATC LAT

Submitter : **Dr. Thomas Bright** **Date: 08/31/2007**

Organization : **Urology Tyler, PA**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See Attachment

CMS-1385-P-15405-Attach-1.DOC

15405

August 31, 2007

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1385-P
P O Box 8018
Baltimore, MD 21244-8018

Re: Physician Self-Referral Provision

Ladies and Gentlemen:

As a physician practicing at Urology Tyler, PA, in Tyler, Texas, I am acutely aware of both the clinical and cost issues that are important to the Medicare beneficiary and CMS. As a urologist, I have been involved with providing my patients lithotripsy and other cutting edge therapies for urological disease – services that would not have been widely available to the Medicare beneficiary without the involvement of urology joint ventures that dramatically expanded patient access by taking the risk of providing costly services. Yet in the July 2, 2007 released 2008 Physician Fee Schedule proposal, CMS attacks the substance of the very joint ventures that by all accounts have saved Medicare millions of dollars. Let me address the different anti-physician ownership proposals separately and as they were enumerated in the proposal.

1. **Under Arrangements**

The substance of the CMS proposal is to ban legitimate physician joint ventures from contracting with hospitals to provide therapeutic services that are designated health services (DHS) *only* because they are performed in a hospital setting. These therapeutic services include a variety of laser procedures for benign prostate disease and cryotherapy for cancer of the prostate. CMS takes the view that physicians who invest in these ventures do so at the expense of good patient care. My experience is quite the opposite.

Indeed, hospitals balk at buying state of the art technology, such as the new laser, even if it is clinically superior, because of the expense and the fact that rapidly changing technology makes today's "best" tomorrow's "obsolete". Through urology joint ventures, we have been able to improve clinical care and take that risk of obsolescence, when our institutions would not. Sometimes hospitals will not invest in a new capital because it will result in lesser use of other services that they currently provide. They do not want to make a capital investment and lose an existing revenue source. Lithotripsy is a good example of this. Physicians formed joint ventures to buy lithotripters because hospitals did not want to make a large capital investment and at the same time cut off a revenue stream for their operating

rooms. Physicians wanted a better and less invasive treatment for their patients and were fought at every turn by hospitals.

In addition, a single hospital often does not have enough volume to justify the expense of a large capital investment. Physicians who want to have up-to-date treatment for their patients are willing to invest with other physicians who practice at other hospitals. Joint ventures involve physicians so that usage can be spread among several hospitals. The healthcare system, including CMS, benefits because our ventures mobilize technology and take it far and wide, to both urban and rural settings, and spread the cost among several providers, reducing overall capital costs.

As the court in ASL v. Thompson noted, extracorporeal shockwave lithotripsy is not a DHS, and common sense would dictate that the other therapeutic services that urologist's join together to bring their communities though the hospital would fall in the same category.

Most important, it appears that the reason that CMS wants to ban services under arrangements where there is a physician ownership is it has heard of questionable diagnostic imaging arrangements that are referenced in your commentary. Diagnostic imaging is a DHS in any setting as the result of overutilization and improper referrals identified in bona fide studies. CMS does not identify any overuse or improper referrals for other services such as laser services and other urological procedures. Simple fairness would dictate that under arrangements should not be banned for services that are not otherwise DHS (if not furnished in a hospital).

Where urologists perform therapeutic procedures, the professional fee is greater that the distribution for any particular referred procedure that the physician will earn from his investment in the joint venture. In this case the referring physician is not likely to be induced to refer based on the portion of the technical fee that he will earn in distributions from the investment. CMS should not prohibit services under arrangements where the investor physician performs the professional portion of the procedure.

2. **Per Click Fee**

CMS's proposal to ban per click fees flies directly in the face of Congressional intent, as you note in your commentary. CMS should not ban a compensation method that Congress stated is permitted.

Further, the commentary indicates that CMS is concerned with the per click arrangements for DHS, yet the proposed rule suggests that it is to be more broadly applied and no per click arrangements would be permitted if physicians have ownership in the service. I believe that per click payments should be permitted. But, at the very least, the ban should not apply to services that are not DHS.

Sometimes a patient will need a procedure that is less often performed and it is difficult to calculate this into the compensation arrangements. For example, in some cases a patient who receives a lithotripsy procedure also needs to have a stent inserted or removed. Or, the patient may need an ureturoscopy or a cystoscopy. The company furnishing the service and the hospital receiving the service cannot calculate in advance how often this will occur or which procedures will be required. Per click fees balance the risk.

As mentioned above, physician joint ventures have brought new, innovative therapeutic technology to my community because the doctors were willing to bear the risk of failure. Our hospitals are risk averse and, thus, wanted physician groups to bear the risk of low volume. As a consequence, hospitals would only enter into per click arrangements in order to protect themselves from low or no volume. Thus, the per click fee arrangement is essential to bringing new, improved treatments to many places in America, by allowing cash strapped hospital to pay the risk-taking doctor joint venture to bring the new treatment to them, without the hospital having any financial risk for less that projected use or adoption.

3. Percentage Fee Reimbursement

The same entrepreneurial spirit that created value for the per click fee arrangement did the same for the percentage fee arrangement. Again, the driving force for the origin of these payment methods to doctor joint ventures was apportionment of the risk of failure of adoption or low volume of new therapeutic modalities. As new therapies are developed in the future, the Medicare patient will be harmed by denial of access to these procedures, unless CMS understands the utility of the past.

4. Stand in the Shoes

CMS's goal seems to be the push as many procedures are possible into the ambulatory surgical center (ASC) setting where the reimbursement will be lower, and thus save Medicare money. But many community ASCs are owned partially or entirely by a local hospital. If referral to an ASC owned or controlled by a hospital is viewed as a referral to the hospital, it would make it impossible for legitimate physician joint ventures to provide services at those ASCs. The likely result would be for physicians to withdraw from hospital-owned ASCs and build additional ASCs to provide service to their patients, with the attendant costs and very likely the demise of the efficiencies of the current methodology.

5. Burden of Proof

CMS proposes in any action involving Stark regulation it is the provider that would have to prove that referrals were not made in violation of Stark. Further, Stark penalties extend to anyone who "causes a claim to be submitted in violation of the regulations." That could be interpreted to mean that any party to a contract that

CMS believes is in violation could be subject to huge fines. Most Stark exceptions require payments to be made at fair market value and in a manner that does not reflect the volume or value of referrals or other business generated between the parties. How are providers and physicians going to prove the negative – that compensation does not reflect the volume or value of referrals or other business generated between the parties? Moreover, valuation experts often disagree on what is fair market value. If a better example of predatory behavior or abuse of power can be shown, I would like to see it. Not only do I take care of the health problems of the Medicare beneficiary at the price set arbitrarily by CMS, I now fact eh undeclared burden of a hidden tax in which I must prove my actions were legal, rather than the governmental agency which writes the law proving that my action was illegal. CMS will sit as judge and jury.

In conclusion, I would ask CMS to differentiate beneficial therapeutic joint ventures which are not of themselves DHS from the questionable diagnostic ventures that physicians and hospitals may have propagated. With certainty both CMS and the urology community can say that our therapy joint ventures have broadened access to new technology for Medicare patients, brought needed efficiency to the market and simultaneously saved CMS hundreds of millions of dollars. To jeopardize such a time tested and proven model would seem foolhardy, even in CMS's rational attempt to eliminate some bad behavior.

Sincerely,

Thomas C. Bright, III, MD
Urology Tyler, PA
700 Olympic Plaza #700
Tyler, Texas 75701

Submitter : Dr. Robert Zwolak **Date:** 08/31/2007

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please consider the attached MS Word Document that contains the entire Society for Vascular Surgery comment fore 1385 P.

Thank You
R. Zwolak MD, Ph.D.

Submitter : Mr. Jay Greissing **Date:** 08/31/2007

Organization : Plasma Protein Therapeutics Assoc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15407-Attach-1.DOC

CMS-1385-P-15407-Attach-2.PDF

15407

PPTA
Plasma Protein Therapeutics Association

August 31, 2007
Reference No.: FASC07XX v2

Kerry Weems
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS–1385–P (Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008)

Dear Administrator Weems:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the proposed rule regarding revisions to payment policies under the Medicare physician fee schedule, published in the *Federal Register* on July 12, 2007 ("Proposed Rule").[1] As an association deeply committed to the health and safety of the patients it serves, these comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("plasma protein therapies") in the physician office setting.

PPTA is the association that represents the manufacturers of plasma protein therapies. These therapies, which include albumin, blood clotting factor, alpha-1 antitrypsin, and intravenous immunoglobulin ("IVIG"), are used to treat a variety of orphan diseases and serious medical conditions for a very small, fragile patient population in the United States. PPTA members produce more than 80 percent of the plasma protein therapies for the U.S. market and more than 60 percent of such therapies for global consumption.

Patient access to plasma protein therapies is dependent on adequate physician reimbursement for the acquisition and administration of these biologicals. Because PPTA remains very concerned that the manner in which physicians and suppliers are reimbursed for the costs they incur related to furnishing IVIG therapies is insufficient, we applaud the Centers for Medicare and Medicaid Services ("CMS") for its proposal to

[1] Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 72 Fed. Reg. 38122 (July 12, 2007).

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continue to reimburse for IVIG preadministration-related services (G0332) for calendar year ("CY") 2008 at the current reimbursement rate. PPTA further supports the agency's proposal with regard to the future publication of the blood clotting factor furnishing fee update.

I. DISCUSSION

A. BACKGROUND

PPTA remains concerned with the access difficulties afflicting more than 10,000 Medicare beneficiaries who rely on regular infusions of IVIG therapies. PPTA has consistently argued that the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") (Pub. L. No. 108-173, 117 Stat. 2066 et. seq. (2003)) led to a reimbursement shortfall for IVIG therapies in the physician office setting. The MMA instituted the market-based manufacturer's average sales price ("ASP") for payment for most drugs under Medicare Part B, including IVIG when furnished by physicians and suppliers.[2] By shifting reimbursement methodology in this site of service for IVIG from 95 percent of the average wholesale price ("AWP") to 85 percent of the AWP in 2004, and then finally to 106 percent of the ASP in 2005, the MMA significantly reduced reimbursement levels for IVIG in the physician office.[3] the ASP methodology went into effect in physician office in 2005,[4] some physicians were unable to continue to offer IVIG therapies to their patients in this setting because 106 percent of the ASP does not adequately reimburse providers for the acquisition of IVIG.

Both the U.S. Department of Health and Human Services ("HHS")[5] and the Immune Deficiency Foundation and ("IDF")[6] have issued recent reports that support PPTA claims that insufficient reimbursement is a leading factor in the difficulties patients face in accessing IVIG. This reimbursement shortfall resulted in patient migration from

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[2] *See* 42 U.S.C. § 1395w-3a (2007).
[3] *See* 42 U.S.C. § 1395u(o)(1)(E) (2007).
[4] *See* Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 Fed. Reg. 66236, 66299 (Nov. 15, 2004) (codified by 42 C.F.R. § 414.804 (2007)).
[5] *See* OFFICE OF THE ASS'T SEC. FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH AND HUMAN SERV., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV) (2007) [hereinafter "ASPE Report"], at 4-22 (discussing reimbursement levels and noting difficulties Medicare beneficiaries confront in finding infusion sites); *see* OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH AND HUMAN SERVS., INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (2007) [hereinafter "OIG Report"], at 15 (concluding that a significant percentage of sales of IVIG to hospitals and physicians were at prices at or above the Medicare payment rate for the third quarter of 2006).
[6] *See* IMMUNE DEFICIENCY FOUNDATION, ASSESSING THE IMPACT OF CHANGES IN REIMBURSEMENT REGULATIONS AND PRODUCT AVAILABILITY ON ACCESS TO INTRAVENOUS GAMMAGLOBULIN TREATMENT AMONG PRIMARY IMMUNE DEFICIENCY PATIENTS 17 (2006) (revealing that a significant majority of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).

the physician office to the hospital outpatient department.[7] The shift in site of service for those patients requiring IVIG has led to further access difficulties because of the allocation system for IVIG.[8] PPTA believes, however, that Medicare beneficiaries should be able to obtain IVIG therapies best suited for their individual needs in the most appropriate site of service, and more suitable reimbursement levels would effectuate such patient autonomy.

PPTA welcomes the attention given and action taken by CMS to address this very difficult patient access situation. We are especially grateful that the agency decided to grant new brand specific "Q" codes effective July 1, 2007 to four liquid IVIG therapies and two other immune globulin therapies in response to PPTA's February 21, 2007 request that IVIG products that were not on the market as of October 1, 2003 be assigned separate codes in order to be consistent with the ASP statute. PPTA further appreciates the agency's decision to implement an additional payment for IVIG preadministration-related services and the proposal to continue this payment at the current level. As we will discuss later, PPTA hopes your proposal to extend this payment through CY 2008 will be finalized. We believe such actions taken by the agency are a good first step to help improve patient access to IVIG therapies.

As the recent HHS studies illustrate, the ASP methodology does not reflect the true acquisition cost of IVIG therapies.[9] The Government Accountability Office ("GAO") has further argued that "a sufficient empirical foundation does not exist for setting the payment rate for Medicare Part B drugs at 6 percent above ASP."[10] Additionally, in a 2005 study commissioned by PPTA, The Lewin Group determined there is an 8 percent shortfall for the acquisition of IVIG in the physician office. Such analysis by HHS and GAO should provide CMS with enough support to consider a payment adjustment to the ASP plus six percent in order to address the reimbursement shortfall providers experience in acquiring this critical therapy. The analysis from The Lewin Group could be used to provide guidance on what the appropriate amount may be.

In addition to the reimbursement for the product and preadministration-related services, CMS also reimburses providers for the costs of administering the infusion of

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[7] *See, e.g.*, Ricardo Alonso-Zaldivar, *Crucial But Costly Treatment Is Drying Up With Funding: Thousands Of Elderly Patients Who Need Intravenous Antibodies Are Hurt By Medicare Cutbacks - More Pain Could Be On The Way,* L.A. TIMES, February 28, 2006, at A8 (illustrating the challenges, including shifts in sites of service, patients must overcome to receive IVIG therapies because of the Medicare reimbursement cuts).

[8] *See* ASPE Report, *supra* note 5 at 2-29.

[9] *See, e.g.* OIG Report, *supra* note 5 at 9 (demonstrating that physicians are experiencing a significant reimbursement shortfall in acquiring IVIG therapies because the majority of IVIG sales to physicians in the third quarter of 2006 by the three largest IVIG distributors are at prices exceeding the reimbursement levels for that quarter).

[10] *See Hearing on Medicare Reimbursement of Physician-Administered Drugs Before the House Comm. on Ways and Means Subcomm. on Health*, 109th Cong. (2006) (statement of A. Bruce Greenwald, Director, Health Care, GAO).

IVIG. As you know, the Current Procedural Terminology ("CPT") codes of the American Medical Association ("AMA") are used for reporting medical services and procedures, including IVIG infusions. For example, the first hour of infusing IVIG is assigned to CPT code 90765, while the second hour of infusing IVIG is assigned to CPT code 90766.[11] For each CPT code, CMS assigns relative value units ("RVUs") to services that reflect (1) physician work, such as the time, skill, and intensity it takes to provide the service, (2) practice expenses, and (3) malpractice costs.[12] After the RVUs are adjusted for geographic variations in costs by the geographic practice cost indices ("GPCI"),[13] they are then converted into a dollar payment amount by a conversion factor, which for 2007 is $37.8975.[14] According to CMS, this conversion factor is scheduled to be reduced by 9.9 percent for CY 2008.[15] Without Congressional intervention, such a reduction could further hinder patient access to IVIG and other important drugs and biologicals.

PPTA would also like to comment on the CPT codes to which IVIG is assigned. PPTA respectfully disagrees with the inadequate work RVUs that CMS assigned to CPT codes 90765 and 90766 for CY 2007, and proposes for 2008. Although the AMA's Relative Value Update Committee ("RUC") recommends RVUs to CMS, CMS ultimately decides the pertinent figures comprising each RVU. While PPTA has not completed an analysis on the work RVUs assigned to CPT codes 90765 and 90766, we respectfully contend that assigning the first and additional hours of IVIG infusion to these codes is an oversight because the work RVUs fail to account for the complexities of infusing IVIG.

The MMA called for CMS to evaluate drugs according to the complexity of administration. The resulting statutory provision requires CMS to promptly evaluate drug administration codes for physicians' services to ensure accurate reporting and billing of those services, taking into account levels of complexity of the administration and resource consumption.[16] Although IVIG infusions are more complex and resource intensive than many other types of infusions currently reported using the same drug administration CPT codes 90765 and 90766, the RUC and CMS evidently believe IVIG infusions to be of low complexity, similar to a saline infusion. The resources required to administer IVIG, however, exceed reimbursement.

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[11] *See* Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; 71 Fed. Reg. 69623, 69974 (Dec. 1, 2006).

[12] *See* 42 U.S.C. § 1395w-4(c) (2007).

[13] *See* 42 U.S.C. § 1395w-4(e).

[14] In determining the administration payment for IVIG and other Part B drugs, one must use the following equation for each CPT code as appropriate: [(RVU work x budget neutrality adjustor x GPCI work) + (RVU PE x GPCI PE) + (RVU malpractice x GPCI malpractice)] x the conversion factor.

[15] *See* Letter from Thomas A. Gustafson, Ph.D., Acting Director, Center for Medicare Management, U.S. Dep't of Health & Human Servs., to Glen M. Hackbarth, Chair, Medicare Payment Advisory Commission (Feb. 28, 2007).

[16] 42 U.S.C. § 1395w-4(c)(2)(J).

For CY 2008, until CMS and the RUC can better evaluate the costs of the administration of IVIG, PPTA urges CMS to issue two G codes that will provide a more accurate reimbursement payment for the administration of an IVIG infusion -- one to account for the first hour of infusion and one to be used for each additional hour of infusion. In terms of resources required, PPTA believes the infusion of IVIG is most similar to the infusion of chemotherapy drugs and issuing this temporary payment code will help alleviate any problems that may arise in providing patients with safe and effective infusions of this lifesaving therapy.

Similar to the infusion of chemotherapy, an IVIG infusion requires the presence of a trained infusion nurse to administer the infusion and to monitor the patient during the entire infusion. As you may know, the infusion of IVIG has been associated with:

- renal dysfunction;
- acute renal failure;
- osmotic nephrosis;
- thrombotic events; and
- death.

If CMS does not more accurately reimburse the administration of an IVIG infusion, patient safety could be compromised because providers may be forced to make a business decision to no longer continue to use these nurses to administer IVIG and monitor the patients receiving the infusion. The continued presence of a trained infusion nurse for the entirety of an IVIG infusion is essential to ensure that both IVIG is properly administered to Medicare beneficiaries and such patients are appropriately monitored for these adverse reactions. For example, IVIG must be administered at the minimum concentration available and the minimum rate of infusion practicable to those patients with a predisposition to acute renal failure. In addition, the nurse can monitor those patients at risk for thrombotic events, including those patients with hyperviscosity, atherosclerosis, and cardiovascular disease. PPTA implores CMS to consider these complexities and dangers associated with this infusion and for CY 2008, assign the administration of IVIG infusion to more appropriate G codes.

B. CODING—PAYMENT FOR IVIG ADD-ON CODE : CMS SHOULD FINALIZE THE PROPOSAL TO CONTINUE THE SEPARATE PAYMENT FOR IVIG PREADMINISTRATION_RELATED SERVICES AND SHOULD MAKE THIS PAYMENT PERMANENT

IVIG therapies are single source, as defined by the ASP statute,[17] orphan drugs[18] that treat patients with immune deficiencies and other serious, chronic medical disorders. According to the IDF, these therapies are the only effective treatment for primary immune deficiency disease ("PIDD").[19] Currently, the FDA has approved existing IVIG therapies for six clinical indications, including treatment of: (1) PIDD; secondary immune deficiency diseases, such as (2) pediatric HIV and (3) B-cell chronic lymphocytic leukemia, (4) idiopathic thrombocytopenic purpura, which is an autoimmune bleeding disorder, (5) Kawasaki disease, and (6) bone marrow transplantation.[20] For indications such as PIDD, IVIG enhances the defective components of a patient's immunity to fight and protect against infection and complications of infection. Patients relying upon IVIG therapies usually require infusions every three to four weeks for the duration of their lives.[21]

As you know, CMS established a G-code (G0332), effective January 1, 2006, in order to address the significant resources necessary to manage inventory, locate and acquire product, reschedule infusions due to product availability and patient needs, and provide the proper therapy and dose to patients.[22] PPTA appreciates the recognition by CMS of these additional costs incurred by physicians in providing IVIG therapies to Medicare beneficiaries. We agree with the Secretary of HHS about the importance of this payment.[23]

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[17] 42 U.S.C. § 1395w-3(c)(6)(D) (2007) (specifying that a biological, which each IVIG therapy is, is a "single source drug or biological").

[18] An "orphan drug" is a drug used to treat a rare disease or condition that "affects less than 200,000 persons in the United States, or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug." *See* 21 U.S.C. § 360bb(a)(2) (2007).

[19] *See* Immune Deficiency Foundation *at* http://www primaryimmune.org/igivreimb/igivreimb_bkgnd.htm (last visited August 12, 2007).

[20] PRIMARY IMMUNODEFICIENCY COMMITTEE OF THE AMERICAN ACADEMY OF ALLERGY, ASTHMA, AND IMMUNOLOGY, PRACTICE PAPER ON THE APPROPRIATE USE OF INTRAVENOUSLY ADMINISTERED IMMUNOGLOBULIN 6 (Jordan S. Orange, MD, PhD, ed., 2005).

[21] *Id.* at 15.

[22] 70 Fed. Reg. 70116, 70220 (Nov. 21, 2005).

[23] *See, e.g.*, Letter from Michael O. Leavitt, Secretary Dep't of Health & Human Servs., to Rep. Ellen O. Tauscher (Aug. 29, 2006) (demonstrating the agency's support for the preadministration payment in his response to a May 31st letter which was led by Representative Joe Pitts and signed by 34 other Members of Congress, urging CMS to consider a both a payment adjustment and brand-specific reimbursement for IVIG to address its reimbursement shortfall and improve patient access to this lifesaving therapy).

The Proposed Rule would continue payment for G0332 for CY 2008 at the current reimbursement rate, which is $71 in the physician office.[24] PPTA supports the agency's proposal, which is consistent with the position of the Secretary of HHS. We note that, in the Proposed Rule, CMS expresses a concern that continuing this payment could "further distort the [IVIG] market" or create incentives for inappropriate utilization.[25] In the more than 20 months that CMS has made payments for IVIG preadministration-related services, PPTA has seen no evidence that this payment has created market distortions or incentives for inappropriate utilization. Rather, PPTA believes that without this payment, a greater number of health care providers would have discontinued providing IVIG to Medicare beneficiaries. As a result, we see no foundation for the concerns raised by CMS and urge CMS to both finalize the proposal and make the additional payment permanent.

We believe maintaining G0332 for CY 2008 and beyond, as well as the agency's recent decision to provide brand-specific reimbursement for the four liquid IVIG therapies should play a significant role in improving patient access to IVIG therapies. This provision in the Proposed Rule to continue to reimburse G0332 in CY 2008 is another example of the tremendous effort CMS has undertaken to resolve the existing IVIG access barriers faced by Medicare beneficiaries that rely on these lifesaving therapies. PPTA does request that the agency, when finalizing the continuation of the payment for preadministration-related services for IVIG in CY 2008, please include G-0332 in Addendum B as it is not currently present in that location in the Proposed Rule. In the interest of improving patient access to IVIG, PPTA also urges that CMS consider increasing the payment amount for G0332 for CY 2008 if CMS is unable to provide a payment adjustment to the ASP plus six percent for the product. We again thank you for your commitment in this area.

C. ASP ISSUES: CMS SHOULD PROVIDE MORE GUIDANCE AND REVISIONS TO ITS PROPOSAL ON BUNDLED PRICE CONCESSIONS

In the interest of reimbursing physicians as accurately as possible for all physician-administered drugs, especially IVIG therapies, PPTA appreciates the efforts taken by CMS to provide additional guidance in calculating the ASP. PPTA, however, is seeking more guidance from the agency on not only the proposed definition of bundled arrangements, but also the proposed application of this definition in calculating the ASP. We are especially concerned that one may interpret the proposed definition to include any line-item discount contract a "bundled arrangement" if such contract includes a price concession on more than one nine-digit NDC, even if such drugs are not tied together for the purpose of a discount. PPTA believes such a broad interpretation could actually further distort ASP calculations, rather than bring more clarity and accuracy to the process. Until more guidance is provided, PPTA urges CMS to continue to allow for

[24] 72 Fed. Reg. at 38143.
[25] *Id.*

manufacturers to make reasonable assumptions in accounting for price concessions in bundled arrangements in their calculation of the ASP for their products.

In response to a January 2007 report from the Medicare Payment Advisory Committee ("MedPAC"), *Report to Congress: Impact of Changes in Medicare Payments for Part B Drugs*, CMS now believes it should define bundled sales arrangements and specify the methodology for manufacturers to use in allocating price concessions earned under such arrangements in calculating the ASP. CMS had proposed addressing this issue in its CY 2007 Physician Fee Schedule proposed rule,[26] but opted against including it in its final rule last year.[27] In the absence of any specific guidance from CMS on how to allocate price concessions in such arrangements, CMS directed manufacturers to "make reasonable assumptions in its calculations of the ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices."[28] Currently, the ASP must include price concession such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates, except for the Medicaid outpatient drug rebates.[29] Bona fide service fees are not considered price concessions for the purpose of calculating the ASP.[30]

Although the flexibility to use "reasonable assumptions" has been beneficial in some instances, PPTA agrees with both MedPAC and CMS that without clear guidance on how to treat bundled sales arrangements, the ASP for some Medicare Part B drugs may be inaccurate, which could potentially drive some products from the marketplace, and possibly create a reimbursement shortfall for physicians. In the case of IVIG, such a result would be very dangerous for patients. We further support CMS' desire that any definition of bundled sales arrangements under the ASP be consistent with the definition of "bundled sales" as recently proposed and finalized for the purpose of the average manufacturer's price ("AMP"). Without more guidance and revisions to the language, however, PPTA does not believe the proposed definition and proposed application of that definition in calculating the ASP, as drafted, will further the goals of MedPAC and CMS.

In the Proposed Rule, CMS summarizes the MedPAC Report and discusses the two proposals offered by MedPAC for consideration to achieve more accurate ASP calculations. The MedPAC report recommends that the CMS clarify ASP reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug.[31] MedPAC further stated that CMS should

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[26] 71 Fed. Reg. at 49903
[27] 71 Fed. Reg. at 69673.
[28] *Id.* at 69675.
[29] *See* 42 C.F.R. § 414.804(a)(2)(i).
[30] *See* 42 C.F.R. § 414.804(a)(2)(ii).
[31] *See* MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO CONGRESS: IMPACT OF CHANGES IN MEDICARE PAYMENTS FOR PART B DRUGS 9 (2007)

ensure any guidance it issues with regard to the allocation of discounts be "clear" and can be implemented by manufacturers "in a timely fashion."[32] If CMS were to require manufacturer's to reflect contingencies in their sales contracts, MedPAC believes the ASPs for the drugs involved in a bundling arrangement that relies on contingencies will be more accurate.[33] CMS could also require manufacturers to allocate bundled discounts in proportion to sales of each drug sold under the bundled arrangement.[34] Although the latter recommendation is most consistent with the AMP calculation, as discussed below, it may not accurately account for contingency sales, according to MedPAC.[35]

According to CMS in its final rule on the AMP, which was issued pursuant to the Deficit Reduction Act of 2005 (Pub. L. 109-171, 120 Stat. 4 (2006)), a bundled sale is "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement."[36] In accounting for such price concessions, the discounts must be "allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement."[37] When discounts are offered on multiple drugs in a bundled arrangement, however, "the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle."[38] CMS further believes that a "consistent methodology for addressing bundled sales in [both] the Medicaid and [the] Medicare Part B programs will reduce the burden and likelihood of errors for manufacturers calculating and reporting Medicaid rebate prices and ASP."[39] CMS echoes this sentiment throughout the Proposed Rule and proposes to adopt a definition for "bundled arrangements" under the ASP that is very similar to the above-mentioned definition of "bundled sales" under the AMP.[40]

The Proposed Rule defines a "bundled arrangement" for the purpose of the ASP to mean "an arrangement, regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement (for

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[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *See* Medicaid Program; Prescription Drugs: Final Rule, 72 Fed. Reg. 39142, 39240 to be codified in 42 C.F.R. § 447.502.
[37] *Id.*
[38] *Id.*
[39] *See* 72 Fed. Reg. at 39159.
[40] *See* 72 Fed. Reg. at 38151.

example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), *or where the resulting discount or other price concessions are greater than those that would have been available had the drugs or biologicals sold under the bundled arrangement been purchased separately or outside of the bundled arrangement.*"[41] CMS further proposes that "the manufacturer must allocate the total value of all price concessions proportionately according to the dollar value of the units of each drug sold under a bundled arrangement."[42] If multiple drugs are discounted under a single bundled arrangement, "the aggregate value of all the discounts would be proportionately allocated across all of the drugs sold under the bundled arrangement."[43]

PPTA appreciates CMS' efforts to provide clear guidance on bundled arrangements for the purpose of calculating the ASP. We are, however, concerned that this definition of bundled arrangement, similar to the definition of bundled sale for the purpose of the AMP, could be interpreted to mean that any contract that provides for discounts on multiple products, even when those discounts are not linked in any way, would qualify as a "bundled arrangement" for the purpose of calculating the ASP. Under the italicized language quoted above, such contracts could be viewed as bundled arrangements because they contain price concessions for a nine-digit NDC that are "greater than those that would have been available had the drugs or biologicals sold under [the contract] been purchased separately or outside [the contract]." If this definition of "bundled arrangement" is finalized as proposed and without additional guidance by CMS, PPTA believes that CMS could consider <u>any</u> line-item discount contract a "bundled arrangement" if such contract includes a price concession on more than one nine-digit NDC, even if such drugs are not tied together for the purpose of a discount. PPTA envisions an excessive administrative burden on manufacturers and the agency if all GPO contracts are considered "bundled arrangements" for the purpose of calculating the ASP and requests CMS to amend the definition as appropriate to clarify that those nine-digit NDCs that are not part of a contingency arrangement in larger contracts do not fall under the definition of a bundled arrangement for the purpose of calculating the ASP.

Such a broad definition also creates complications when allocating the price concessions across all sales in the bundle as would be required by the Proposed Rule. This could be especially problematic for lagged price concessions. As you know, data on price concessions is either available at the time of purchase of a product, or on a lagged basis. If the data on these price concessions are lagged, then the manufacturer is required to estimate costs attributable to these price concessions using the required estimation methodology.[44] A definition of bundled arrangement that requires reallocation of discounts that do not involve any contingencies, particularly where those

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[41] *Id.* (emphasis added).
[42] *Id.*
[43] *Id.*
[44] *See* 42 C.F.R. § 414.804(a)(8).

discounts otherwise are not lagged, could be read to require the treatment of these discounts as lagged and not includable in the estimation methodology until the performance period for the bundled arrangement is completed, because only then will the universe of sales involved in the bundle be known so that the discounts can be allocated proportionately based on the sales involved in the bundle as the proposed rule requires. Without more guidance on how to reallocate lagged price concessions in transactions that would qualify as "bundled arrangements," it appears manufacturers would be required to reallocate all the price concessions, both lagged and non-lagged, across the entire universe of sales included in the arrangement, which could be one quarter, unless the sales contract specifies a longer or shorter duration. PPTA urges CMS to provide more guidance to clarify how to reallocate lagged price concessions in order to further the agency's goal of receiving the most accurate ASP calculations by manufacturers.

Because, under Section 1847A(d) of the Social Security Act, the AMP may be used as an alternative payment methodology for Part B drugs, PPTA further believes that definition of "bundled sales" for the purpose of the AMP and "bundled arrangements" for the purpose of the ASP should be consistent. The Proposed Rule, however, includes in the definition of a "bundled arrangement" as examples of a "performance requirement" both "purchasing patterns" and "prior purchases," neither of which are included in the definition of "bundled sales." In the interest of consistency and less administrative burden for manufacturers, PPTA respectfully urges you to remove "purchasing patterns" and "prior purchases" as possible conditions for bundling arrangements in calculating the ASP.

D. ASP ISSUES: PPTA SUPPORTS THE DECISION BY CMS TO DISCONTINUE PUBLISHING THE ANNUAL BLOOD CLOTTING FACTOR FURNISHING FEE UPDATE IN THE ANNUAL PHYSICIAN FEE SCHEDULE RULE, BUT INSTEAD POST THE RELEVANT INFORMATION ON THE CMS WEBSITE

As you know, the MMA established a furnishing fee for blood clotting factor,[45] which is currently $0.152.[46] We believe this furnishing fee has been instrumental in preserving patient access to blood clotting factor in the physician office since the ASP plus six percent went into effect in 2005. PPTA supports CMS' decision in the Proposed Rule, consistent with the Social Security Act,[47] to increase this payment according to the annual consumer price index for medical care ending in June 2007. We further support the agency's proposal that, beginning in CY 2009, CMS will announce the blood clotting furnishing fee update using the applicable program instructions and posting on the CMS Web site.

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[45] *See* 42 U.S.C. § 1395u(o)(5).
[46] *See* 71 Fed. Reg. at 69680.
[47] 42 U.S.C. § 1395u(o)(5)(C).

CMS determined it is not necessary to announce the furnishing fee update as part of the rulemaking process because: (1) the timing of the rulemaking process makes it impossible to release the blood clotting factor furnishing fee for the upcoming year in the proposed rule because the annual CPI information for medical care is not available when CMS issues its proposed rule; and (2) the blood clotting factor furnishing fee is determined by statute and the CPI for medical care cannot be affected by the rulemaking process so it is not imperative that this information is released in such a manner. Moreover, removing the blood clotting factor furnishing fee update from the rulemaking process and issuing it through program instructions will expedite receipt of this information by the necessary stakeholders, who currently must wait until the issuance of the final rule, which is several months after the information could be made available. PPTA fully agrees with this rationale on how to proceed for CY 2009, and looks forward to the issuance of the blood clotting factor furnishing fee for CY 2008 in the forthcoming final rule for the physician fee schedule.

E. ASP ISSUES: CMS MUST BE CAUTIOUS IN CONSIDERING WHETHER IT IS APPROPRIATE TO APPLY THE WAMP AND AMP THRESHOLD IN REIMBURSING IVIG"

Under the ASP statute, if the OIG finds that the ASP for a product exceeds the widely available market price ("WAMP") or the AMP by a percentage threshold, the OIG informs CMS and the agency, in the next quarter, shall replace the ASP amount with the lesser of the WAMP or 103 percent of the AMP.[48] The OIG must conduct studies, which can include surveys, to determine the WAMP.[49] In the Proposed Rule, CMS proposes to continue to set the WAMP and AMP threshold at 5 percent for CY 2008.[50] While PPTA does not oppose this threshold generally, we caution CMS that any decision to apply this statutory provision to the reimbursement of IVIG could exacerbate existing difficulties a fragile patient population is experiencing in attempting to access these therapies in the physician office. Because as the two recent studies by HHS has confirmed,[51] reimbursement for the acquisition of IVIG at 106 percent of the ASP is inadequate, any reduction from that reimbursement level would be devastating to these patients who rely upon these lifesaving therapies.

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[48] 42 U.S.C. § 1395w-3a(d)(3).
[49] 42 U.S.C. § 1395w-3a(d)(1).
[50] 72 Fed. Reg. at 33152.
[51] *See* discussion, *supra* at Section II.A.

II. CONCLUSION

PPTA appreciates the opportunity to comment on the Proposed Rule. Again, we are especially grateful for your decision to continue to reimburse temporary code G0332. We urge CMS to consider carefully these comments, particularly those related to IVIG access. Many beneficiaries depend on this therapy and reimbursement should not impede their access to this necessary treatment. Please contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Julie Birkofer
Vice President, North America

PPTA
Plasma Protein Therapeutics Association

August 31, 2007
Reference No.: FASC07055

Kerry Weems
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS–1385–P (Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008)

Dear Administrator Weems:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the proposed rule regarding revisions to payment policies under the Medicare physician fee schedule, published in the *Federal Register* on July 12, 2007 ("Proposed Rule").[1] As an association deeply committed to the health and safety of the patients it serves, these comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("plasma protein therapies") in the physician office setting.

PPTA is the association that represents the manufacturers of plasma protein therapies. These therapies, which include albumin, blood clotting factor, alpha-1 antitrypsin, and intravenous immunoglobulin ("IVIG"), are used to treat a variety of orphan diseases and serious medical conditions for a very small, fragile patient population in the United States. PPTA members produce more than 80 percent of the plasma protein therapies for the U.S. market and more than 60 percent of such therapies for global consumption.

Patient access to plasma protein therapies is dependent on adequate physician reimbursement for the acquisition and administration of these biologicals. Because PPTA remains very concerned that the manner in which physicians and suppliers are reimbursed for the costs they incur related to furnishing IVIG therapies is insufficient, we applaud the Centers for Medicare and Medicaid Services ("CMS") for its proposal to

[1] Medicare Program, Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 72 Fed. Reg. 38122 (July 12, 2007).

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continue to reimburse for IVIG preadministration-related services (G0332) for calendar year ("CY") 2008 at the current reimbursement rate. PPTA further supports the agency's proposal with regard to the future publication of the blood clotting factor furnishing fee update.

I. DISCUSSION

A. BACKGROUND

PPTA remains concerned with the access difficulties afflicting more than 10,000 Medicare beneficiaries who rely on regular infusions of IVIG therapies. PPTA has consistently argued that the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") (Pub. L. No. 108-173, 117 Stat. 2066 et. seq. (2003)) led to a reimbursement shortfall for IVIG therapies in the physician office setting. The MMA instituted the market-based manufacturer's average sales price ("ASP") for payment for most drugs under Medicare Part B, including IVIG when furnished by physicians and suppliers.[2] By shifting reimbursement methodology in this site of service for IVIG from 95 percent of the average wholesale price ("AWP") to 85 percent of the AWP in 2004, and then finally to 106 percent of the ASP in 2005, the MMA significantly reduced reimbursement levels for IVIG in the physician office.[3] the ASP methodology went into effect in physician office in 2005,[4] some physicians were unable to continue to offer IVIG therapies to their patients in this setting because 106 percent of the ASP does not adequately reimburse providers for the acquisition of IVIG.

Both the U.S. Department of Health and Human Services ("HHS")[5] and the Immune Deficiency Foundation and ("IDF")[6] have issued recent reports that support PPTA claims that insufficient reimbursement is a leading factor in the difficulties patients face in accessing IVIG. This reimbursement shortfall resulted in patient migration from

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[2] *See* 42 U.S.C. § 1395w-3a (2007).

[3] *See* 42 U.S.C. § 1395u(o)(1)(E) (2007).

[4] *See* Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 Fed. Reg. 66236, 66299 (Nov. 15, 2004) (codified by 42 C.F.R. § 414.804 (2007)).

[5] *See* OFFICE OF THE ASS'T SEC. FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH AND HUMAN SERV., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV) (2007) [hereinafter "ASPE Report"], at 4-22 (discussing reimbursement levels and noting difficulties Medicare beneficiaries confront in finding infusion sites); *see* OFFICE OF INSPECTOR GENERAL U.S. DEP'T OF HEALTH AND HUMAN SERVS., INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (2007) [hereinafter "OIG Report"], at 15 (concluding that a significant percentage of sales of IVIG to hospitals and physicians were at prices at or above the Medicare payment rate for the third quarter of 2006).

[6] *See* IMMUNE DEFICIENCY FOUNDATION, ASSESSING THE IMPACT OF CHANGES IN REIMBURSEMENT REGULATIONS AND PRODUCT AVAILABILITY ON ACCESS TO INTRAVENOUS GAMMAGLOBULIN TREATMENT AMONG PRIMARY IMMUNE DEFICIENCY PATIENTS 17 (2006) (revealing that a significant majority of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).

the physician office to the hospital outpatient department.[7] The shift in site of service for those patients requiring IVIG has led to further access difficulties because of the allocation system for IVIG.[8] PPTA believes, however, that Medicare beneficiaries should be able to obtain IVIG therapies best suited for their individual needs in the most appropriate site of service, and more suitable reimbursement levels would effectuate such patient autonomy.

PPTA welcomes the attention given and action taken by CMS to address this very difficult patient access situation. We are especially grateful that the agency decided to grant new brand specific "Q" codes effective July 1, 2007 to four liquid IVIG therapies and two other immune globulin therapies in response to PPTA's February 21, 2007 request that IVIG products that were not on the market as of October 1, 2003 be assigned separate codes in order to be consistent with the ASP statute. PPTA further appreciates the agency's decision to implement an additional payment for IVIG preadministration-related services and the proposal to continue this payment at the current level. As we will discuss later, PPTA hopes your proposal to extend this payment through CY 2008 will be finalized. We believe such actions taken by the agency are a good first step to help improve patient access to IVIG therapies.

As the recent HHS studies illustrate, the ASP methodology does not reflect the true acquisition cost of IVIG therapies.[9] The Government Accountability Office ("GAO") has further argued that "a sufficient empirical foundation does not exist for setting the payment rate for Medicare Part B drugs at 6 percent above ASP."[10] Additionally, in a 2005 study commissioned by PPTA, The Lewin Group determined there is an 8 percent shortfall for the acquisition of IVIG in the physician office. Such analysis by HHS and GAO should provide CMS with enough support to consider a payment adjustment to the ASP plus six percent in order to address the reimbursement shortfall providers experience in acquiring this critical therapy. The analysis from The Lewin Group could be used to provide guidance on what the appropriate amount may be.

In addition to the reimbursement for the product and preadministration-related services, CMS also reimburses providers for the costs of administering the infusion of

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[7] *See, e.g.*, Ricardo Alonso-Zaldivar, *Crucial But Costly Treatment Is Drying Up With Funding: Thousands Of Elderly Patients Who Need Intravenous Antibodies Are Hurt By Medicare Cutbacks - More Pain Could Be On The Way*, L.A. Times, February 28, 2006, at A8 (illustrating the challenges, including shifts in sites of service, patients must overcome to receive IVIG therapies because of the Medicare reimbursement cuts).

[8] *See* ASPE Report, *supra* note 5 at 2-29.

[9] *See, e.g.* OIG Report, *supra* note 6 at 9 (demonstrating that physicians are experiencing a significant reimbursement shortfall in acquiring IVIG therapies because the majority of IVIG sales to physicians in the third quarter of 2005 by the three largest IVIG distributors are at prices exceeding the reimbursement levels for that quarter).

[10] *See Hearing on Medicare Reimbursement of Physician-Administered Drugs Before the House Comm. on Ways and Means Subcomm. on Health*, 109th Cong. (2006) (statement of A. Bruce Greenwald, Director, Health Care, GAO).

IVIG. As you know, the Current Procedural Terminology ("CPT") codes of the American Medical Association ("AMA") are used for reporting medical services and procedures, including IVIG infusions. For example, the first hour of infusing IVIG is assigned to CPT code 90765, while the second hour of infusing IVIG is assigned to CPT code 90766.[11] For each CPT code, CMS assigns relative value units ("RVUs") to services that reflect (1) physician work, such as the time, skill, and intensity it takes to provide the service, (2) practice expenses, and (3) malpractice costs.[12] After the RVUs are adjusted for geographic variations in costs by the geographic practice cost indices ("GPCI"),[13] they are then converted into a dollar payment amount by a conversion factor, which for 2007 is $37.8975.[14] According to CMS, this conversion factor is scheduled to be reduced by 9.9 percent for CY 2008.[15] Without Congressional intervention, such a reduction could further hinder patient access to IVIG and other important drugs and biologicals.

PPTA would also like to comment on the CPT codes to which IVIG is assigned. PPTA respectfully disagrees with the inadequate work RVUs that CMS assigned to CPT codes 90765 and 90766 for CY 2007, and proposes for 2008. Although the AMA's Relative Value Update Committee ("RUC") recommends RVUs to CMS, CMS ultimately decides the pertinent figures comprising each RVU. While PPTA has not completed an analysis on the work RVUs assigned to CPT codes 90765 and 90766, we respectfully contend that assigning the first and additional hours of IVIG infusion to these codes is an oversight because the work RVUs fail to account for the complexities of infusing IVIG.

The MMA called for CMS to evaluate drugs according to the complexity of administration. The resulting statutory provision requires CMS to promptly evaluate drug administration codes for physicians' services to ensure accurate reporting and billing of those services, taking into account levels of complexity of the administration and resource consumption.[16] Although IVIG infusions are more complex and resource intensive than many other types of infusions currently reported using the same drug administration CPT codes 90765 and 90766, the RUC and CMS evidently believe IVIG infusions to be of low complexity, similar to a saline infusion. The resources required to administer IVIG, however, exceed reimbursement.

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[11] See Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; 71 Fed. Reg. 69623, 69774 (Dec. 1, 2006).

[12] See 42 U.S.C. § 1395w-4(c) (2007).

[13] See 42 U.S.C. § 1395w-4(e).

[14] In determining the administration payment for IVIG and other Part B drugs, one must use the following equation for each CPT code as appropriate: [(RVU work x budget neutrality adjustor x GPCI work) + (RVU PE x GPCI PE) + (RVU malpractice x GPCI malpractice)] x the conversion factor.

[15] See Letter from Thomas A. Gustafson, Ph.D., Acting Director, Center for Medicare Management, U.S. Dep't of Health & Human Servs., to Glen M. Hackbarth, Chair, Medicare Payment Advisory Commission (Feb. 28, 2007).

[16] 42 U.S.C. § 1395w-4(c)(2)(J).

For CY 2008, until CMS and the RUC can better evaluate the costs of the administration of IVIG, PPTA urges CMS to issue two G codes that will provide a more accurate reimbursement payment for the administration of an IVIG infusion -- one to account for the first hour of infusion and one to be used for each additional hour of infusion. In terms of resources required, PPTA believes the infusion of IVIG is most similar to the infusion of chemotherapy drugs and issuing this temporary payment code will help alleviate any problems that may arise in providing patients with safe and effective infusions of this lifesaving therapy.

Similar to the infusion of chemotherapy, an IVIG infusion requires the presence of a trained infusion nurse to administer the infusion and to monitor the patient during the entire infusion. As you may know, the infusion of IVIG has been associated with:

- renal dysfunction;
- acute renal failure;
- osmotic nephrosis;
- thrombotic events; and
- death.

If CMS does not more accurately reimburse the administration of an IVIG infusion, patient safety could be compromised because providers may be forced to make a business decision to no longer continue to use these nurses to administer IVIG and monitor the patients receiving the infusion. The continued presence of a trained infusion nurse for the entirety of an IVIG infusion is essential to ensure that both IVIG is properly administered to Medicare beneficiaries and such patients are appropriately monitored for these adverse reactions. For example, IVIG must be administered at the minimum concentration available and the minimum rate of infusion practicable to those patients with a predisposition to acute renal failure. In addition, the nurse can monitor those patients at risk for thrombotic events, including those patients with hyperviscosity, atherosclerosis, and cardiovascular disease. PPTA implores CMS to consider these complexities and dangers associated with this infusion and for CY 2008, assign the administration of IVIG infusion to more appropriate G codes.

B. CODING—PAYMENT FOR IVIG ADD-ON CODE : CMS SHOULD FINALIZE THE PROPOSAL TO CONTINUE THE SEPARATE PAYMENT FOR IVIG PREADMINISTRATION_RELATED SERVICES AND SHOULD MAKE THIS PAYMENT PERMANENT

IVIG therapies are single source, as defined by the ASP statute,[17] orphan drugs[18] that treat patients with immune deficiencies and other serious, chronic medical disorders. According to the IDF, these therapies are the only effective treatment for primary immune deficiency disease ("PIDD").[19] Currently, the FDA has approved existing IVIG therapies for six clinical indications, including treatment of: (1) PIDD; secondary immune deficiency diseases, such as (2) pediatric HIV and (3) B-cell chronic lymphocytic leukemia; (4) idiopathic thrombocytopenic purpura, which is an autoimmune bleeding disorder; (5) Kawasaki disease; and (6) bone marrow transplantation.[20] For indications such as PIDD, IVIG enhances the defective components of a patient's immunity to fight and protect against infection and complications of infection. Patients relying upon IVIG therapies usually require infusions every three to four weeks for the duration of their lives.[21]

As you know, CMS established a G-code (G0332), effective January 1, 2006, in order to address the significant resources necessary to manage inventory, locate and acquire product, reschedule infusions due to product availability and patient needs, and provide the proper therapy and dose to patients.[22] PPTA appreciates the recognition by CMS of these additional costs incurred by physicians in providing IVIG therapies to Medicare beneficiaries. We agree with the Secretary of HHS about the importance of this payment.[23]

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[17] 42 U.S.C. § 1395w-3(c)(6)(D) (2007) (specifying that a biological, which each IVIG therapy is, is a "single source drug or biological").

[18] An "orphan drug" is a drug used to treat a rare disease or condition that "affects less than 200,000 persons in the United States, or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug." *See* 21 U.S.C. § 360bb(a)(2) (2007).

[19] *See* Immune Deficiency Foundation at http://www.primaryimmune.org/igivreimb/igivreimb_bkgnd.htm (last visited August 12, 2007).

[20] PRIMARY IMMUNODEFICIENCY COMMITTEE OF THE AMERICAN ACADEMY OF ALLERGY, ASTHMA, AND IMMUNOLOGY. PRACTICE PAPER ON THE APPROPRIATE USE OF INTRAVENOUSLY ADMINISTERED IMMUNOGLOBULIN 6 (Jordan S. Orange, MD. PhD, ed., 2005).

[21] *Id.* at 15.

[22] 70 Fed. Reg. 70116, 70220 (Nov. 21, 2005).

[23] *See, e.g.*, Letter from Michael O. Leavitt, Secretary Dep't of Health & Human Servs., to Rep. Ellen O. Tauscher (Aug. 29, 2006) (demonstrating the agency's support for the preadministration payment in his response to a May 31st letter, which was led by Representative Joe Pitts and signed by 34 other Members of Congress, urging CMS to consider both a payment adjustment and brand-specific reimbursement for IVIG to address its reimbursement shortfall and improve patient access to this lifesaving therapy).

The Proposed Rule would continue payment for G0332 for CY 2008 at the current reimbursement rate, which is $71 in the physician office.[24] PPTA supports the agency's proposal, which is consistent with the position of the Secretary of HHS. We note that, in the Proposed Rule, CMS expresses a concern that continuing this payment could "further distort the IVIG market" or create incentives for inappropriate utilization.[25] In the more than 20 months that CMS has made payments for IVIG preadministration-related services, PPTA has seen no evidence that this payment has created market distortions or incentives for inappropriate utilization. Rather, PPTA believes that without this payment, a greater number of health care providers would have discontinued providing IVIG to Medicare beneficiaries. As a result, we see no foundation for the concerns raised by CMS and urge CMS to both finalize the proposal and make the additional payment permanent.

We believe maintaining G0332 for CY 2008 and beyond, as well as the agency's recent decision to provide brand-specific reimbursement for the four liquid IVIG therapies should play a significant role in improving patient access to IVIG therapies. This provision in the Proposed Rule to continue to reimburse G0332 in CY 2008 is another example of the tremendous effort CMS has undertaken to resolve the existing IVIG access barriers faced by Medicare beneficiaries that rely on these lifesaving therapies. PPTA does request that the agency, when finalizing the continuation of the payment for preadministration-related services for IVIG in CY 2008, please include G-0332 in Addendum B as it is not currently present in that location in the Proposed Rule. In the interest of improving patient access to IVIG, PPTA also urges that CMS consider increasing the payment amount for G0332 for CY 2008 if CMS is unable to provide a payment adjustment to the ASP plus six percent for the product. We again thank you for your commitment in this area.

C. ASP ISSUES: CMS SHOULD PROVIDE MORE GUIDANCE AND REVISIONS TO ITS PROPOSAL ON BUNDLED PRICE CONCESSIONS

In the interest of reimbursing physicians as accurately as possible for all physician-administered drugs, especially IVIG therapies, PPTA appreciates the efforts taken by CMS to provide additional guidance in calculating the ASP. PPTA, however, is seeking more guidance from the agency on not only the proposed definition of bundled arrangements, but also the proposed application of this definition in calculating the ASP. We are especially concerned that one may interpret the proposed definition to include any line-item discount contract a "bundled arrangement" if such contract includes a price concession on more than one nine-digit NDC, even if such drugs are not tied together for the purpose of a discount. PPTA believes such a broad interpretation could actually further distort ASP calculations, rather than bring more clarity and accuracy to the process. Until more guidance is provided, PPTA urges CMS to continue to allow for

[24] 72 Fed. Reg. at 38149.
[25] *Id.*

manufacturers to make reasonable assumptions in accounting for price concessions in bundled arrangements in their calculation of the ASP for their products.

In response to a January 2007 report from the Medicare Payment Advisory Committee ("MedPAC"), *Report to Congress: Impact of Changes in Medicare Payments for Part B Drugs*, CMS now believes it should define bundled sales arrangements and specify the methodology for manufacturers to use in allocating price concessions earned under such arrangements in calculating the ASP. CMS had proposed addressing this issue in its CY 2007 Physician Fee Schedule proposed rule,[26] but opted against including it in its final rule last year.[27] In the absence of any specific guidance from CMS on how to allocate price concessions in such arrangements, CMS directed manufacturers to "make reasonable assumptions in its calculations of the ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices."[28] Currently, the ASP must include price concession such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates, except for the Medicaid outpatient drug rebates.[29] Bona fide service fees are not considered price concessions for the purpose of calculating the ASP.[30]

Although the flexibility to use "reasonable assumptions" has been beneficial in some instances, PPTA agrees with both MedPAC and CMS that without clear guidance on how to treat bundled sales arrangements, the ASP for some Medicare Part B drugs may be inaccurate, which could potentially drive some products from the marketplace, and possibly create a reimbursement shortfall for physicians. In the case of IVIG, such a result would be very dangerous for patients. We further support CMS' desire that any definition of bundled sales arrangements under the ASP be consistent with the definition of "bundled sales" as recently proposed and finalized for the purpose of the average manufacturer's price ("AMP"). Without more guidance and revisions to the language, however, PPTA does not believe the proposed definition and proposed application of that definition in calculating the ASP, as drafted, will further the goals of MedPAC and CMS.

In the Proposed Rule, CMS summarizes the MedPAC Report and discusses the two proposals offered by MedPAC for consideration to achieve more accurate ASP calculations. The MedPAC report recommends that the CMS clarify ASP reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug.[31] MedPAC further stated that CMS should

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[26] 71 Fed. Reg. at 49003.
[27] 71 Fed. Reg. at 69673.
[28] *Id.* at 69675.
[29] *See* 42 C.F.R. § 414.804(a)(2)(i).
[30] *See* 42 C.F.R. § 414.804(a)(2)(ii).
[31] *See* MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO CONGRESS: IMPACT OF CHANGES IN MEDICARE PAYMENTS FOR PART B DRUGS (2007).

ensure any guidance it issues with regard to the allocation of discounts be "clear" and can be implemented by manufacturers "in a timely fashion."[32] If CMS were to require manufacturer's to reflect contingencies in their sales contracts, MedPAC believes the ASPs for the drugs involved in a bundling arrangement that relies on contingencies will be more accurate.[33] CMS could also require manufacturers to allocate bundled discounts in proportion to sales of each drug sold under the bundled arrangement.[34] Although the latter recommendation is most consistent with the AMP calculation, as discussed below, it may not accurately account for contingency sales, according to MedPAC.[35]

According to CMS in its final rule on the AMP, which was issued pursuant to the Deficit Reduction Act of 2005 (Pub. L. 109-171, 120 Stat. 4 (2006)), a bundled sale is "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement."[36] In accounting for such price concessions, the discounts must be "allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement."[37] When discounts are offered on multiple drugs in a bundled arrangement, however, "the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle."[38] CMS further believes that a "consistent methodology for addressing bundled sales in [both] the Medicaid and [the] Medicare Part B programs will reduce the burden and likelihood of errors for manufacturers calculating and reporting Medicaid rebate prices and ASP."[39] CMS evinces this sentiment throughout the Proposed Rule and proposes to adopt a definition for "bundled arrangements" under the ASP that is very similar to the above-mentioned definition of "bundled sales" under the AMP.[40]

The Proposed Rule defines a "bundled arrangement" for the purpose of the ASP to mean "an arrangement, regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement (for

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[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *See* Medicaid Program; Prescription Drugs; Final Rule, 72 Fed. Reg. 39142, 39240 to be codified in 42 C.F.R. § 447.502.
[37] *Id.*
[38] *Id.*
[39] *See* 72 Fed. Reg. at 39159.
[40] *See* 73 Fed. Reg. at 30,

example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), *or where the resulting discount or other price concessions are greater than those that would have been available had the drugs or biologicals sold under the bundled arrangement been purchased separately or outside of the bundled arrangement.*"[41] CMS further proposes that "the manufacturer must allocate the total value of all price concessions proportionately according to the dollar value of the units of each drug sold under a bundled arrangement."[42] If multiple drugs are discounted under a single bundled arrangement, "the aggregate value of all the discounts would be proportionately allocated across all of the drugs sold under the bundled arrangement."[43]

PPTA appreciates CMS' efforts to provide clear guidance on bundled arrangements for the purpose of calculating the ASP. We are, however, concerned that this definition of bundled arrangement, similar to the definition of bundled sale for the purpose of the AMP, could be interpreted to mean that any contract that provides for discounts on multiple products, even when those discounts are not linked in any way, would qualify as a "bundled arrangement" for the purpose of calculating the ASP. Under the italicized language quoted above, such contracts could be viewed as bundled arrangements because they contain price concessions for a nine-digit NDC that are "greater than those that would have been available had the drugs or biologicals sold under [the contract] been purchased separately or outside [the contract]." If this definition of "bundled arrangement" is finalized as proposed and without additional guidance by CMS, PPTA believes that CMS could consider any line-item discount contract a "bundled arrangement" if such contract includes a price concession on more than one nine-digit NDC, even if such drugs are not tied together for the purpose of a discount. PPTA envisions an excessive administrative burden on manufacturers and the agency if all GPO contracts are considered "bundled arrangements" for the purpose of calculating the ASP and requests CMS to amend the definition as appropriate to clarify that those nine-digit NDCs that are not part of a contingency arrangement in larger contracts do not fall under the definition of a bundled arrangement for the purpose of calculating the ASP.

Such a broad definition also creates complications when allocating the price concessions across all sales in the bundle as would be required by the Proposed Rule. This could be especially problematic for lagged price concessions. As you know, data on price concessions is either available at the time of purchase of a product, or on a lagged basis. If the data on these price concessions are lagged, then the manufacturer is required to estimate costs attributable to these price concessions using the required estimation methodology.[44] A definition of bundled arrangement that requires reallocation of discounts that do not involve any contingencies, particularly where those

[41] *Id.* (emphasis added).
[42] *Id.*
[43] *Id.*
[44] See 42 C.F.R. § 414.804(a)(3).

discounts otherwise are not lagged, could be read to require the treatment of these discounts as lagged and not includable in the estimation methodology until the performance period for the bundled arrangement is completed, because only then will the universe of sales involved in the bundle be known so that the discounts can be allocated proportionately based on the sales involved in the bundle as the proposed rule requires. Without more guidance on how to reallocate lagged price concessions in transactions that would qualify as 'bundled arrangements,' it appears manufacturers would be required to reallocate all the price concessions, both lagged and non-lagged, across the entire universe of sales included in the arrangement, which could be one quarter, unless the sales contract specifies a longer or shorter duration. PPTA urges CMS to provide more guidance to clarify how to reallocate lagged price concessions in order to further the agency's goal of receiving the most accurate ASP calculations by manufacturers.

Because, under Section 1847A(d) of the Social Security Act, the AMP may be used as an alternative payment methodology for Part B drugs. PPTA further believes that definition of "bundled sales" for the purpose of the AMP and "bundled arrangements" for the purpose of the ASP should be consistent. The Proposed Rule, however, includes in the definition of a "bundled arrangement" as examples of a "performance requirement" both "purchasing patterns" and "prior purchases," neither of which are included in the definition of "bundled sales." In the interest of consistency and less administrative burden for manufacturers, PPTA respectfully urges you to remove "purchasing patterns" and "prior purchases" as possible conditions for bundling arrangements in calculating the ASP.

D. ASP ISSUES: PPTA SUPPORTS THE DECISION BY CMS TO DISCONTINUE PUBLISHING THE ANNUAL BLOOD CLOTTING FACTOR FURNISHING FEE UPDATE IN THE ANNUAL PHYSICIAN FEE SCHEDULE RULE, BUT INSTEAD POST THE RELEVANT INFORMATION ON THE CMS WEBSITE

As you know, the MMA established a furnishing fee for blood clotting factor,[45] which is currently $0.1752.[46] We believe this furnishing fee has been instrumental in preserving patient access to blood clotting factor in the physician office since the ASP plus six percent went into effect in 2005. PPTA supports CMS' decision in the Proposed Rule, consistent with the Social Security Act,[47] to increase this payment according to the annual consumer price index for medical care ending in June 2007. We further support the agency's proposal that, beginning in CY 2009, CMS will announce the blood clotting furnishing fee update using the applicable program instructions and posting on the CMS Web site.

[45] See 42 U.S.C. § 1395u(o)(5)
[46] See 71 Fed. Reg. at 69680.
[47] 42 U.S.C. § 1395u(o)(5)(C)

CMS determined it is not necessary to announce the furnishing fee update as part of the rulemaking process because: (1) the timing of the rulemaking process makes it impossible to release the blood clotting factor furnishing fee for the upcoming year in the proposed rule because the annual CPI information for medical care is not available when CMS issues its proposed rule; and (2) the blood clotting factor furnishing fee is determined by statute and the CPI for medical care cannot be affected by the rulemaking process so it is not imperative that this information is released in such a manner. Moreover, removing the blood clotting factor furnishing fee update from the rulemaking process and issuing it through program instructions will expedite receipt of this information by the necessary stakeholders, who currently must wait until the issuance of the final rule, which is several months after the information could be made available. PPTA fully agrees with this rationale on how to proceed for CY 2009, and looks forward to the issuance of the blood clotting factor furnishing fee for CY 2008 in the forthcoming final rule for the physician fee schedule.

E. ASP ISSUES: CMS MUST BE CAUTIOUS IN CONSIDERING WHETHER IT IS APPROPRIATE TO APPLY THE WAMP AND AMP THRESHOLD IN REIMBURSING IVIG"

Under the ASP statute, if the OIG finds that the ASP for a product exceeds the widely available market price ("WAMP") or the AMP by a percentage threshold, the OIG informs CMS and the agency in the next quarter, shall replace the ASP amount with the lesser of the WAMP or 103 percent of the AMP.[48] The OIG must conduct studies, which can include surveys, to determine the WAMP.[49] In the Proposed Rule, CMS proposes to continue to set the WAMP and AMP threshold at 5 percent for CY 2008.[50] While PPTA does not oppose this threshold generally, we caution CMS that any decision to apply this statutory provision to the reimbursement of IVIG could exacerbate existing difficulties a fragile patient population is experiencing in attempting to access these therapies in the physician office. Because, as the two recent studies by HHS has confirmed,[51] reimbursement for the acquisition of IVIG at 106 percent of the ASP is inadequate, any reduction from that reimbursement level would be devastating to these patients who rely upon these lifesaving therapies.

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[48] 42 U.S.C. § 1395w-3a(c)(3).
[49] 42 U.S.C. § 1395w-3a(c)(5).
[50] 72 Fed. Reg. at 38152.
[51] *See* discussion, *supra* at Section II.A.

II. CONCLUSION

PPTA appreciates the opportunity to comment on the Proposed Rule. Again, we are especially grateful for your decision to continue to reimburse temporary code G0332. We urge CMS to consider carefully these comments, particularly those related to IVIG access. Many beneficiaries depend on this therapy and reimbursement should not impede their access to this necessary treatment. Please contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Julie Birkofer
Vice President, North America

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Ms. Erin Arlinghaus** **Date: 08/31/2007**

Organization : **Physical Therapy and Wellness Institute**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I would like to take a moment to introduce myself. My name is Erin Arlinghaus and I completed my athletic training cirriculum at Sacred Heart University and completed my doctorate work in physical therapy at Arcadia University. I sat for both my athletic training as well as my physical therapy certifications. I am currently working in a private physical therapy practive as a physical therapist, however, I will also be working in a high school as their head athletic trainer.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of aecess to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Erin Arlinghaus, ATC, PT, BS, DPT

Submitter : Mr. Keith Berman **Date:** 08/31/2007

Organization : Health Research Associates

Category : Individual

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Please see attached comment letter.

CMS-1385-P-15410-Attach-1.DOC

Health Research Associates

HRA

2500 E. Foothill Blvd., Suite 408
Pasadena, CA 91107-7125 USA
(626) 564-0456 fax: (626) 564-1010
e-mail: kberman@sbcglobal.net

August 30, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: **CMS-1385-P**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: RESOURCE-BASED PE RVUs – Photopheresis and Therapeutic Plasma Exchange

Extracorporeal photopheresis (CPT 36522) and therapeutic plasma exchange (TPE; CPT 36514) can be safely provided in a physician-directed clinic, and are each covered by Medicare for a number of serious hematological, neurological and/or autoimmune disorders in this setting.[1],[2]

Like many other procedures that began in the hospital setting and have moved to the physician office or clinic, benefits of doing so with photopheresis and TPE include an improved patient treatment experience, reduced nosocomial infection risk in these usually immunocompromised patients, and potentially significant overall cost savings to the Medicare Trust Fund.

Unfortunately, physicians interested in bringing these two historically hospital-based apheresis procedures into the office-based setting are being completely stymied by severe under-valuations of their proposed "fully implemented" practice expense RVUs (PE RVUs). The proposed valuations will yield payment rates that fall far short of actual direct and indirect costs of providing these unusually supply-intensive procedures.

The basis for this undervaluation is driven by CMS' application of a roughly 40% "direct PE budget neutrality adjustment" ("direct adjustment"),[3] which CMS applies equally to clinical labor, supplies and equipment expenses. The impact of this "direct adjuster" then

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[1] Medicare Coverage Manual Sect. 110.14 (Coverage Issues Manual §35.60).
[2] *Fed Reg.* July 12, 2007; 72(133):38273.
[3] This direct adjuster appears likely to range between the 0.584 value published in the July 12 *Federal Register* and the 0.6186 value used in a sample PE RVU calculation for TPE which was provided to me by CMS

ripples through the entire calculation of PE RVUs: the "adjusted direct RVUs," reduced by about 40%, are fed into the indirect RVU calculation: *Indirect Pct * (Adj. Direct RVU/Direct Pct.) + Work RVU*, which in turn is further sharply reduced by an "indirect adjustment."

Applying SMS and supplemental survey data across all physicians, a hypothetical procedure involving 5 physician work RVUs and $100 in direct practice expense is accompanied by roughly $200 in indirect practice expense, for a total of $300.[4] At the end of the sequence of adjustments that CMS uses to bring down payments to match available budget dollars, that presumptive $300 in non-physician practice expenses has been pared to an average payment rate of roughly $130.

One might ask how physician providers, for whom Medicare patients often constitute a large share if not the bulk of their caseload, can afford to accept and treat Medicare patients without losing huge amounts of money and quickly going out of business. That they *are* accepting Medicare patients and not going out of business all but dictates that there is a large and widespread overstatement of direct cost inputs for many or most of the 7,000-odd procedures and services, despite having passed through the AMA "refinement" process by its RUC and PEAC bodies.

Because the allocation of RVUs is a "zero-sum" game where more RVUs assigned for some procedures means less for others, there is unfortunately a powerful incentive for physician survey respondents and medical specialty societies to exaggerate cost inputs.

In the case of photopheresis and TPE, I will document that the direct cost inputs for these two services are significantly overstated and that proposed fully transitioned PE RVUs fall well short of actual costs. I will then address how these and likely certain other highly supply-intensive procedures are systematically undervalued using the proposed PE RVU development methodology, and finally I will suggest an methodological "fix" that will enable providers to cover their actual costs and provide this pair of important services.

For each procedure, below are:

1. Aggregated direct clinical labor, supply and equipment costs;
2. Total direct PE RVUs and "adjusted" total direct PE RVUs
3. Calculated indirect PE RVUs applying direct cost-adjusted PE RVUs;
4. Total direct costs restated in RVUs, applying the originally scheduled 2007 conversion factor (CF) of $35.9848 per RVU..

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[4] *Fed Reg.* July 13, 2007; 72(133):38132. Table 2 (all physicians).

Some values presented below in Table 1 may not exactly agree with your calculated values, but I believe they are fair approximations for purposes of understanding the nature and rough magnitude of our underpayment issue.

Table 1. Unadjusted and adjusted direct and indirect PEs

Therapeutic Plasma Exchange (CPT 36514):

	Direct Costs (CPEP)	Direct PE RVUs	Total Direct RVUs Total Direct Adj. RVUs[5]
Clinical labor	$76.86	2.136	*9.13* ↓ **5.65**
Supplies	$210.08	5.838	
Equipment	$41.67	1.158	
Total direct costs:	**$328.61**	***9.13***	+ Total Indirect Adj. RVUs[6] **4.76**

Proposed fully implemented non-facility PE RVUs: **10.41**

Photopheresis (CPT 36522):

	Direct Costs (CPEP)	Direct PE RVUs	Total Direct RVUs Total Direct RVUs (Adj.)[5]
Clinical labor	$92	2.56	*32.98* ↓ **20.40**
Supplies[7]	$1,045	29.03	
Equipment[8]	$50	1.39	
Total direct costs:	**$1,187**	***32.98***	+ Total Indirect Adj. RVUs[9] **16.64**

Proposed fully implemented non-facility PE RVUs: **37.04**

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[5] Applying a "direct adjustment" factor of 0.60 to total direct RVUs; CMS applied 0.584 in 7/12/07 *Fed. Reg.*

[6] Applying an indirect adjustment factor of 0.362 to total indirect RVUs, followed by a 0.973 PCI adjustment

[7] Based on CPEP supply, updated with current average prices for photopheresis procedure kit ($976.39) and methoxsalen ($59.48) which have been submitted separately in a comment letter from the American Academy of Dermatology. NOTE: procedure kit price reflects discounts based on very high volume orders by large hospital users.

[8] Estimated from CPEP equipment with addition of light source, photopheresis, whose average price is approximately $3.64 per procedure (source: Therakos Inc.).

[9] Applying an indirect adjustment factor of 0.362 to total indirect RVUs, followed by a 0.973 PCI adjustment

The mathematics of arriving at total PE RVUs that "fully implement" the CMS "bottom-up" methodology are no different for any of the other 7,000-odd procedures and services in the Physician Fee Schedule. However, one very important distinction sets these two services (and likely a small number of others) apart: disposable supplies account for most -- 64% and 88% -- of the direct practice expense for TPE and photopheresis, respectively.

CPEP database – direct supply costs

TPE procedure. The CPEP supply inputs accurately reflect both the types and quantities of supplies that are actually used for this procedure. Notably, the major disposable item, the tubing set used in tandem with the apheresis machine, accounts for about 83% of total supply costs, while the remaining 17% comprises mostly inexpensive items commonly used in IV injection and blood collection procedures.

The $173.33 price identified for the tubing set, entered into the CPEP file in 2004, reasonably approximates the average selling price (ASP) by the product's leading supplier, which serves approximately 85-90% of the U.S. market.[10] However, this ASP reflects the heavy influence of very large-volume purchase activity – in the thousands of units – by the small minority of its largest customers, whose pricing is well below $173. Approximately 80% of customers – individual hospitals and clinics – pay between $190 and $215 (the current list price) per tubing set, reflecting in part their higher transaction and customer service-related costs. Generally the smaller the customer, the higher the unit price; according to the leading manufacturer, the ASP for most physician-directed clinics will fall close to the list price.[10]

The price for the tubing set in the CPEP database is therefore roughly $20 to $40 below the actual cost that applies for relatively low-volume physician-directed offices. The total of $210.08 that CMS presumes to reflect actual supply costs therefore may underestimate actual costs by roughly 10% to 15%; more importantly, it certainly is not an overestimate.

Photopheresis procedure. While most supply items in the CPEP database are accurate, a few important corrections need to be made. I have collaborated with the American Academy of Dermatology on these issues, and you should receive comments from the Academy requesting specific item and pricing corrections. In particular, the price identified for the photopheresis procedure kit ($858) is about $118 lower than the year-to-date ASP supplied by the manufacturer ($976.39).

Like the circumstance with the TPE tubing set, the price of this item is tiered according to customer ordering volume. At one end of the pricing spectrum are very large hospital-based cancer centers, which pay marginally less than $976 per kit. At the other end are

[10] Personal communication: Dawson Smith, Director of Sales, Therapeutics Division, North America, Gambro BCT, Inc

smaller programs, including the office-based photopheresis provider, which ordinarily purchase between 4 to 36 kits ($1,100 per kit) or 37 to 104 kits ($1,013.25 per kit). At an order quantity of more than 104 kits, the price drops to about $900 per kit.

Thus, the current CPEP price for the kit, which accounts for fully 93% of total procedural supply costs, is more accurately between $155 and $245 lower than the actual price now paid by the small office-based customer that is extremely unlikely to purchase more than $100,000 worth of inventory of this supply item.

Again, the supply component of direct costs for photopheresis are moderately understated, and certainly not overstated.

CPEP database – direct clinical labor costs

For both TPE and photopheresis, direct labor costs are a significant element of total costs, but are dwarfed by supply costs. It happens that these procedures are unusual, however, for the fact that a highly trained nurse specialist must work one-on-one through the set-up, intra-procedural phase and post-procedural phase. I understand that CMS officers have personally observed this procedure and are aware that there are no meaningful opportunities for staff "multi-tasking" during this complex procedure, which requires many steps and close monitoring of the patient's vital signs and overall health status.

Underpayment for TPE and photopheresis: a formula-driven problem

As noted earlier and presented in Table 1, supply costs account for about 64% and 83% of total direct costs in TPE and photopheresis procedures, respectively. According to data supplied by CMS at a February 15, 2006 Town Hall meeting[11] to address PE methodology options, supplies accounted for just 18% of total practice expense-related payments under the PFS.

In contrast, two other survey processes found that supplies account for 28% or 32.3% of total direct costs (Table 2):

[11] Summary of CMS Town Hall Meeting on Practice Expense (PE) Methodology, Feb. 15, 2006. Prepared by the American Society of Nuclear Cardiology. File attached to this comment letter and available online at: http://www.asnc.org/imageuploads/TEM%206%20-%20Summary%20of%20CMS%20February%2015%20Town%20Hall%20meeting%20on%20PE.pdf

Table 2. Classification of direct PEs by SMS and SMS/supplemental surveys

Source	Clinical labor	Supplies	Equipment
SMS surveys[11]	57%	**28%**	16%
Fed Reg 7/12/07; 38132; Table 2	53.7% ($15.68/hr)	**32.3%** ($9.44/hr)	14.0% ($4.08/hr)

While random surveys of physicians imply that supplies account for roughly 30% of direct practice expenses, the contribution of supplies driven by CPEP inputs via the RUC/PEAC process is (or recently was) just 18% of the total.

This suggests that supplies are underrepresented as a proportion of overall direct practice expenses. I propose that the review and audit of procedural supply inputs is far more objective and readily auditable than is the case for either clinical labor or equipment. Both clinical labor time and equipment amortization demand very close and extensive investigation, of a nature that I believe was at best partly accomplished by the RUC/PEAC direct PE "refinement" process.

The most obvious means of clinical labor overstatement is assignment of more activity minutes by clinical staff persons than actually are devoted to the procedure or service. Equipment cost overstatement can be occur, for example, through overstatement of the cost of capital equipment items and/or useful life of those items. In the instance of the two procedures in consideration here, equipment-related costs account for a small contribution (13% and 4% for TPE and photopheresis, respectively).

Consequently, the dramatic formulaic reductions by CMS in direct PE across labor, supplies and equipment is -- and must be -- ameliorated for many or most services by significant overstatements of labor and equipment amortization costs.

In the case of TPE and photopheresis, where direct supply costs constitute most of direct cost burden, the "direct adjustment" factor of approximately 40% reduces very real costs that are actually paid before the procedure can even be initiated.

Consider the direct PEs for these two procedures and the proposed payment rate based on the currently published "fully implemented" PE RVUs:

Procedure	Direct procedural costs	Proposed PE RVUs	Proposed payment ($36/RVU)	Implied indirect RVUs and payment
TPE	$528.61	**10.41**	$374.76	**1.28** ($46.15)
Photophereresis	$1,187	**37.04**	$1,333	**4.05** ($146)

The effective indirect cost contribution of the proposed fully implemented PE RVUs is therefore 1.28/10.41 = 12.3% for TPE and 4.05/37.04 = 10.9% for photopheresis.

These contributions to indirect practice overhead are clearly far below what is financially feasible for office-based providers.

Recommendation

I recommend that CMS make a single modification to its direct PE RVU adjustment formula, to address procedures for which supply costs represent more than 40% to 50% of total direct costs.

Specifically, I recommend that, for procedures for which supply costs represent more than 40% to 50% of total direct costs, that all supply costs be passed through and the direct adjustment factor be applied as usual to direct labor and equipment costs sourced from the CPEP database.

I recognize that, to remain compliant with your budget neutrality imperative, this will necessitate a small adjustment in the direct adjustment factor to assure that total RVUs remain unchanged.

In all the jockeying by various interest groups to capture Medicare practice expense dollars, and CMS' sincere efforts to fairly allocate those dollars, are a relatively small number of procedures, provided by a small cadre of trained specialists, that do not have the good fortune to have a vocal or well-financed organization to aggressively advocate for them. For two of these procedures – photopheresis and TPE – the losers stand to be seriously ill patients with such diagnoses as cutaneous T-cell lymphoma, chronic graft-versus-host disease, myasthenia gravis and chronic relapsing polyneuropathy.

While I ask you to resolve the unfair and financially untenable impact of the "direct adjustment" on these two supply-intensive services, I would also like to commend the work of the CMS staff, who face the unenviable task of balancing the interests of U.S. taxpayers, providers and the Medicare beneficiaries they ultimately serve.

In a phone discussion recently about our particular concern, the CMS officer reassured me that "we want to get this right."

On behalf of office-based providers and Medicare beneficiaries who require photopheresis and therapeutic plasma exchange, I am confident that you will get this right.

Sincerely,

Keith E. Berman, MPH, MBA

Submitter : **Dr. Gordon Harris** **Date: 08/31/2007**

Organization : **Massachusetts General Hospital**

Category : **Other Health Care Professional**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

see attachment

CMS-1385-P-15411-Attach-1.DOC

1541-11

VIA eMail

August 31, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1385-P—Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 (72 *Federal Register* No. 133), July 12, 2007

Comment regarding: Resource-Based PE RVU Calculations for CPTs 76376, 76377, G0288

Dear Sir or Madam:

Massachusetts General Hospital (MGH) and its colleagues in diagnostic radiology appreciate the opportunity to submit comments in response to the Centers for Medicare and Medicaid Services' (CMS's) proposed revisions to the Medicare Physician Fee Schedule (MPFS) for 2008, as published in the *Federal Register* on July 12, 2007. Our comment is in regards to changes being phased in for practice expense (PE) relative value unit (RVU) calculations. These changes result from the transitioning between two methods for calculating PE RVU values, with the phase in period occurring between CY 2006 and CY 2010. We note that these changes result in severe reductions in PE RVU values applied to numerous CPT codes. As examples, we will discuss RVU changes in CPT 76377 (and 76376) and G0288 as codes that are particularly hard-hit by these method changes. We propose consideration of setting a limit to the amount of decline a code may suffer from this method change, as some codes are so severely cut, that they are reimbursed well below cost by 2010, to the effect of coverage being effectively discontinued.

We are submitting this comment letter to do the following:

- provide background on our computer-aided diagnostics laboratory, its clinical applications, and its resource use;
- highlight the historical application of the add-on Current Procedural Terminology (CPT) code 76375: *coronal, sagittal, multiplanar, oblique, 3-dimensional and/or holographic reconstruction of computerized tomography, magnetic resonance imaging, or other tomographic modality*; and its replacement in 2006 by new 3D add-on CPT codes 76377 and 76376, as well as CPT G0288, instituted in 2001 for aortic aneurysm treatment planning and surveillance;
- explain the need for CMS to reevaluate the method change in PE RVUs, and determine whether a limit should be set on the amount of decline applied to a given CPT code under the new method.

BACKGROUND ON OUR FACILITY'S DIAGNOSTIC RADIOLOGY IMAGE-PROCESSING SERVICE

Our 3-D image-processing service performs 3-D reconstructions, for which we bill CPT 76377, on Computed Tomography (CT), Magnetic Resonance (MR), and Ultrasound (US) exams for approximately 40 outpatient cases per work day. Our lab is part of our physicians' organization (all equipment, staff, space is paid by the physicians' organization), and we bill the technical portion of CPT 76377 under the MPFS.

MGH established its 3-D imaging service to meet the clinical need of the community. Image reconstructions require a specialized staff member and specialized equipment to process images for proper clinical interpretation, and these images are often urgently awaited for diagnostic and treatment decisions. The changes in reimbursement impact our lab as well as those at many other institutions.

CLINICAL BENEFITS OF 3-D RECONSTRUCTION

Tomographic imaging with CT, MR, or US produces cross-sectional views of the body. However, when viewing the scan alone, all that is seen are cross-sectional views. This type of cross-sectional image does not show life-like three-dimensional views of the anatomy that are as diagnostically clear in many indications compared with 3D reconstructions of the anatomy and pathology, as created on dedicated 3D Imaging workstations by highly trained experts in clinical 3D imaging. In the absence of image post-processing by computer, these CT, MR, and US exams are often less informative and clear for radiologists and referring clinicians to efficiently and confidently make the best possible diagnosis and treatment plans.

In comparison, by creating a volume of image data from the CT, MR, or US scan and performing 3-D processing on a specialized computer workstation, the anatomy and pathology can often be visualized in full anatomical detail. Images produced using 3D post-processing are used routinely for both clinical diagnosis and detailed surgical planning.

EVOLUTION OF CPT CODING AND ASSOCIATED RVUs FOR 3D

In 2006, CPT 76375 (coronal, sagittal, and 3D post-processing code), was replaced by CPT 76376 (3D not on an independent workstation) and CPT 76377 (3D on an independent workstation), removing all reimbursement for coronal sagittal (2D) reformatting. The new codes were established with RVU values based on new cost-survey data. In addition to these 3D codes, in 2001, CMS created a new code for aortic aneurysm treatment planning and surveillance (G0288).

ADDITIONAL RESOURCES REQUIRED FOR 3D IMAGING

3-D image post-processing on an independent workstation under CPT 76377 requires additional resources compared to a standard CT exam. At our facility, a highly skilled radiologist or technologist, supervised by a radiologist, will spend 30 to 40 minutes processing a case to produce optimal views of all the major anatomy and pathology to be evaluated. The technologist must be an expert in the anatomy to identify the proper regions to be focused upon, the scanning techniques to recognize artifacts, and the complex operations of the computer software to create the images. Furthermore, the computer workstations are expensive and complex machines that must seamlessly integrate with the image network, scanners, and picture-archive and communication system (PACS). Each of these 3-D machines costs between $70,000 and $200,000.

At a February 27, 2002 meeting with CMS and ACR, we also presented data to CMS from the ACR cost survey of 3D post-processing costs, showing that the associated technical costs for post-processing additional to the CT acquisition costs are approximately $138. The additional 3D TC costs used for the $138 calculation include: the technologist processing time for creating 3D images; the depreciated cost of a 3D imaging workstation; additional films and supplies for the 3D images (30-40 3D images per study); and hospital overhead costs. These costs were closely reflected in the TC RVU values assigned to the new CPT 76377 code, which was initiated in 2006 with RVU values based on cost surveys through the RUC (See Table 1 below). The PE values determined for CPT

76377 and CPT 76376 for the new codes in 2006 (see Table 2), based on the recent RUC surveys closely match the data we presented to CMS for 3D post-processing costs based on earlier ACR survey data: The TC RVUs for 76377 in 2006 were calculated at $142, which almost exactly matches our 2002 estimates of $138 with a small inflation adjustment. Thus, we believe these new codes were reimbursed in 2006 at rates that closely reflected the costs of the 3D procedures, as calculated by the old methodology in 2006 in comparison to actual computed costs from the RUC and ACR survey data.

However, as shown in Table 2 below. The PE RVU values for these new codes are being severely cut by the new PE RVU method changes. CPT 76377 is suffering a **68% reduction** in PE RVUs from 3.43 in 2006 to 1.11 in 2010. G0288 will see a **90% decline** in PE RVUs. As a result, these changes will result in a **62% decline in TC reimbursement** in CPT 76377, and an **89% decline** in G0288 reimbursement between 2006 and 2010. The 2010 TC reimbursement rates for CPT 76377 of $54 and for G0288 of $45 are well below the costs of providing these services.

CONCLUSION

We understand that CMS needed to derive PE RVU values based on the new methodology. However, we also believe that CMS should consider whether the method changes are appropriate in all cases. If these changes result in such severe cuts to reimbursement for certain codes, leading to reimbursements well below the costs of services, perhaps some mitigation of the reimbursement cuts should be implemented in severe cases.

Under these new PE RVU methods, labs that specialize in performing 3-D imaging reconstruction can no longer cover the costs of services by billing Medicare to pay for 3-D services. At our facility, the reimbursement from the add-on CPT code 76377 is always applied to support the additional expense of the image-processing, including the costs of the specialized staff and equipment.

Therefore, we propose that CMS consider a limit to the amount any particular code can be cut in its PE RVU value based on the change in method. For example, a limit of a certain percentage could be set, such as 30%, after which, the value will not decline further. Or the TC RVU decline could be limited to the 2006 HOPPS APC value for the same CPT code. These are a couple examples of stop limits to insure that method changes do not result in codes being decrease to so extreme an extent that they are effectively no longer being covered by reimbursement. Some codes are being decreased to an extent so great that further changes in methodology by CMS may push the reimbursement rates close to zero.

We understand that coding decisions and RVU allocations for physician fees are complex and that CMS must be judicious. At the same time, we believe that our case is strong and should not be controversial. We hope that CMS will act favorably on our suggestions regarding the adjustment of the TC RVUs for 76377, 76376, and G0288 to mitigate the severe cuts of 70%-90% in reimbursement and practice expense RVUs associated with image post-processing for these services, and that other codes in similar circumstances be considered for similar adjustments to severe cuts in PE RVUs. We hope that this correction can be completed in time for the 2008 rule, or that the issues can be addressed as timely as possible.

* * * * *

I realize that some of these issues may require more information, which I would be happy to provide on request. If you have any questions regarding these comments, please do not hesitate to contact me at 617/726-9464.

Sincerely,

Gordon J. Harris, Ph.D.
Director, Computer-Aided Diagnostics Laboratory
Massachusetts General Hospital

Table 1: Practice Expense survey data for 76377, 76376, and G0288

	76376 3D w/o postp RUC	76377 3D w/ postp RUC	G0288 Recon, CTA for surg plan CMS
Clinical Time	20	38	60
X-ray film, 14x17	4	8	
X-ray developer solution	4	8	
x-ray fixer solution	4	8	
Film processor, wet	5	9	5
Film alternator	5	9	5
3D Computer workstation		38	20
Ultrasound room	20		

Table 2: Changes in PE RVUs, total RVUs, MPFS reimbursement rate changes for 76376, 76377, G0288 from 2006-2010. HOPPS 2007 APC rates provided for reference.

Code	Mod	Description (2008 NPRM)	2006 NF PE	2007 NF PE	2008 NF PE	2010 NF PE	2006 NF Total	2007 NF Total	2008 NF Total	2010 NF Total
76376	26	3d render w/o postprocess	0.07	0.07	0.07	0.07	0.29	0.27	0.27	
76376	**TC**	**3d render w/o postprocess**	**3.43**	**2.88**	**2.36**	**1.32**	**3.51**	**2.96**	**2.44**	**1.40**
76377	26	3d rendering w/postprocess	0.27	0.26	0.27	0.28	1.14	1.05	1.05	
76377	**TC**	**3d rendering w/postprocess**	**3.43**	**2.83**	**2.26**	**1.11**	**3.74**	**3.14**	**2.57**	**1.42**
G0288		Recon, CTA for surg plan	**10.64**	**8.21**	**5.81**	**1.02**	**10.82**	**8.39**	**5.99**	**1.20**

Code	Mod	Description (2008 NPRM)	2006 Rate	2007 Rate	2008 Rate	2010 Rate	2007 APC Rate
76376	26	3d render w/o postprocess	$10.99	$10.23	$10.23		$37.51
76376	**TC**	**3d render w/o postprocess**	**$133.02**	$112.18	$92.47	**$53.06**	$37.51
76377	26	3d rendering w/postprocess	$43.20	$39.79	$39.79		$94.53
76377	TC	**3d rendering w/postprocess**	**$141.74**	$119.00	$97.40	**$53.81**	$94.53
G0288		Recon, CTA for surg plan	**$410.05**	$317.96	$227.01	**$45.48**	$199.11

Submitter : **Ernest Boyd** **Date: 08/31/2007**

Organization : **Ohio Pharmacists Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-generated Facsimiles

I am pleased to submit these comments on behalf of the Ohio Pharmacists Association. We represent pharmacists throughout the state of Ohio in all practice settings. We are supportive of CMS s desire to facilitate and foster adoption of e-prescribing. However, we are very concerned with the removal of the ability of physicians and pharmacists to gradually move to adopt this technology. Electronic faxes have represented the first step in removing bad handwriting as a cause of prescription errors. The prescriptions created by fax are readable, and the printout gives physicians one last chance to be sure they prescribed the correct drug. There are also high costs affiliated with eprescribing on the pharmacists side, and we believe these costs will drop over time, allowing pharmacies to adopt the technology with less damage to our economic well being.

The cost to a pharmacy to accept each prescription from a prescriber is sometimes as high as 25 cents. Many pharmacists report a net profit of only 50 cents on many prescriptions. Often, a patient will have 8 or more prescriptions sent in electronically, but will tell the pharmacist that they only want to fill 3 or 4. That means the pharmacist will lose $1 in transmission fees with no way to recoup the costs. In some instances, pharmacists have reported that they received a number of prescriptions, only to have a patient tell them to transfer them to a store offering free gift cards. The cost to receive a fax, on the other hand, is only about 5 cents, counting paper and ink costs. Forcing eprescribing this quickly may financially jeopardize some pharmacies.

In Ohio, we are involved in a several year eprescribing project with physicians. We have noted that in some cases, errors were created by using the small hand-held devices. The errors were quite readable and neat, but a new source of error. Again, we support the move to this technology, but we need to move slowly enough to not cause new types of errors.

We also need time to be sure that we coordinate our state health technology policy with federal policy. Many state laws' definition of electronic prescriptions include computer generated faxes. In addition, the DEA does not recognize an electronic signature for any controlled substance (schedule II V). Promotion to prescribers to e-prescribe, when pharmacies must then follow up and inform prescribers the prescriptions are not valid and either need to be written (in the case of schedule II drugs) or taken as verbal orders causes further confusion in an already stressed health care system.

We strongly recommend that there be a more incremental implementation. There should be financial incentives for both pharmacists and physicians to adopt the technology. We would like to see exemptions for long term care, rural areas, and others that already have sophisticated methods of communication.

The faxing of prescriptions that are computer-generated represents a step forward in reducing errors. It allows the thousands of physicians who are currently writing prescriptions by hand to have an interim step to get comfortable with the concept of computer-generation of prescriptions. After they adopt the fax method, it will be far easier to move to the next step of eprescribing.

Thank you for the opportunity to comment. Ernest Boyd, R.Ph.

Submitter : **Ms. Gina Otterbein** **Date: 08/31/2007**

Organization : **Northern Physical Therapy Services**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am strongly opposed to physician self-referral related to the July 12 proposed physician fee schedule rule. I own a physical therapy practice in rural western Michigan with five locations that serve Medicare beneficiaries. In this area there has been dramatic growth of physician owned physical therapy businesses due to the in-office ancillary services exception. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices.

" I have watched orthopedic physician who referred patients to therapy infrequently begin to send the majority of their patients to physical therapy once there is a vested interest in the physical therapy clinic.
" I been told by patients that live 30 miles from the physician owned physical therapy clinic been told that by their doctor that they need to come to PT at their clinic rather than a PT office that is less than 2 miles from their house.
" I have experienced a request to meet a pain management physician and was told that he only send to his own PT clinic, physician owned clinic.
" I have been told by a physician with a physician owned clinic that have this clinic is a way to off set expenses and replace revenue due to declining reimbursement. The potential abuse and fraud exists when physicians are able to self refer Medicare patients because they have a financial interest.
" I recently had a patient pulled from one of my clinic where she was making progress because her pain Dr said she must go to the PT in his office. She went for a second evaluation and one treatment was very displeased with her experience. Fortunately she realized it was her choice and she insisted on returning to Northern Physical

The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician-owned physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, over-utilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

Thank you for your consideration of my comments.

Respectfully,
Gina Otterbein PT
President
Northern Physical Therapy Services
ginaotterbein@northernpts.com
25 Conran
Coopersville, MI 49404
616-430-9674

Submitter : **Dr. Jennifer Plos** **Date: 08/31/2007**

Organization : **Western Illinois University**

Category : **Academic**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I have been a Certified Athletic Trainer for almost 10 years and around the profession for approximatley 18 years. I was introduced to and became interested in Athletic Training from my experiences of working with athletic trainers at an outreach rehabilitation clinic when I was an injured athlete in high school. Their expertise, knowledge, and patient care had a very positive and lasting impact on my life. Thc quality of service I recieved from the Certified Athletic Trainers was far above other healthcare providers I had worked with in the past. I would not be where I am today without those athletic trainers that helped me rehabilitate from my injury.

I currently am an instructor and clinical coordinator for Western Illinois University's Athletic Training Education Program. The clinical setting is a huge employment attraction for many of our students because most come from small rural communities in which they want to go back and provide their services to patients in the rehabilitation clinics/hospitals as well as work side by side as equally respected colleagues with the physical therapists. Removing that opportunity would be devastating to our profession and a disservice to the public.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw thc proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Jennifer Plos, ATC, EdD

Submitter : Mr. Trent Cox **Date:** 08/31/2007

Organization : Mr. Trent Cox

Category : Health Care Professional or Association

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
I am a licensed athletic trainer in the state of Texas. I am also, a a graduate athletic training student that will be graduating in May, and entering the working world as a nationaly certified athletic trainer. I will soon be employed in the secondary school systems, and as such, I am very concerned with the changes your are proposing to make. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualificd to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Trent Cox, LAT, Future ATC

Submitter : **Mr. Nathan Twedt** **Date: 08/31/2007**

Organization : **Valparaiso University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Nathan Twedt and I am a Certified Athletic Trainer working at Valparaiso University. In the past I worked in a hospital rehab setting but due to new regulations put out by CMS my job duties were changed and I had to find a different job in order to utilize my capabilities. This led to a the high schools that I provided coverage for to no longer have that coverage as my position was not filled.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Nathan Twedt, ATC

Submitter : **Julie Patterson** **Date: 08/31/2007**

Organization : **Student**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am an entry-level graduate athletic training student and very concerened by this current proposal.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Julie Patterson

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To Whom It May Concern:
Please consider removing physical therapy services from the in-office ancillary services exception. The current policy allows for a loop hole in which physicians delegate physical therapy services to nonqualified individuals. This is a harmful situation for the public. I have had patients report a painful response to procedures that normally are painless, when they were provided by office staff in a physician's office.

Again PT services should not be included in the in-office ancillary services exception. Thank you for your thoughtful consideration in this matter.

Submitter : **Dr. Jiri Heger** **Date: 08/31/2007**

Organization : **Billings Anesthesiology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

To: Leslie V.Norwalk,Esq
Acting Administrator
Center for Medicare and Medicaid Services
Attention:CMS-1385-P
PO Box 8018
Baltimore,MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-year Review)

Dear Ms. Norwalk:

With this letter I would like to maintain my support for the proposed increase in anesthesia services payments.
This increase would help to partially correct the undervalued anesthesia work compared to the work of other physicians. This would also improve the access of anesthesia care in areas of disproportionately high Medicare population and services.

Thank you for your consideration in this important matter,

Jiri Heger,MD
1800 60th Street West
Billings, MT 59106

Submitter : Dr. Norbert Dombrowsky **Date:** 08/31/2007

Organization : Dr. Norbert Dombrowsky

Category : Physician

Issue Areas/Comments

Coding--Reduction In TC For Imaging Services

Coding--Reduction In TC For Imaging Services

CMS - 1385-P

I'm sure that the medical litature would show that the majority of older patients that require chiropractic care have conditions that can only be detected by radiographs. For example, would it not be prudent to know about an abdominal aortic aneurysm prior to chiropractic care?

Why are we making more diffult for our seniors to receive appropriate care? why does the patient have to to provider A when the DC can provide the appropriate service.

This approach doesn't make clinical or common sense.

Submitter : Mr. Jaime Garcia **Date:** 08/31/2007

Organization : Stephen F. Austin State University

Category : Health Care Professional or Association

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a licensed athletic trainer in the state of Texas. I am also a second year graduate student at Stephen F. Austin State University in athletic training.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jaime V. Garcia, LAT, future ATC.

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Thank you for giving me the opportunity to write you about the CMS-1385-P policy. I have been a physical therapist for 19 years and I have owned my own practice for 13 years. As a provider of physical therapy and consumer of health care I strongly feel physical therapy should be removed from the "in-office ancillary services" exception to the federal physician self-referral laws. I am foremost concerned about the abuse that can and does take place in this environment. Physicians own their own PT facility to make money. They are not trained as physical therapist and they do not directly supervise the physical theapy in their facility. Our facility has an excellent reputation of providing quality care. ALL physicians in our area have recommneded patients to us for this reason. One ortho group in particular has referred a large number of their patients to us. In 12/2006 they opened a physical therapy facility on the secoind floor in their office building. Since that time our referrals from this group has decreased nearly 100%. Patients have told us that these physicians are actively presuading them to attend their physical theapy facility. Some patients feel the need to listen to their doctor and they attend therapy there. This group clearly opened up a physieal therapy facility for profit under the pre-text of "keeping an eye on their patient". A captive referral base will lead to abuse. Can a physician own their own pharmacy? Physicians should not own their own physical therapy facility. Another example is a group was referring patients for 2X/week now at their facility they are prescribing therapy at 3X/week. Physician owned therapy facility creates unfair competition. There is no benefit for the consumer and this environment allows for abuse.
Thank you again for consideration of my comments.

CMS-1385-P-15422-Attach-1.TXT

[5422

August 31, 2007

To Whom It May Concern:

I am writing to you today to urge the Centers for Medicare and Medicaid Services to remove physical therapy services from the in-house ancillary services exception in the Stark physician self-referral law. I believe MDs *should not* be allowed to refer their patients to an in-house physical therapy office. This clearly is a conflict of interest with regard to the patient's best interests.

I am a physical therapist with 7 years experience in privately owned out-patient physical therapy settings. As private clinicians, we strive to deliver the best in personalized care to all of our patients, while actively trying to maintain excellent working relationships with area physicians. We rely on a vast number of local physicians to include our clinic in their PT referral list. If these MDs are allowed to refer to an in-house PT practice (consequently benefiting their own bustling practice), they will certainly choose not to mention the private PTs as options to their patients. This puts in jeopardizes the future viability of PT owned private practices, as well as the best interest of patients.

Please do not include physical therapy under the in-office ancillary services exception. Patients that are not given the choice of where to receive their physical therapy may not actually receive the best care available to them. I personally know of a few patients that were told by their MD to go to their in-house PT clinic so that they could "keep an eye on them". When these patients said they knew of a different facility they wished to attend, they were actively discouraged from doing so. In my experience, most people feel that they should do exactly as their doctor tells them. When MDs stand to gain financially from how a patient is treated, those financial interests will dictate certain aspects of the patients care. This is clearly unethical and unfair to patients as consumers of the healthcare system, and needs to end now.

Sincerely,

Michelle Cahill, MSPT

Submitter : **Dr. Michael Hudson** **Date: 08/31/2007**

Organization : **Missouri State University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

Please let me begin by introducing myself. My name is Michael Hudson and I am an Assistant Professor of Athletic Training in the Department of Sports Medicine and Athletic Training at Missouri State University. In addition to my scholarly activities at Missouri State University, I also teach in the professional (i.e., entry-level) athletic training education program. The graduates of our program are eligible for the national Board of Certification athletic trainer certification examination, which is the entry point for this health care profession. I am writing you today to voice my opposition to the Therapy Standards and Requirements section of CMS-1385-P, specifically in regards to the staffing provisions for rehabilitation services in hospitals, clinics, and other facilities. While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned these proposed rules will limit access to quality health care for my patients.

As an athletic trainer, I am more than qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, national certification exam, and state license (2006009453) ensure that my patients receive quality health care. However, the regulations proposed in CMS-1385-P are attempting to circumvent these standards by denying my qualifications to perform physical medicine and rehabilitation services.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for the CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The current standards of staffing in hospitals and other rehabilitation facilities are important to ensuring patients receive the best, most cost-effective treatment available.

Since the CMS appears to have come to these proposed changes without clinical or financial justification, I strongly encourage the CMS to consider the recommendations of those professionals who are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Michael Hudson, PhD, ATC
Assistant Professor
Missouri State University
Department of Sports Medicine and Athletic Training
Professional Building 160
901 South National Avenue
Springfield, Missouri 65897
Office: 417-836-6222
Fax: 417-836-8554
E-mail: michaelhudson@missouristate.edu

Submitter : Dr. Robert Zwolak **Date:** 08/31/2007

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Please see the enclosed data analysis for six vascular surgery codes that we contend were mis-valued during the five-year review process. We have commented on these at each NPRM opportunity and each final rule, and we held a meeting with Mr. Kay, Dr. Hambrick and Dr. Simon about these on 5/16/07.

Submitter : Dr. Michael Casagrande **Date:** 08/31/2007

Organization : Michael G Casagrande, MD, PA

Category : Physician

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

See Attached Comment

CMS-1385-P-15425-Attach-1.DOC

15425

MICHAEL G. CASAGRANDE, MD, PA, FAAFP
13406 Medical Complex Dr., Suite 190
Tomball, Texas 77375
(281)357-1934

August 31, 2007

Amy Bassano
Director, Division of Practitioner Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, C4-01-26
Baltimore, MD 21244

Re: CMS-1285-P: CY 2008 Physician Fee Schedule Proposed Rule
Practice Expense -- Equipment Usage Percentage

Dear Ms. Bassano:

Thank you for considering this comment on the 2008 Physician Fee Schedule Proposed Rule. I am a physician and I am writing to discuss payment for Microvolt T-wave Alternans (MTWA) diagnostic test. MTWA is an important tool to determine a patient's risk of sudden cardiac death. I am concerned that Medicare payment for physicians for MTWA is based on an incorrect utilization assumption that results in a significantly lower payment. CMS should consider the actual utilization of MTWA when calculating the practice expense for MTWA.

In patients at high risk for sudden cardiac death, Medicare has expanded coverage of implantable cardioverter defibrillators (ICDs) as a preventive measure. MTWA is extremely valuable in identifying which patients will benefit most from an ICD. Published data indicates that patients with negative MTWA tests will typically receive no significant reduction in cardiac arrest-related deaths, allowing us to identify patients who are more likely to benefit from an ICD.

MTWA testing is a non-invasive procedure that takes about 45 minutes. Unfortunately, the Medicare Practice Expense formula significantly decreases physician payment for MTWA. Reimbursement for MTWA is calculated using an "equipment usage assumption" of 50 percent. The assumption that the MTWA equipment is used 50 percent of the time is inaccurate and results in an inappropriately low payment. In my practice, MTWA is typically used only for the specific high-risk patients who will benefit greatly from its analysis. On average, we use MTWA several times per month, but significantly less than 10 percent of the time.

In order for Medicare to pay appropriately for this valuable technology, and to ensure that physicians continue to use it for their patients when appropriate, CMS should use the actual usage rate when available. I would be happy to provide documentation to demonstrate our actual utilization rate. Please do not hesitate to contact me for this information or if I can answer any other questions about MTWA.

Sincerely,

Michael G. Casagrande, MD

Submitter : **sukdeb datta** **Date: 08/31/2007**

Organization : **Vanderbilt university**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Dr. Verna Baughman** **Date: 08/31/2007**

Organization : **University of Illinois Department of Anesthesiolog**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Mrs. Jamie Krzykowski** **Date: 08/31/2007**

Organization : **Orthopaedic Associates of Wisconsin**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Jamie Krzykowski and I am a licensed athletic trainer at Orthopaedic Associates of Wisconsin, a prominent sports medicine and rehabilitation facility in our area. I currently work as an aide to the physical therapists in our rehab center. I have a master's degree in Sports Medicine with and emphasis in Exercise Physiology and am in the dissertation phase of my doctorate degree in Nutrition. I have been a certified athletic trainer for 10 years now.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jamie Krzykowski
Licensed Athletic Trainer

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **William Griffin** **Date: 08/31/2007**

Organization : **William Griffin**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a certified athletic trainer with an advanced Master's degree specializing in Gerontological Exercise Physiology. I have worked in multiple work settings and could in the future be affected by the proposed rule.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Sincerely,

William T. Griffin, MA, LAT, ATC, CEAS, CWCE

Submitter : Mr. **Date:** 08/31/2007

Organization : Mr.

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My Name is Bryan Rogers and I am the Head Athletic Trainer for the Dayton Bombers Professional Hockey Team in Dayton, Ohio. I have a Masters Degree in Kinesiology Sports Medicine, a National Certification as well as a State Licensure with an EMT background. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Sincerely,

Bryan Rogers MS, ATC, EMT
Head Athletic Trainer
Dayton Bombers Hockey

Submitter : Dr. Kam Nola **Date:** 08/31/2007

Organization : Tennessee Pharmacist Association

Category : Pharmacist

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

The Tennessee Pharmacists Association (TPA) appreciates the opportunity to provide comment on the proposed elimination of exemption for computer-generated facsimiles.

TPA is supportive of CMS desire to facilitate and foster adoption of electronic prescribing and understands the proposed elimination of the Exemption for Computer-Generated Facsimile deadline as an effort to drive adoption. However, systematic and economic investments need to occur to be in compliance and safely implement true electronic prescribing. Given the magnitude of the transformation needed by both on the prescriber and pharmacy, we are concerned that some of the fine operational considerations may not have been thoroughly considered when drafting this proposed rule. As a result, patient care may be compromised which would be counterproductive to the efforts by the Administration to advance patient safety and increase efficiencies in the health care system.

CMS-1385-P-15432-Attach-1.DOC

Tennessee Pharmacists Association

500 Church Street, Suite 650
Nashville, Tennessee 37219
Phone: 615/256.3023 Fax: 615/255.3528
tpa@tnpharm.org www.tnpharm.org

August 31, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS 1385-P
PO Box 8018
7500 Security Blvd
Baltimore, Maryland 21244-8018

Subject: Proposed Elimination of Exemption for Computer-Generated Facsimiles (Docket no. CMS-1385-P)

[Submitted electronically to www.cms.hss.gov/eRulemaking]

On behalf of the Tennessee Pharmacists Association (TPA), we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed regulations and revisions (published in the *Federal Register* notice on July 12, 2007 72FR.17559 38122, Docket NO. CMS-1385-P) to the proposed elimination of the Exemption for Computer-Generated Facsimile Transmission from the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard for Transmitting Prescription and Certain Prescription Related Information.

Pharmacists are the medication use experts helping patients and communities safely make the best use of medicines to improve health, reduce overall healthcare costs, and prevent the unnecessary costs and suffering of chronic disease. In order to maximize pharmacists' potential as the medication expert, we recognize the importance of a more holistic approach to electronic medical records (EMR) and the role electronic prescribing plays in that evolution. Pharmacists' access to and active participation in the creation and support of the EMR is critical to assure optimal health outcomes.

TPA is supportive of CMS' desire to facilitate and foster adoption of electronic prescribing and understands the proposed elimination of the Exemption for Computer-Generated Facsimile deadline as an effort to drive adoption. However, systematic and economic investments need to occur to be in compliance and safely implement true electronic prescribing. Given the magnitude of the transformation needed by both the prescriber and pharmacy, we are concerned that some of the fine operational considerations may not have been thoroughly considered when drafting this proposed rule. As a result, patient care may be compromised which would be counterproductive to the efforts by the Administration to advance patient safety and increase efficiencies in the health care system.

Operational considerations that CMS should consider regarding implementation:

- The impact such exemption elimination would have on patients of prescribers and pharmacies whose system capabilities do not meet the NCPDP SCRIPT standard, and recommend that the exemption continue to apply for these prescribers and pharmacies;
- Acknowledge the additional per transaction costs charged pharmacies for true electronic prescribing versus computer generated faxes;
- Acknowledge that a large number of pharmacies who are currently utilizing pharmacy systems that are "certified" to accept electronic prescribing have not yet invested the necessary funds to activate their systems;
- The Drug Enforcement Administration (DEA) needs to finalize regulations for the electronic prescribing of controlled substances;

- Address situations in which faxed prescriptions may be the preferred alternate method for transmitting a prescription electronically, such as computer system and software problems, technology failures, maintenance operations, etc.;
- Explore potential unintended outcomes that may limit adoption of true electronic prescribing if computer-generated faxes are not allowed and prescribers revert to paper prescriptions as some entities use computer-generated faxes as an intermediate step towards true electronic prescribing;
- Explore the impact on faxed prescribing practices within the long-term care industry;
- Impact of confusion created in pharmacy practice and prescriber practice in States that include computer generated faxed prescriptions within the definition of electronic prescriptions;
- Impact of the inevitable transitional systematic errors that are unique to electronic prescribing and the resolution of those errors on pharmacists and prescribers workflow and time;
- Potential impact on patient choice and access to pharmacies if prescribers are limited to sending electronic prescriptions only to pharmacies that are capable of accepting NCPDP SCRIPT messages;
- Consideration for rural areas where access to networks and services are currently limited.

Conclusion

In conclusion, TPA strongly supports CMS' efforts to facilitate and foster adoption of electronic prescribing. We recognize that pharmacy systems and prescribing processes have had substantial growth in electronic information exchange and we support the Agency's commitment to further advance the exchange of electronic information within the health care system.

If you have any questions or need any additional information, please do not hesitate to contact Kam Nola, Pharm.D., M.S. Associate Executive Director TPA, at (615) 256-3023 or via email at kam@tnpharm.org.

Sincerely,

Kam Nola, Pharm.D., M.S.
Associate Executive Director
Tennessee Pharmacists Association

Submitter : Dr. Robert Zwolak **Date:** 08/31/2007

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

This is my second attempt to transfer a PDF file outlining data compiled by SVS regarding six vascular surgery codes we believe were undervalued during the 5-year review process, primarily because CMS chose not to believe NSQIP data. We submitted a very large compendium of other supportive data, and it is included and updated here along with new regression analyses presnted to Mr. Kay, Dr. Simon and Dr. Hambrick on 5/16/07. Thanks for your consideration. I apologize if this reaches you twice, but the first receipt said "no attachments".

CMS-1385-P-15433-Attach-1.PDF

[redacted] SVS

SOCIETY FOR VASCULAR SURGERY

SVS Work RVU Appeal from 5-Year Review updated from May 16, 2007 CMS mtg

1. Aortic Aneurysm repairs CPT 35081, 35102
2. Lower extremity arterial bypass grafts, CPT 35556, 35566, 35583, 35585

SVS believes 6 Procedures we submitted to the 5-Year Review Process were inappropriately undervalued

Two Complex Open Aneurysm Repairs

35102 – Abdominal Aortic Aneurysm requiring bifurcated graft

35081 – Abdominal Aortic Aneurysm requiring tube graft

Four Complex Lower Extremity Bypass Operations

35556 – femoral-popliteal with vein

35566 – femoral-tibial with vein

35583 – femoral-popliteal with vein "in-situ"

35585 – femoral-tibial with vein "in-situ"

All 6 Codes were involved in the NSQIP fracas

- NSQIP time was available for 10 of the 21 vascular surgery procedures we submitted, including the 6 in question here.

- When available, SVS used NSQIP because we felt accuracy was a goal in the 5-year review. That turned out to be a mistake, as CMS chose relativity as the primary determinant

- NSQIP intra-service times were:
  higher than survey time for 6 codes,
  equal to survey time for 1 code
  LESS THAN survey time for 3 codes.

- SVS used the data in all instances

CPT 35102 Open Repair of abdominal aortic aneurysm requiring bifurcated graft

CPT 35102 is open repair of an infrarenal abdominal aortic aneurysm using a bifurcated graft. This service was submitted to the five-year review because the work has changed. Endovascular aortic aneurysm repair is performed in patients with 15 mm or longer normal segments of aorta below the renal artery origins plus non-calcified, minimally angulated infrarenal necks. This leaves aneurysms with short, angulated and calcified infrarenal necks for open aneurysm repair. All of these factors increase the intensity and complexity of this service. The net result is that this service is more complex and time consuming than it was five years ago.

Source	Work RVU	IWPUT*
2005 SVS Recommendation:	39.80	0.096
RUC Recommendation:	36.28	0.083
CMS Value*:	34.00	0.074
2007/8 CMS Value w new EM	36.37	0.074
2008 SVS Recommendation*	42.20	0.096

***calculated using RUC time/visit & old 2005 E/M RVUs**

Service Components and IWPUT for 35102, SVS recommendation vs. CMS value. The CMS RVW resulted in an inappropriately low IWPUT intensity.

SVS Rec RVU with RUC time & Visits	[redacted]	RVW:	39.80
	RUC time	RUC Std.	RVW
Pre-service:	Time	Intensity	(=time x intensity)
Pre-service eval & positioning	75	0.0224	1.68
Pre-service scrub, dress, wait	15	0.0081	0.12
Pre-service total			1.80
Post-service:	Time	Intensity	(=time x intensity)
Immediate post	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
ICU 99291	1	4.00	4.00
ICU 99292		2.00	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	0	1.51	0.00
99232	3	1.06	3.18
99231	2	0.64	1.28
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.75	0.00
99215		1.73	0.00
99214	1	1.08	1.08
99213	1	0.65	0.65
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			12.57
	Time	IWPUT	INTRA-RVW
Intra-service:	265	0.096	25.43
Total Time:	688		

CMS Rec RVU with RUC time & visits	[redacted]	RVW:	34.00
	RUC Time	RUC Std.	RVW
Pre-service:	Time	Intensity	(=time x intensity)
Pre-service eval & positi	75	0.0224	1.68
Pre-service scrub, dress,	15	0.0081	0.12
Pre-service total			1.80
Post-service:	Time	Intensity	(=time x Intensity)
Immediate post	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
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99232	3	1.06	3.18
99231	2	0.64	1.28
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.75	0.00
99215		1.73	0.00
99214	1	1.08	1.08
99213	1	0.65	0.65
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			12.57
	Time	IWPUT	INTRA-RVW
Intra-service:	265	0.074	19.63
Total Time:	688		

These are calculated with 2005 EM values but IWPUT does not change with corresponding 2007/8 EM values

CMS RVW of 34.00* for 35102 created a Rank Order Anomaly in aneurysm & aortic surgery family for RUC evaluated codes

RUC/CMS IWPUT Intensity Measure for Aneurysm Repairs and Aortic Surgery

Code	Short Descriptor	Year Implemented	IWPUT
****CMS places 35102 Aortic Aneurysm Repair here**			**0.074**
35141	Repair femoral aneurysm	2002 5Yr	0.082
34900	Endovasc rep iliac aneurysm	2003 new	0.088
35646	Aorto-bifemoral bypass synth	2002 new	0.093
35151	Rep popliteal aneurysm	2002 5 Yr	0.094
33881	Endovasc rep thoracic aorta	2006 new	0.095
****SVS would put 35102 Aortic Aneurysm Repair here**			**0.096**
35011	Rep axillary/brach aneurysm	2002 5 Yr	0.099
35131	Rep Iliac aneurysm	2002 5 Yr	0.101
34802	Endo rep abd AAA 2-piece	2001 new	0.101
34805	Endo rep Abd AAA aorto-uni	2001 new	0.101
35647	Aorto-fem bypass synth	2002 new	0.102
35045	Rep radial/ulnar aneurysm	2002 5 Yr	0.102
34803	Endo rep abd AAA 3-piece	2005 new	0.104
35121	Rep mesenteric aneurysm	2002 5 Yr	0.105
33880	Endovasc rep thoracic	2006 new	0.105
35111	Rep splenic aneurysm	2002 5 Yr	0.109
34800	Endovasc rep abd AAA	2001 new	0.109

*using 2005 EM RVUs

No change in IWPUT with 2007/8 RVUs

Detailed Comparison of 35102 to Vascular Surgery MPC "A" List 35631 using 2005 E/M RVWs

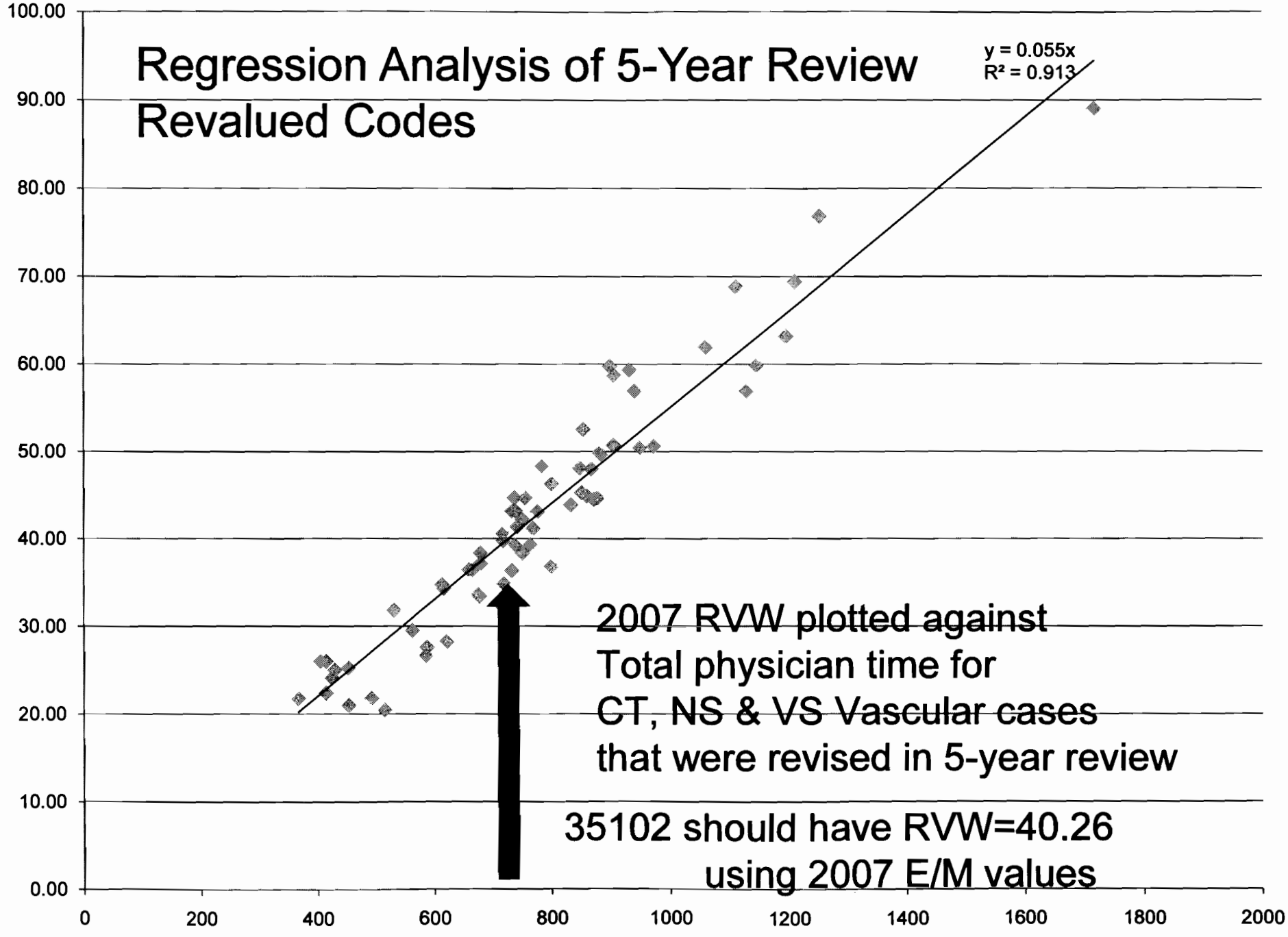
CPT 35631 is "Bypass graft, with other than vein; aortoceliac, aortomesenteric, aortorenal". It serves as a RUC MPC "A" list standard service. 35631 is a 90-day global intra-abdominal operation that was analyzed by the RUC during the 2nd five-year review. 35631 has an RVW of 33.95.

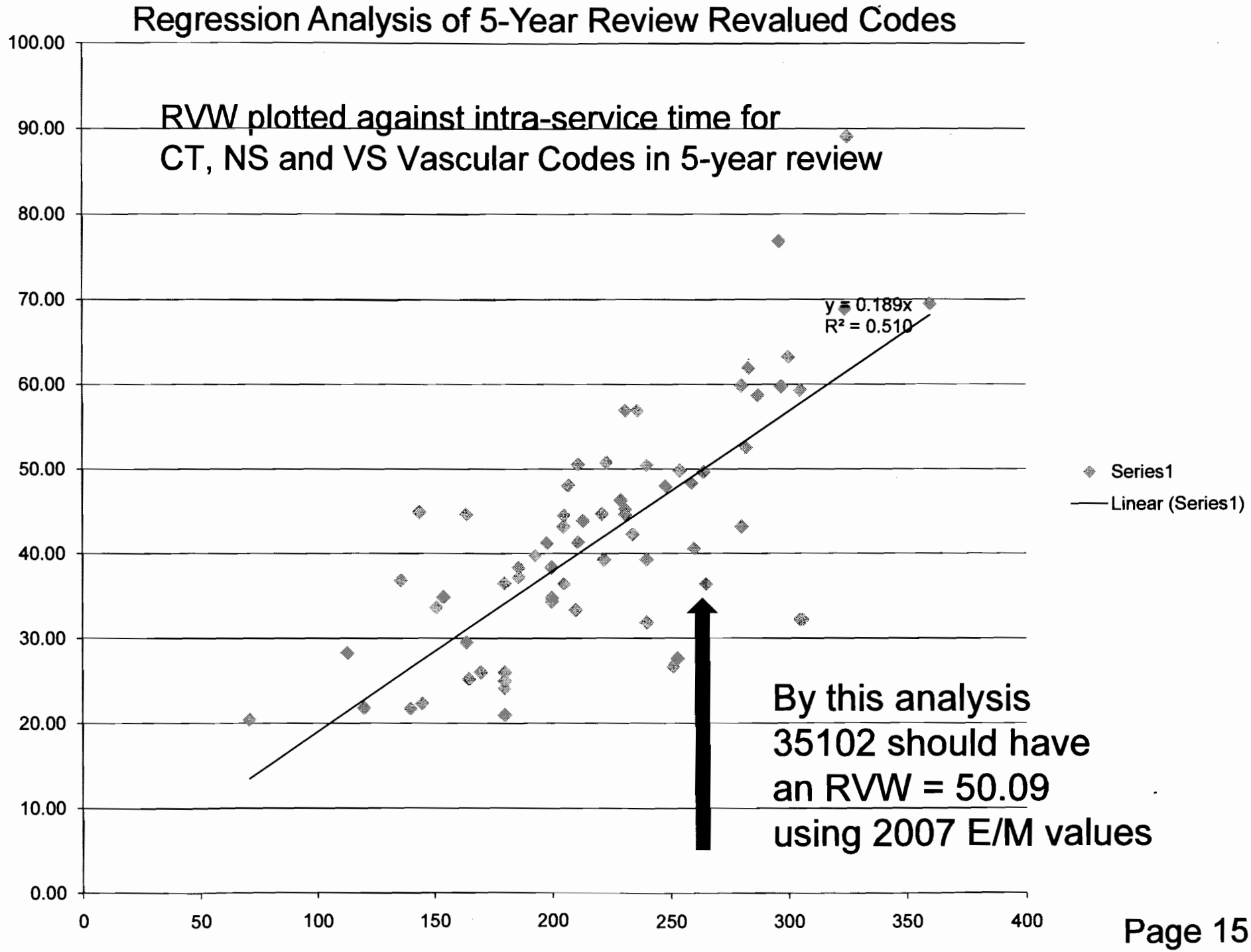
Pre-service time of 35631 (110 minutes) is very slightly more than 35102, which has 90 RUC-approved pre-service minutes (reduced from survey time). This accounts for only a 0.2 rvu difference.

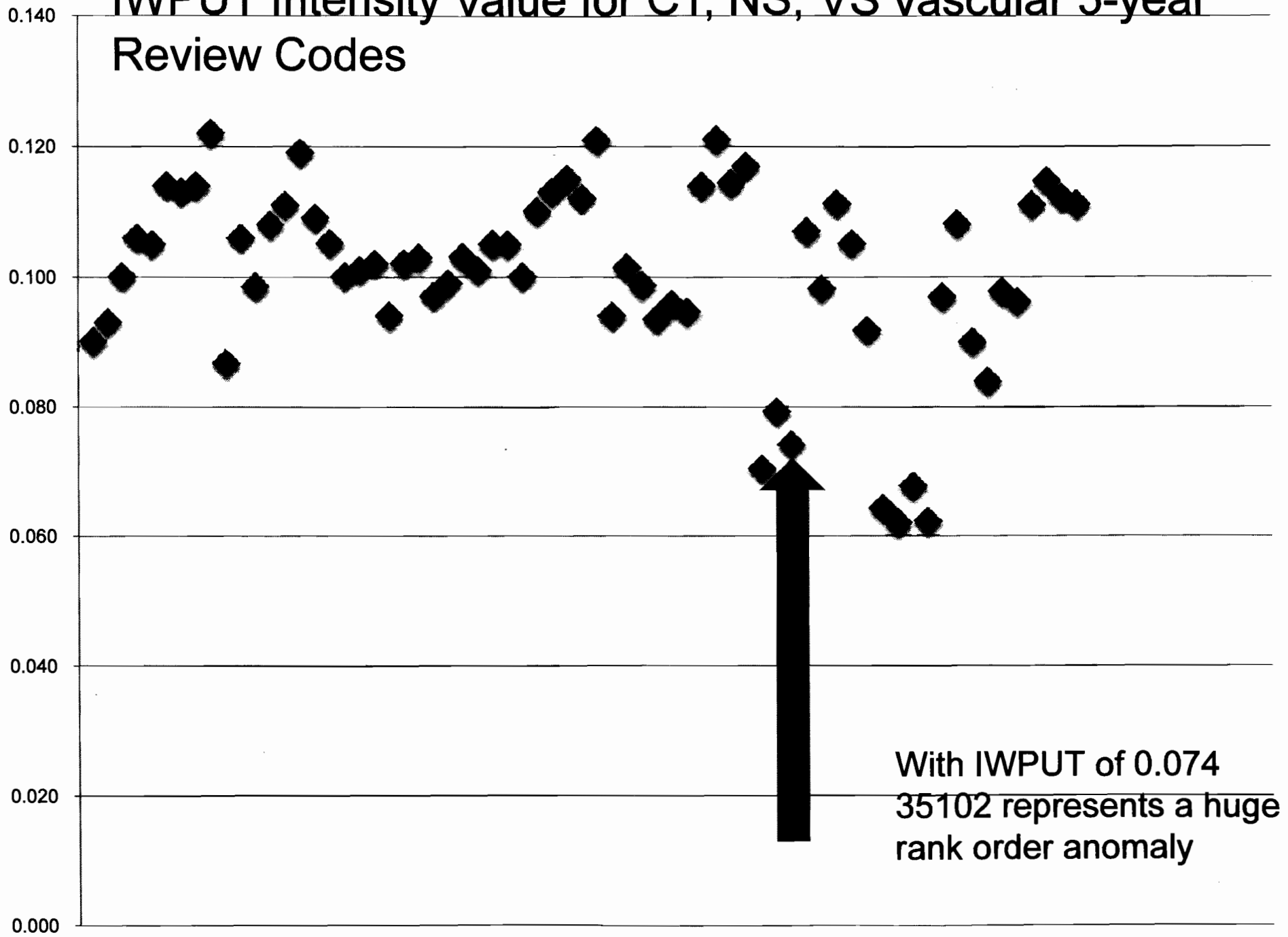
Intra-service work for 35102 at the SVS recommended RVW of 39.40 is 265 min x 0.096 = 25.43 rvus. Intra-service work for 35631 is 225 min x 0.102 = 23.00 rvus. Thus, 35102 has 2.43 rvus more intra-service than 35631.

Post-service work is greater for 35102 (12.57 rvus) compared to 35631 (8.77 rvus) because the patients are generally older and sicker.

Based on this analysis, 35102 should be 0.2 rvus less than 35631 for pre-service work, 2.43 rvus more for intra-service work and 3.80 rvus more for post-service work. 35631 has a work RVU of 33.95. If appropriately valued in comparison to 35631, 35102 should have a work RVU of 33.95 - 0.2 +2.43 + 3.80 = 39.98. Thus, based on this comparison with an MPC "A" list vascular service, the SVS recommended work RVU of 39.80 is totally appropriate.


Regression Analysis of 5-Year Review
Revalued Codes
y = 0.055x
R² = 0.913
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
200
400
600
800
1000
1200
1400
1600
1800
2000
2007 RVW plotted against
Total physician time for
CT, NS & VS Vascular cases
that were revised in 5-year review
35102 should have RVW=40.26
using 2007 E/M values


Regression Analysis of 5-Year Review Revalued Codes
RVW plotted against intra-service time for
CT, NS and VS Vascular Codes in 5-year review
y = 0.189x
R² = 0.510
Series1
Linear (Series1)
By this analysis
35102 should have
an RVW = 50.09
using 2007 E/M values
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
50
100
150
200
250
300
350
400


IWPUT Intensity Value for CT, NS, VS vascular 5-year Review Codes
0.140
0.120
0.100
0.080
0.060
0.040
0.020
0.000
With IWPUT of 0.074 35102 represents a huge rank order anomaly

By Comparison to CT, VS and NS vascular codes evaluated during the just completed 5-year review, and

using RVW vs. Total Time, RVW vs. Intra-time and IWPUT intensity analyses, CPT 35102 is undervalued.

The RVW for this code should lie between 40.26 and 50.09 using linear regression analysis and including the 2007 E/M values in order to avoid rank order anomalies

Our recommendation of 42.20 keeps the intensity level correct while eliminating the rank order problem.

Using 2007 E/M RVUs and all time and visits fixed at 5-year review levels, SVS requests RVW of 42.20 for 35102 based on data presented

35102 for CMS mtg May 2007	[redacted]		42.20
Open AAA repair bifurcated	**Svy Data**	**RUC Std.**	**RVW**
	Time	**Intensity**	**(=time x intensity)**
Pre-service eval & positioning	75	0.0224	1.68
Pre-service scrub, dress, wait	15	0.0081	0.12
Pre-service total			**1.80**
Post-service:	**Time**	**Intensity**	**(=time x intensity)**
Immediate post cut from 30	30	0.0224	0.67
Subsequent visits:	**Visit n**	**E/M RVW**	**(=n x RVW)**
ICU 99291	1	4.50	4.50
ICU 99292		2.25	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	0	2.00	0.00
99232	3	1.39	4.17
99231	2	0.76	1.52
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.9	0.00
99215		2.00	0.00
99214	1	1.42	1.42
99213	1	0.92	0.92
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			**14.91**
	Time	**IWPUT**	**INTRA-RVW**
Intra-service:	265	0.096	25.49

CPT 35081 Open Repair of abdominal aortic aneurysm requiring tube graft

CPT 35081 is open repair of an infrarenal abdominal aortic aneurysm using a cylindrical "tube" graft. This service was submitted to the five-year review because the work has changed. Endovascular aortic aneurysm repair is performed in patients with 15 mm or longer normal segments of aorta below the renal artery origins plus non-calcified, minimally angulated infrarenal necks. This leaves aneurysms with short, angulated and calcified infrarenal necks for open aneurysm repair. All of these factors increase the intensity and complexity of this service. The net result is that this service is more complex and time consuming than it was five years ago.

According to the NPRM, CMS rejected our recommendations because they relied upon NSQIP data. The fact is that NSQIP and SVS Survey hospital length of stay were identical at 7 days. In addition, NSQIP and SVS Survey data for intra-service time varied by only three minutes. Early on during workgroup negotiations, SVS relinquished those 3 minutes of intra-service time such that NSQIP data plays no part in our recommendation for this service.

35081 is inappropriately valued at 31.00 RVUs (2005 E/M values) based on IWPUT Intensity Analysis

Source	Work RVU	IWPUT (using RUC time/visit)
SVS Recommended:	34.55	0.096
CMS RVW:	31.00	0.079
2007/8 CMS RVW *	33.37	0.079
2008 SVS Recommendation	36.80	0.096

* the 2007 RVW represents adjustment for new EM values, no other change

35081 Time, Visit & IWPUT Intensity for SVS Recommended vs. CMS Proposed RVUs. The CMS Proposal results in an inappropriately low IWPUT intensity:

5Yr REC	[redacted]	RVW	34.55
RUC time & visits	Svy Data	RUC Std.	RVW
ervice:	Time	Intensity	(=time x intensity)
ervice eval & positioning	75	0.0224	1.68
ervice scrub, dress, wait	15	0.0081	0.12
ervice total			1.80
service:	Time	Intensity	(=time x intensity)
diate post	30	0.0224	0.67
equent visits:	Visit n	E/M RVW	(=n x RVW)
9291	1	4.00	4.00
9292		2.00	0.00
99296		16.00	0.00
99297		8.00	0.00
3	0	1.51	0.00
2	3	1.06	3.18
1	2	0.64	1.28
arge 99238	1	1.28	1.28
arge 99239	0	1.75	0.00
5		1.73	0.00
4	1	1.08	1.08
3	1	0.65	0.65
2	1	0.43	0.43
1		0.17	0.00
service total			12.57
	Time	IWPUT	INTRA-RVW
Intra-service:	210	0.096	20.18
Total Time:	633		

CMS Proposed		[redacted]	31.00
w RUC time & visits	Svy Data	RUC Std.	RVW
Pre-service:	Time	Intensity	(=time x Intensity)
Pre-service eval & positi	75	0.0224	1.68
Pre-service scrub, dress,	15	0.0081	0.12
Pre-service total			1.80
Post-service:	Time	Intensity	(=time x intensity)
Immediate post	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
ICU 99291	1	4.00	4.00
ICU 99292		2.00	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	0	1.51	0.00
99232	3	1.06	3.18
99231	2	0.64	1.28
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.75	0.00
99215		1.73	0.00
99214	1	1.08	1.08
99213	1	0.65	0.65
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			12.57
	Time	IWPUT	INTRA-RVW
Intra-service:	210	0.079	16.63
Total Time:	633		

Note: These calculations include 2005 E/M RVWs and times

RUC/CMS-Approved IWPUT Intensity for Aneurysm Repairs and Aortic Surgery Indicates that CMS proposed work RVU is too low based on intensity comparison:

Code	Short Descriptor	Year Implemented	IWPUT
****CMS would put 35081 Aortic aneurysm Repair here**			**0.079**
35141	Repair femoral aneurysm	2002 5Yr	0.082
34900	Endovasc rep iliac aneurysm	2003 new	0.088
35646	Aorto-bifemoral bypass synth	2002 new	0.093
35151	Rep popliteal aneurysm	2002 5 Yr	0.094
33881	Endovasc rep thoracic aorta	2006 new	0.095
****SVS would put 35081 Aortic aneurysm Repair here**			**0.096**
35011	Rep axillary/brach aneurysm	2002 5 Yr	0.099
35131	Rep Iliac aneurysm	2002 5 Yr	0.101
34802	Endo rep abd AAA 2-piece	2001 new	0.101
34805	Endo rep Abd AAA aorto-uni	2001 new	0.101
35647	Aorto-fem bypass synth	2002 new	0.102
35045	Rep radial/ulnar aneurysm	2002 5 Yr	0.102
34803	Endo rep abd AAA 3-piece	2005 new	0.104
35121	Rep mesenteric aneurysm	2002 5 Yr	0.105
33880	Endovasc rep thoracic	2006 new	0.105
35111	Rep splenic aneurysm	2002 5 Yr	0.109
34800	Endovasc rep abd AAA	2001 new	0.109

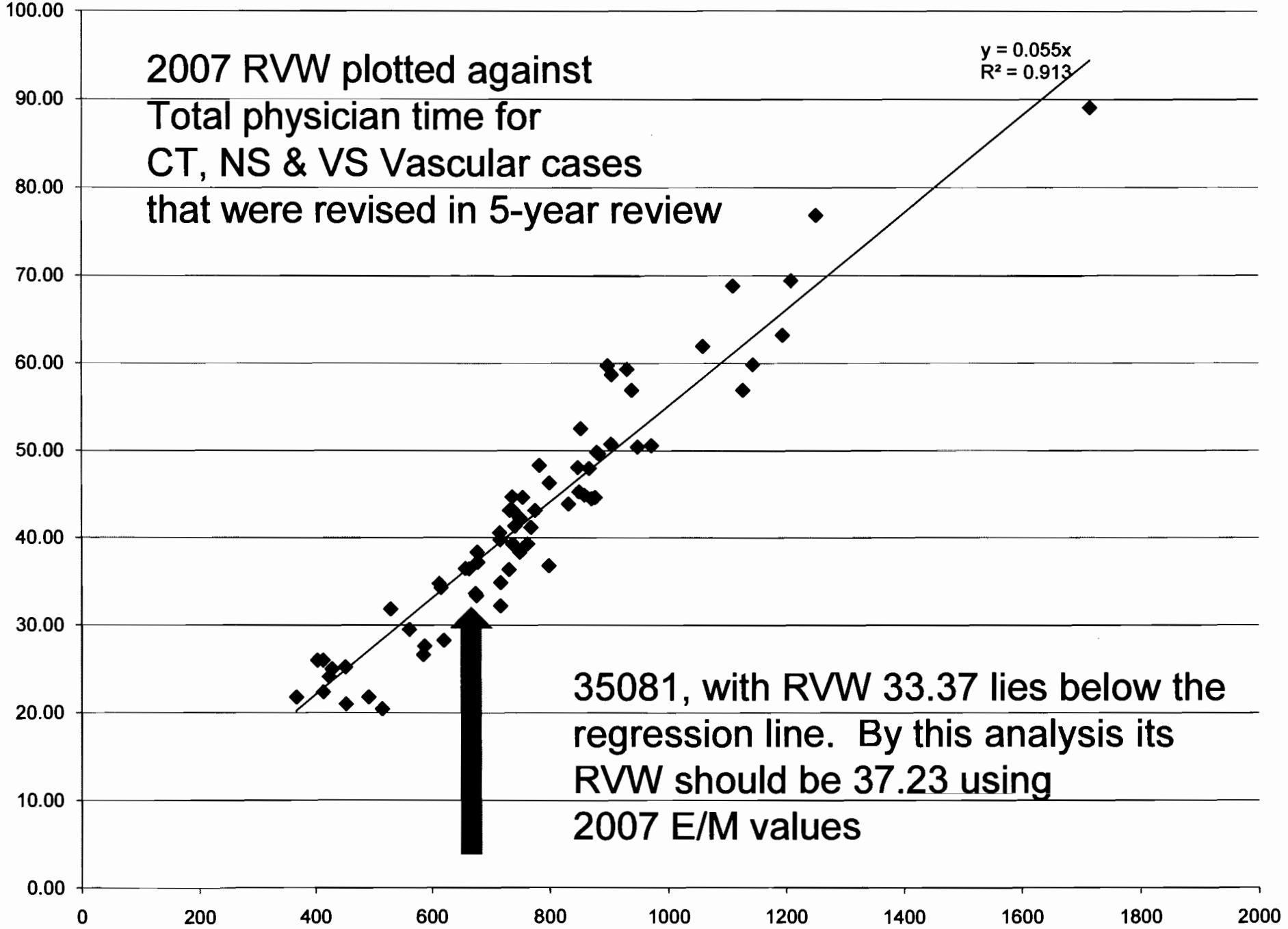
Hospital Visits for 35081 were voluntarily reduced prior to RUC submission

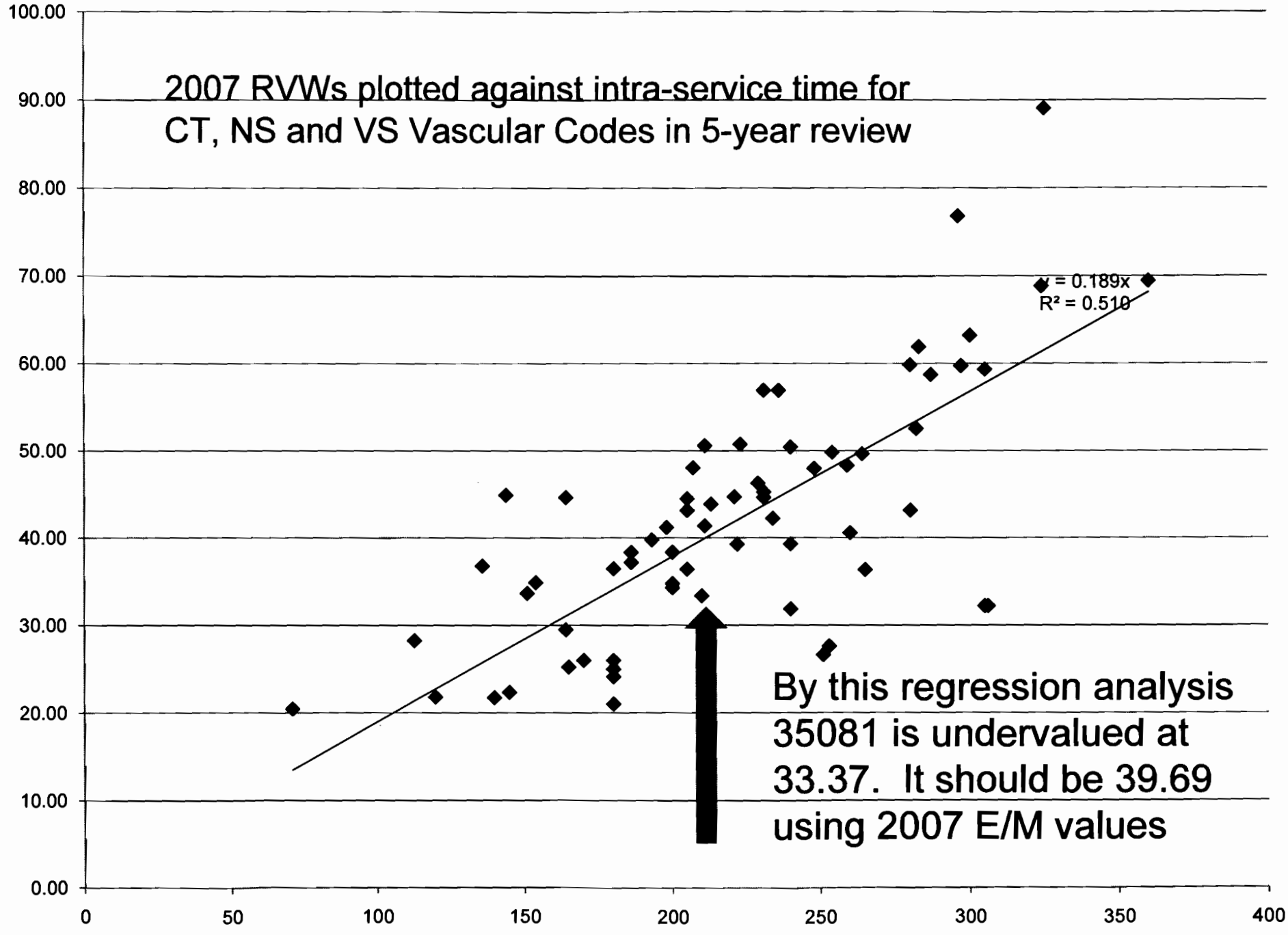
SVS believes that CMS and the RUC failed to take into account the fact that our expert consensus panel voluntarily reduced the hospital visit levels from the raw survey data to provide what we felt was a balanced package to justify the recommended work value.

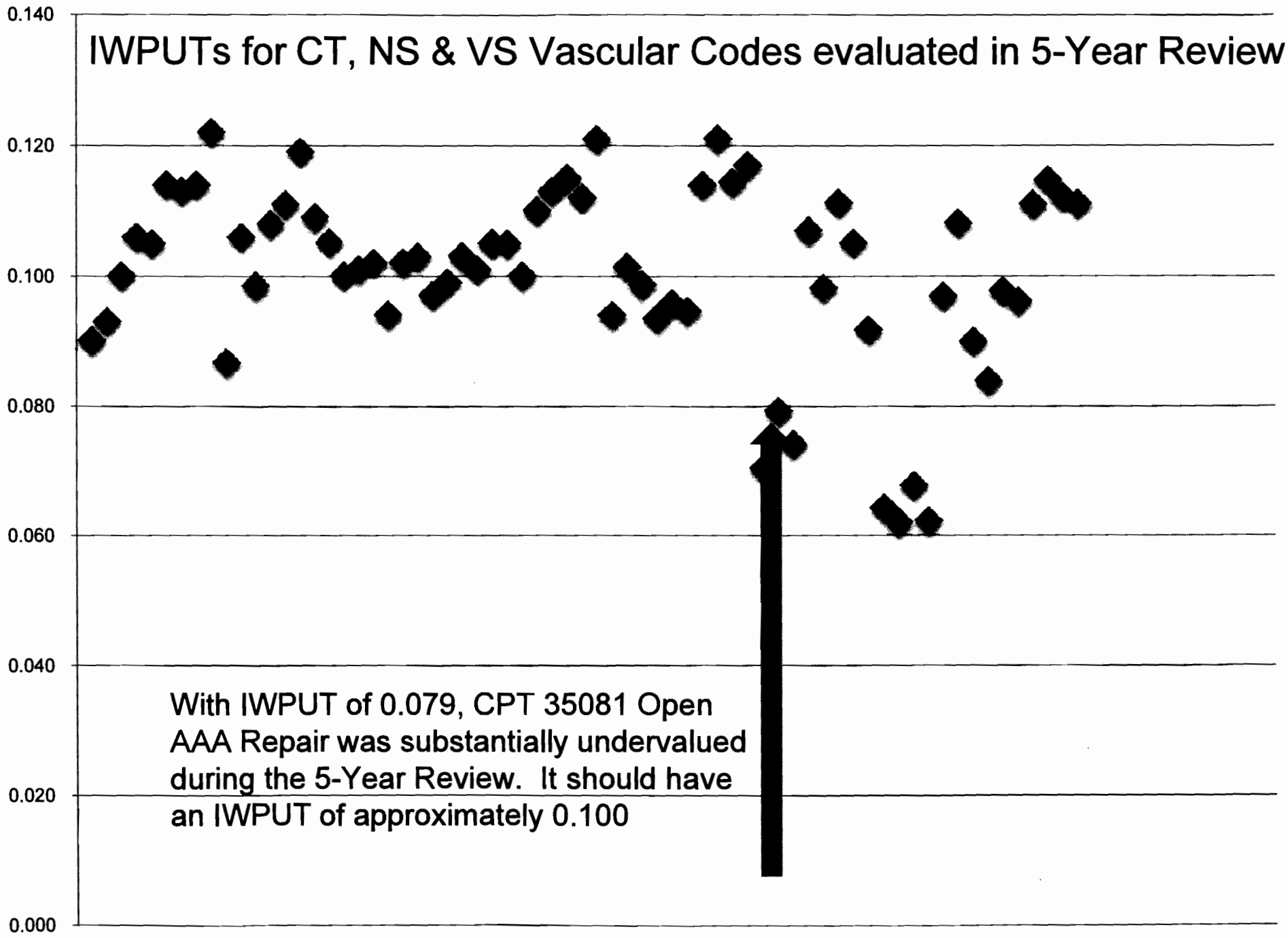
SVS minimized the hospital visit pattern because we believed the packaged service deserved a work RVU of 34.55, and with only one critical care visit all the components fit together very well, resulting in an appropriate IWPUT. In reality, 62% of survey respondents included two or more 99291 critical care visits, some recommending as many as five.

The non-critical care visit pattern in the survey data was a mix between 99233s and 99232s, accounting, in general, for a total of three visits between the two codes. The SVS Expert Panel considered these data and decided to downshift all the 99233s to 99232s, thereby resulting in three 99232s for the typical patient. Although we believe a work RVU of 34.55 is fully justified at the current visit level, the raw data could be revisited if CMS is willing.

In summary, for 35081, SVS has provided an intensity analysis, comparison with other vascular surgery procedures, comparison with aneurysm repairs in the neurosurgical realm, and a review of our treatment of hospital visits. We believe all of this information points to our originally recommended work RVU of 34.55 as the most accurate relative value.


2007 RVW plotted against
Total physician time for
CT, NS & VS Vascular cases
that were revised in 5-year review
y = 0.055x
R² = 0.913
35081, with RVW 33.37 lies below the regression line. By this analysis its RVW should be 37.23 using 2007 E/M values
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
200
400
600
800
1000
1200
1400
1600
1800
2000


2007 RVWs plotted against intra-service time for
CT, NS and VS Vascular Codes in 5-year review
y = 0.189x
R² = 0.510
By this regression analysis
35081 is undervalued at
33.37. It should be 39.69
using 2007 E/M values
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
50
100
150
200
250
300
350
400


IWPUTs for CT, NS & VS Vascular Codes evaluated in 5-Year Review
0.140
0.120
0.100
0.080
0.060
0.040
0.020
0.000
With IWPUT of 0.079, CPT 35081 Open AAA Repair was substantially undervalued during the 5-Year Review. It should have an IWPUT of approximately 0.100

Using 2007 E/M RVUs and all time and visits fixed at 5-year review levels, SVS requests RVW of 36.80 for 35081 to avoid rank order anomalies

[redacted]

35081 for CMS mtg May 2007			36.80
Open AAA repair bifurcated	Svy Data	RUC Std.	RVW
	Time	Intensity	(=time x intensity)
Pre-service eval & positioning	75	0.0224	1.68
Pre-service scrub, dress, wait	15	0.0081	0.12
Pre-service total			**1.80**
Post-service:	Time	Intensity	(=time x intensity)
Immediate post cut from 30	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
ICU 99291	1	4.50	4.50
ICU 99292		2.25	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	0	2.00	0.00
99232	3	1.39	4.17
99231	2	0.76	1.52
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.9	0.00
99215		2.00	0.00
99214	1	1.42	1.42
99213	1	0.92	0.92
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			**14.91**
	Time	IWPUT	INTRA-RVW
Intra-service:	210	0.096	20.09

CPT 35556 Bypass with vein, femoral-popliteal

- 35556 lower extremity bypass graft is performed to prevent leg amputation due to ischemic gangrene and non-healing ischemic foot ulcers.
- SVS believes that this operation, in addition to three others in the same family (35566, 35583, 35585) were undervalued during the just concluded Medicare 5-year Review.
- These operations require many hours of complex surgery, and the patients are extremely ill postoperatively.
- The individuals who require this type of operation are elderly and almost always have coincident atherosclerotic disorders such as coronary artery disease and cerebrovascular disease. Most of these patients has smoked thousands of packs of cigarettes and have advanced COPD.

35556 Fem-Pop Bypass with Vein

SVS 5-year recommendation	31.58
RUC 5-year recommendation	27.25
CMS 5-year value	25.00
2007/8 MFS value with new E/M	26.62
2008 SVS recd with new E/M	33.20

SVS vs. CMS Recommendations for 35556:

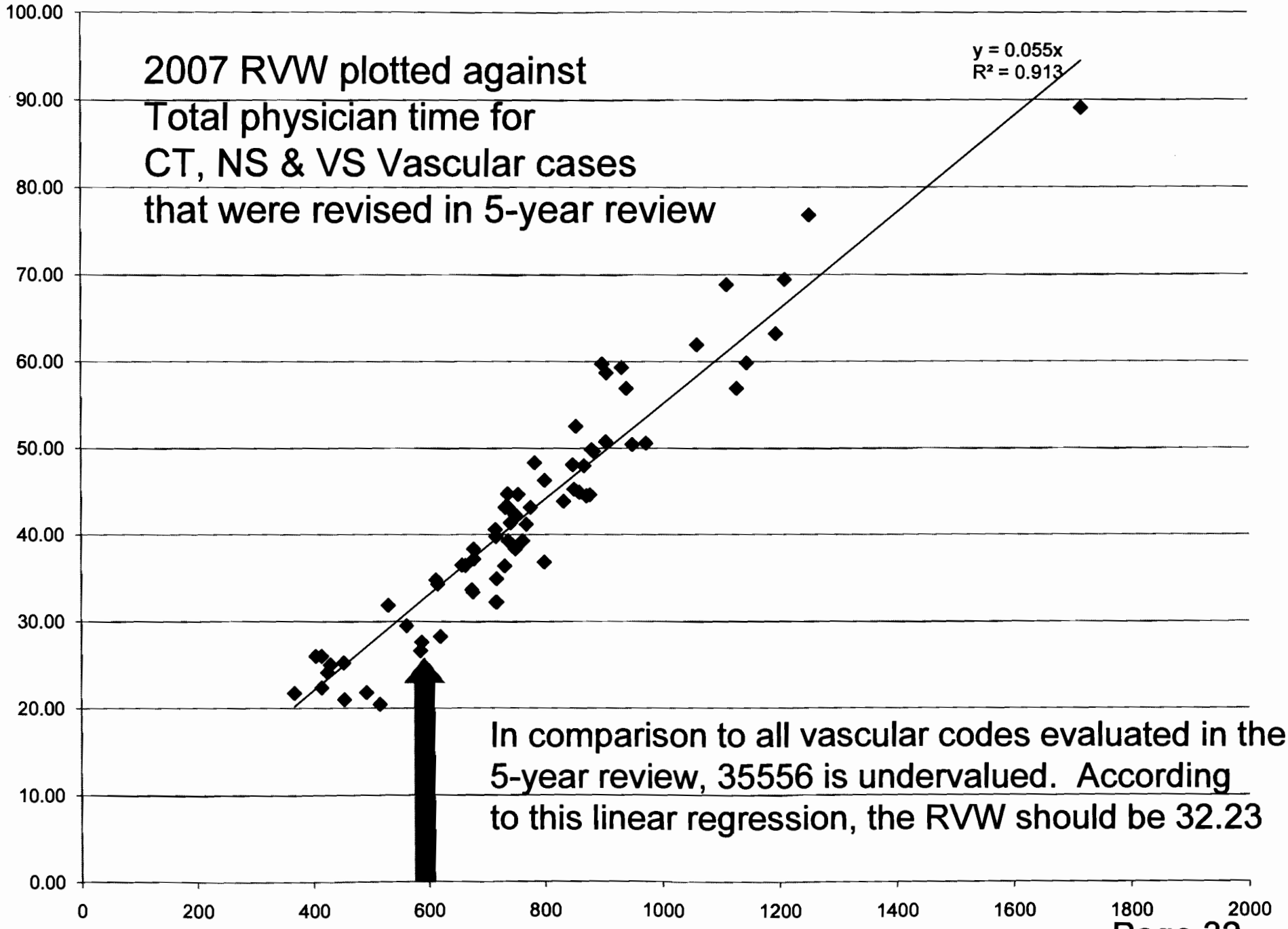
/S Rec RVU	35556	RVW:	31.58
RUC time & visits	RUC Data	RUC Std.	RVW
e-service:	Time	Intensity	(=time x Intensity)
e-service eval & positio	55	0.0224	1.23
e-service scrub, dress,	15	0.0081	0.12
e-service total			1.35
st-service:	Time	Intensity	(=time x Intensity)
mediate post	30	0.0224	0.67
bsequent visits:	Visit n	E/M RVW	(=n x RVW)
U 99291	0	4.00	0.00
U 99292		2.00	0.00
CU 99296		16.00	0.00
CU 99297		8.00	0.00
233	1	1.51	1.51
232	1	1.06	1.06
231	2	0.64	1.28
scharge 99238	1	1.28	1.28
scharge 99239	0	1.75	0.00
215		1.73	0.00
214	0	1.08	0.00
213	2	0.65	1.30
212	1	0.43	0.43
211		0.17	0.00
st-service total			7.53
	Time	IWPUT	INTRA-RVW
Intra-service:	251	0.090	22.69
Total time:	557		

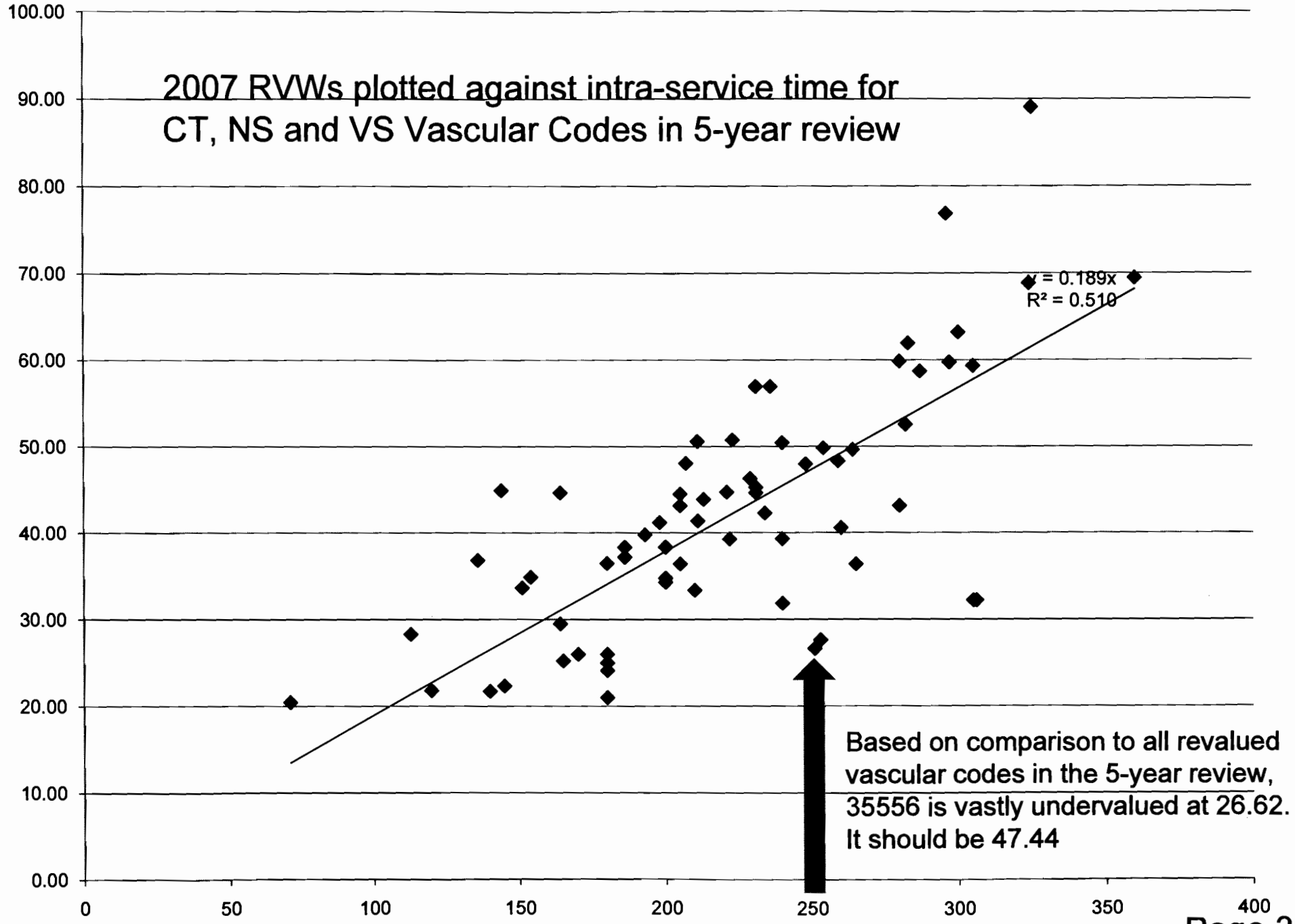
CMS Rec RVU	35556	RVW:	25.00
w RUC time & visits	RUC Data	RUC Std.	RVW
Pre-service:	Time	Intensity	=time x Intensity
Pre-service eval & positi	55	0.0224	1.23
Pre-service scrub, dress,	15	0.0081	0.12
Pre-service total			1.35
Post-service:	Time	Intensity	=time x Intensity
Immediate post	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
ICU 99291	0	4.00	0.00
ICU 99292		2.00	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	1	1.51	1.51
99232	1	1.06	1.06
99231	2	0.64	1.28
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.75	0.00
99215		1.73	0.00
99214	0	1.08	0.00
99213	2	0.65	1.30
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			7.53
	Time	IWPUT	INTRA-RVW
Intra-service:	251	0.064	16.11
Total time:	557		

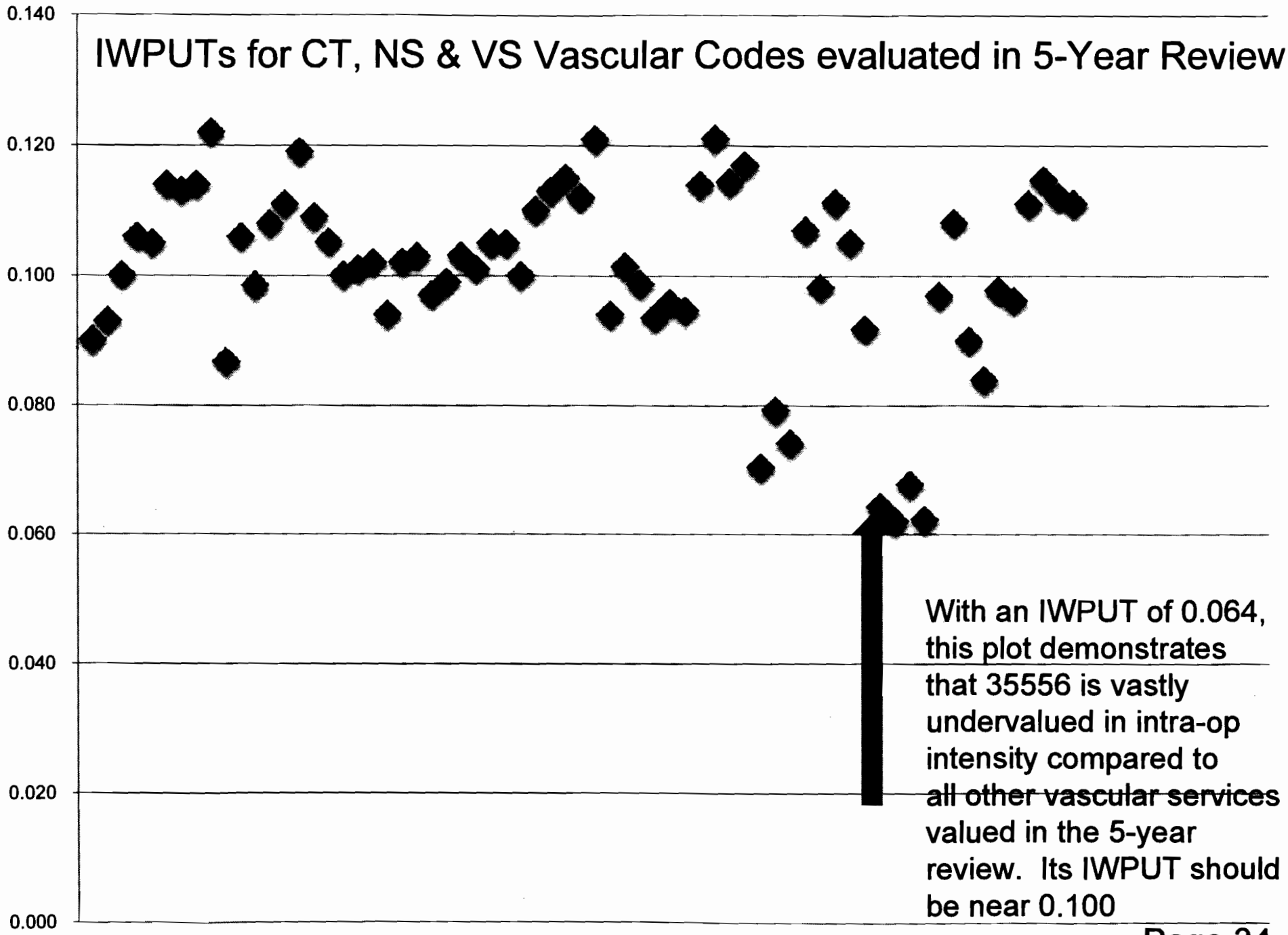
Note: These are original data from 5-year review, calculated with 2005 E/M values

CMS/RUC IWPUTs for Vascular Surgery Bypass Codes 2000-2006

35556	**CMS Rec inappropriately places code here**	**0.064**
35558	BPG w vein femoral-femoral	0.065
35533	BPG w vein axillary-bi-femoral	0.075
35656	BPG w other than vein fem-pop	0.075
35565	BPG w vein ilio-femoral	0.076
35522	BPG w vein axillary-brachial	0.077
35521	BPG w vein axillary-femoral	0.079
35665	BPG w other than vein iliofem	0.080
35563	BPG w vein ilio-iliac	0.081
35571	BPG w vein popliteal-tibial	0.083
35510	BPG w vein carotid-brachial	0.084
35671	BPG w other than vein pop-tib	0.084
35663	BPG w other than vein ilioiliac	0.084
35587	BPG w vein insitu pop-tib	0.085
35512	BPG w vein subclavian-brachial	0.085
35666	BPG w other than vein fem-tib	0.086
35661	BPG w other than vein fem-fem	0.086
35531	BPG w vein aorto-mesenteric	0.086
35654	BPG w other than vein ax-bifem	0.089
35556	**SVS Rec Appropriately Places Code here**	**0.090**
35518	BPG w vein axillary-axillary	0.091
35646	BPG w other than vein aortobifem	0.092
35525	BPG w vein brachial-brachial	0.093
35636	BPG w other than vein splenorenal	0.094
35511	BPG w vein subclavian-subclavian	0.096
35526	BPG w vein aorto-subclavian	0.098
35621	BPG w other than vein ax-fem	0.100
35647	BPG w other than vein aortofem	0.101
35631	BPG w other than vein aorto-mes	0.101
35626	BPG w other than vein aorto-sub	0.104
35560	BPG w vein aorto-renal	0.107
35650	BPG w other than vein ax-ax	0.107
35536	BPG w vien splenorenal	0.120
35623	BPG w other than vein ax-pop	0.120


2007 RVW plotted against
Total physician time for
CT, NS & VS Vascular cases
that were revised in 5-year review
y = 0.055x
R² = 0.913
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
200
400
600
800
1000
1200
1400
1600
1800
2000
In comparison to all vascular codes evaluated in the 5-year review, 35556 is undervalued. According to this linear regression, the RVW should be 32.23


2007 RVWs plotted against intra-service time for
CT, NS and VS Vascular Codes in 5-year review
y = 0.189x
R² = 0.510
Based on comparison to all revalued vascular codes in the 5-year review, 35556 is vastly undervalued at 26.62. It should be 47.44
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
50
100
150
200
250
300
350
400


IWPUTs for CT, NS & VS Vascular Codes evaluated in 5-Year Review
0.140
0.120
0.100
0.080
0.060
0.040
0.020
0.000
With an IWPUT of 0.064, this plot demonstrates that 35556 is vastly undervalued in intra-op intensity compared to all other vascular services valued in the 5-year review. Its IWPUT should be near 0.100

Based on parity with all other vascular codes in the 5-year review, and to resolve a rank order anomaly SVS requests an RVW of 33.20 for 35556, using RUC & CMS approved visits

[redacted]

35556 for CMS mtg May 2007			33.20
Open fem-pop with vein	Svy Data	RUC Std.	RVW
	Time	Intensity	(=time x intensity)
Pre-service eval & positioning	55	0.0224	1.23
Pre-service scrub, dress, wait	15	0.0081	0.12
Pre-service total			**1.35**
Post-service:	Time	Intensity	(=time x intensity)
Immediate post cut from 30	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
ICU 99291		4.50	0.00
ICU 99292		2.25	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	1	2.00	2.00
99232	1	1.39	1.39
99231	2	0.76	1.52
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.9	0.00
99215		2.00	0.00
99214	0	1.42	0.00
99213	2	0.92	1.84
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			**9.13**
	Time	IWPUT	INTRA-RVW
Intra-service:	251	0.090	22.71

CPT 35566 Bypass Graft with vein, Femoral-tibial

- This lower extremity bypass is performed to prevent leg amputation due to ischemic gangrene and non-healing foot ulcers.
- SVS believes that this bypass in addition to three others in the same family (35556, 35583, 35585) number among the most undervalued services in the Medicare physicians fee schedule.
- The frequency of this operation has dropped substantially over the past 10 years.
- The individuals who require this type of operation are elderly and almost always have coincident atherosclerotic disorders such as coronary artery disease and cerebrovascular disease. Most of these patients has smoked thousands of packs of cigarettes and have advanced COPD.
- This operation requires extreme technical skill.

CPT 35566 Bypass Graft with vein, Femoral-tibial

- SVS recommended an RVW of 39.20 in the 5-year review
- RUC recommended an RVW of 32.00
- CMS value was 30.00
- 2007/8 CMS RVW with new E/M values: 32.22
- 2008 SVS recommendation with new E/M values: 40.20

SVS Recommendation vs. CMS Proposed RVU for 35566 Fem-Tib Bypass with vein. The CMS proposal would set a new lowest level for bypass surgery intensity.

/S Rec RVU	35566		39.20
JC-approved time & visi	Svy Data	RUC Std.	RVW
e-service:	Time	Intensity	(=time x intensity)
e-service eval & positio	55	0.0224	1.23
e-service scrub, dress,	15	0.0081	0.12
e-service total			1.35
ost-service:	Time	Intensity	(=time x intensity)
mediate post	30	0.0224	0.67
bsequent visits:	Visit n	E/M RVW	(=n x RVW)
U 99291	0	4.00	0.00
U 99292		2.00	0.00
CU 99296		16.00	0.00
CU 99297		8.00	0.00
233	1	1.51	1.51
232	2	1.06	2.12
231	3	0.64	1.92
scharge 99238	0	1.28	0.00
scharge 99239	1	1.75	1.75
215		1.73	0.00
214	0	1.08	0.00
213	2	0.65	1.30
212	1	0.43	0.43
211		0.17	0.00
ost-service total			9.70
	Time	IWPUT	INTRA-RVW
Intra-service:	306	0.062	28.14
Total Time:	670		

CMS Rec RVU	35566		30.00
RUC-approved time & visits	Svy Data	RUC Std.	RVW
Pre-service:	Time	Intensity	=time x inte
Pre-service eval & positioni	55	0.0224	1.23
Pre-service scrub, dress, wa	15	0.0081	0.12
Pre-service total			1.35
Post-service:	Time	Intensity	=time x inte
Immediate post	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RV
ICU 99291	0	4.00	0.00
ICU 99292		2.00	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	1	1.51	1.51
99232	2	1.06	2.12
99231	3	0.64	1.92
Discharge 99238	0	1.28	0.00
Discharge 99239	1	1.75	1.75
99215		1.73	0.00
99214	0	1.08	0.00
99213	2	0.65	1.30
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			9.70
	Time	IWPUT	INTRA-R
Intra-service:	306	0.062	18.94
Total Time:	670		

Note: These are original 5-year data with 2005 E/M values

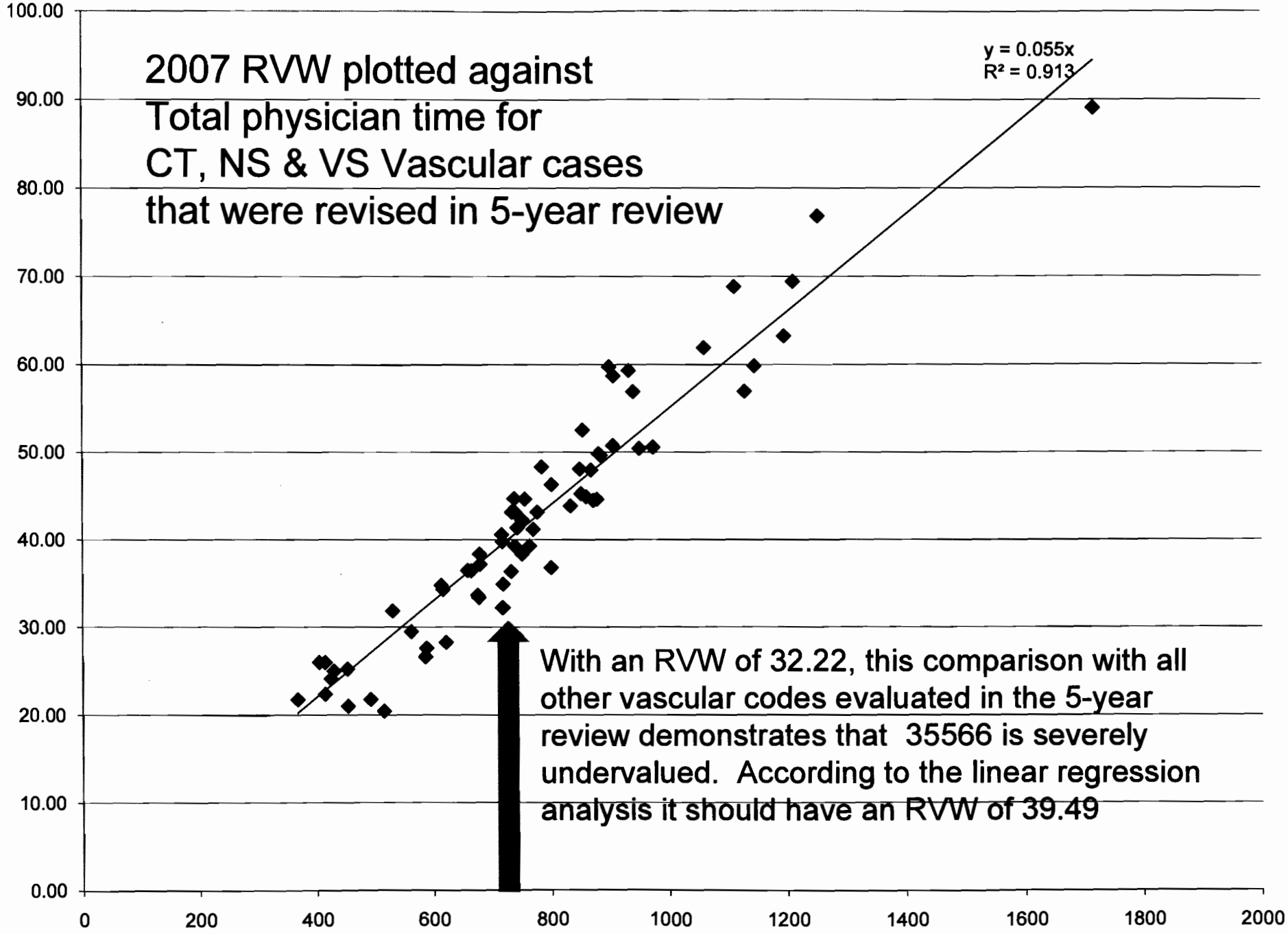
CMS/RUC Approved IWPUTs for Vascular Surgery Bypass Codes 2000-2006

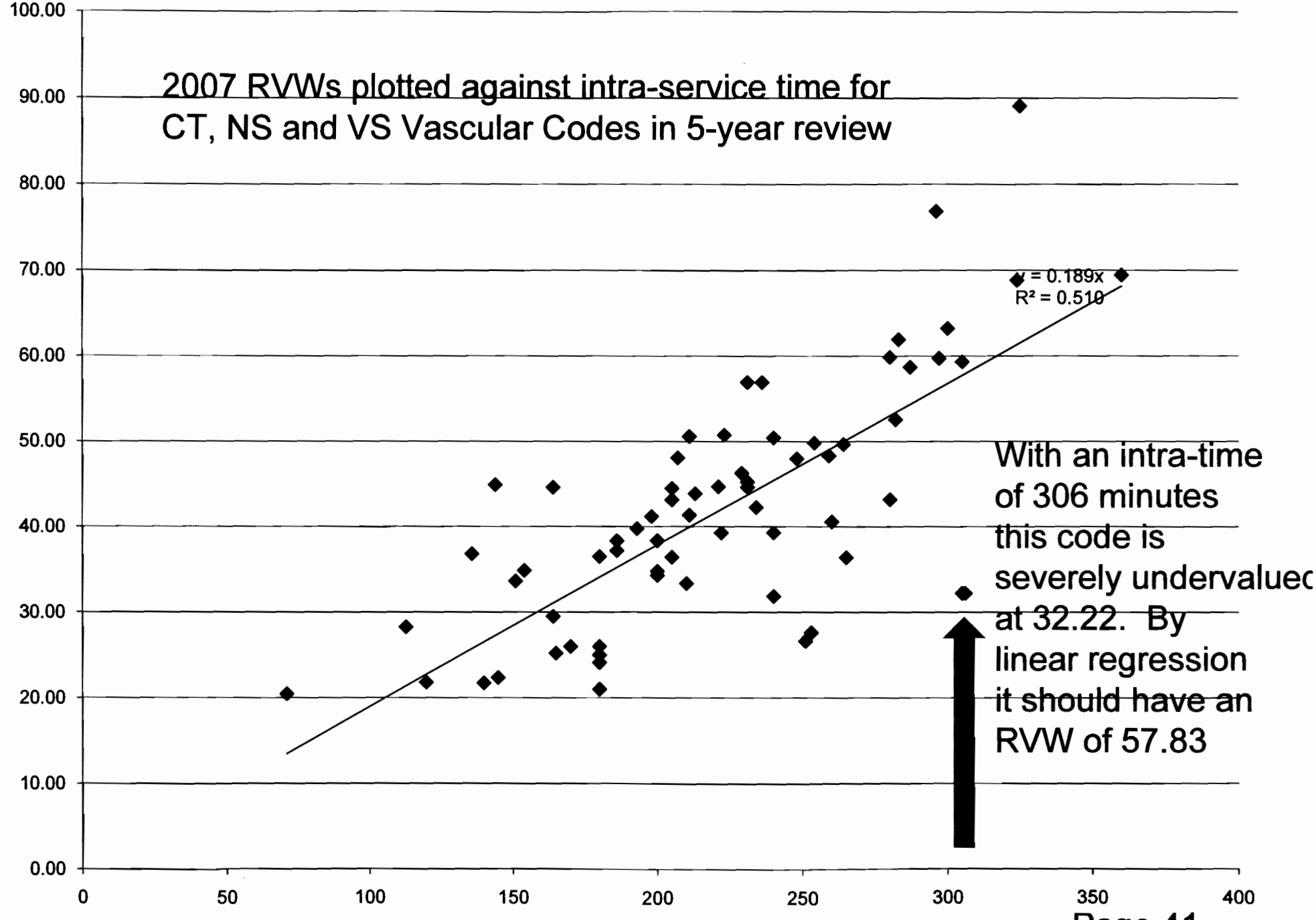
CPT Code	Short Descriptor	IWPUT
35566	CMS Rec inappropriately places code here	0.062
35558	BPG w vein femoral-femoral	0.065
35533	BPG w vein axillary-bi-femoral	0.075
35656	BPG w other than vein fem-pop	0.075
35565	BPG w vein ilio-femoral	0.076
35522	BPG w vein axillary-brachial	0.077
35521	BPG w vein axillary-femoral	0.079
35665	BPG w other than vein iliofem	0.080
35563	BPG w vein ilio-iliac	0.081
35571	BPG w vein popliteal-tibial	0.083
35510	BPG w vein carotid-brachial	0.084
35671	BPG w other than vein pop-tib	0.084
35663	BPG w other than vein ilioiliac	0.084
35587	BPG w vein insitu pop-tib	0.085
35512	BPG w vein subclavian-brachial	0.085
35666	BPG w other than vein fem-tib	0.086
35661	BPG w other than vein fem-fem	0.086
35531	BPG w vein aorto-mesenteric	0.086
35654	BPG w other than vein ax-bifem	0.089
35518	BPG w vein axillary-axillary	0.091
35566	SVS Rec Appropriately places code here	0.092
35646	BPG w other than vein aortobifem	0.092
35525	BPG w vein brachial-brachial	0.093
35636	BPG w other than vein splenorenal	0.094
35511	BPG w vein subclavian-subclavian	0.096
35526	BPG w vein aorto-subclavian	0.098
35621	BPG w other than vein ax-fem	0.100
35647	BPG w other than vein aortofem	0.101
35631	BPG w other than vein aorto-mes	0.101
35626	BPG w other than vein aorto-sub	0.104
35560	BPG w vein aorto-renal	0.107
35650	BPG w other than vein ax-ax	0.107
35536	BPG w vien splenorenal	0.120
35623	BPG w other than vein ax-pop	0.120

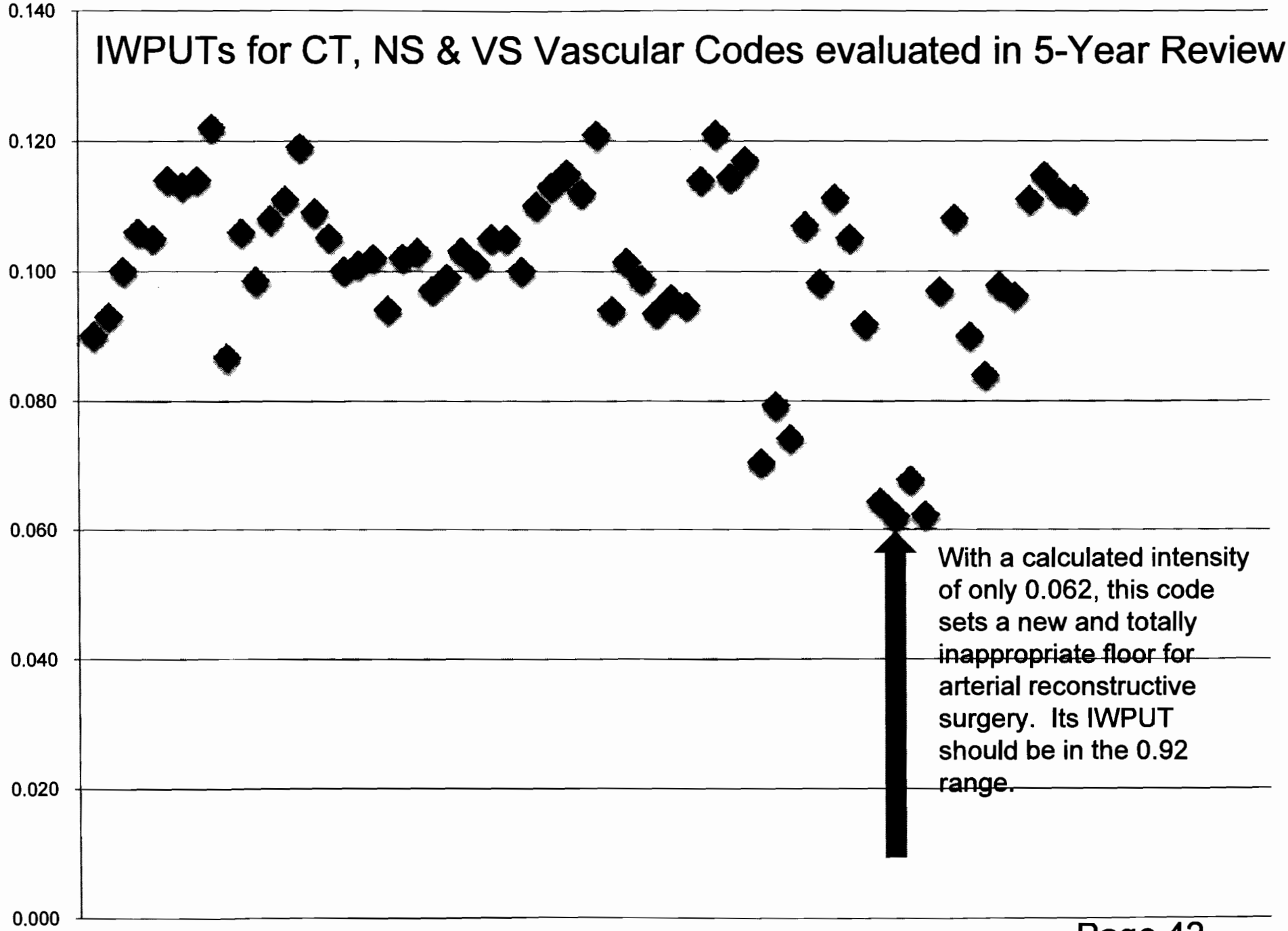
SVS recommended an RVW that would have resulted in an appropriate Intensity score of 0.092.

With the CMS RVW of 30.00 this complex procedure set a new low value for intensity

This is totally inappropriate.


2007 RVW plotted against
Total physician time for
CT, NS & VS Vascular cases
that were revised in 5-year review
y = 0.055x
R² = 0.913
With an RVW of 32.22, this comparison with all other vascular codes evaluated in the 5-year review demonstrates that 35566 is severely undervalued. According to the linear regression analysis it should have an RVW of 39.49
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
200
400
600
800
1000
1200
1400
1600
1800
2000


2007 RVWs plotted against intra-service time for CT, NS and VS Vascular Codes in 5-year review
y = 0.189x
R² = 0.510
With an intra-time of 306 minutes this code is severely undervaluec at 32.22. By linear regression it should have an RVW of 57.83
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
50
100
150
200
250
300
350
400


IWPUTs for CT, NS & VS Vascular Codes evaluated in 5-Year Review
0.140
0.120
0.100
0.080
0.060
0.040
0.020
0.000
With a calculated intensity of only 0.062, this code sets a new and totally inappropriate floor for arterial reconstructive surgery. Its IWPUT should be in the 0.92 range.

Conclusion for CPT 35566

SVS provided multiple comparisons with vascular codes that CMS revalued in this most recent 5-year review. By every standard, this code was severely undervalued. We request an RVW of 40.20. This uses the time and visit values approved by CMS. It also incorporates the new 2007 E/M RVUs.

[redacted]			
35556 for CMS mtg May 2007			40.20
Open fem-tib with vein	Svy Data	RUC Std.	RVW
	Time	Intensity	(=time x intensity)
Pre-service eval & positioning	55	0.0224	1.23
Pre-service scrub, dress, wait	15	0.0081	0.12
Pre-service total			**1.35**
Post-service:	Time	Intensity	(=time x intensity)
Immediate post cut from 30	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
ICU 99291		4.50	0.00
ICU 99292		2.25	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	1	2.00	2.00
99232	2	1.39	2.78
99231	3	0.76	2.28
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.9	0.00
99215		2.00	0.00
99214	0	1.42	0.00
99213	2	0.92	1.84
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			**11.28**
	Time	IWPUT	INTRA-RVW
Intra-service:	306	0.090	27.56

CPT 35583 Bypass graft with vein in-situ, femoral-popliteal:

This lower extremity bypass is performed to prevent leg amputation due to ischemic gangrene and non-healing foot ulcers.

SVS recommended RVW:	32.26
RUC recommended RVW:	26.00
CMS RVW unadjusted for E/M:	26.00
2007/8 CMS RVW with new E/M*	27.62
2008 SVS RVW rec with new E/M:	33.70

•"new EM" simply means that the 2005 values have been upgraded with the new work RVUs assigned to the E/M codes from the 5-year review

SVS Recommendation and CMS Proposed RVU for CPT 35583

Rec RVU	35583		32.26
UC time & visits	RUC Data	RUC Std.	RVW
ervice:	Time	Intensity	(=time x intensity)
ervice eval & positioning	55	0.0224	1.23
ervice scrub, dress, wait	15	0.0081	0.12
ervice total			1.35
service:	Time	Intensity	(=time x intensity)
diate post	30	0.0224	0.67
quent visits:	Visit n	E/M RVW	(=n x RVW)
9291	0	4.00	0.00
9292		2.00	0.00
99296		16.00	0.00
99297		8.00	0.00
	1	1.51	1.51
	1	1.06	1.06
	2	0.64	1.28
arge 99238	1	1.28	1.28
arge 99239	0	1.75	0.00
		1.73	0.00
	0	1.08	0.00
	2	0.65	1.30
	1	0.43	0.43
		0.17	0.00
service total			7.53
	Time	IWPUT	INTRA-RVW
Intra-service:	253	0.092	23.37
Total Time:	559		

CMS Rec RVU	35583		26.00
with RUC time & visits	RUC Data	RUC Std.	RVW
Pre-service:	Time	Intensity	(=time x intensity)
Pre-service eval & positioning	55	0.0224	1.23
Pre-service scrub, dress, wait	15	0.0081	0.12
Pre-service total			1.35
Post-service:	Time	Intensity	(=time x intensity)
Immediate post	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
ICU 99291	0	4.00	0.00
ICU 99292		2.00	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	1	1.51	1.51
99232	1	1.06	1.06
99231	2	0.64	1.28
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.75	0.00
99215		1.73	0.00
99214	0	1.08	0.00
99213	2	0.65	1.30
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			7.53
	Time	IWPUT	INTRA-RVW
Intra-service:	253	0.068	17.11
Total Time:	559		

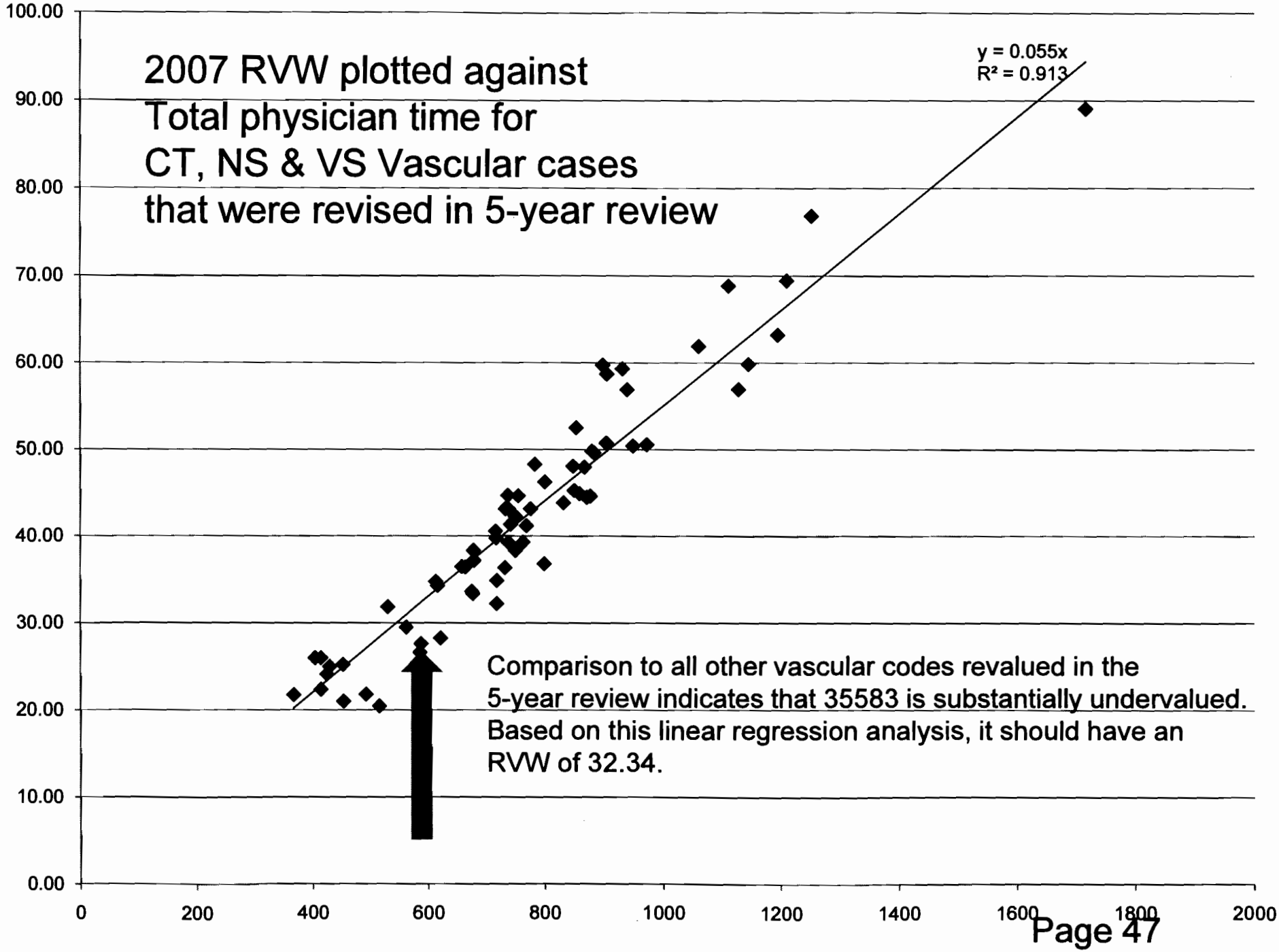
Note: These are the original SVS and CMS values with 2005 E/Ms

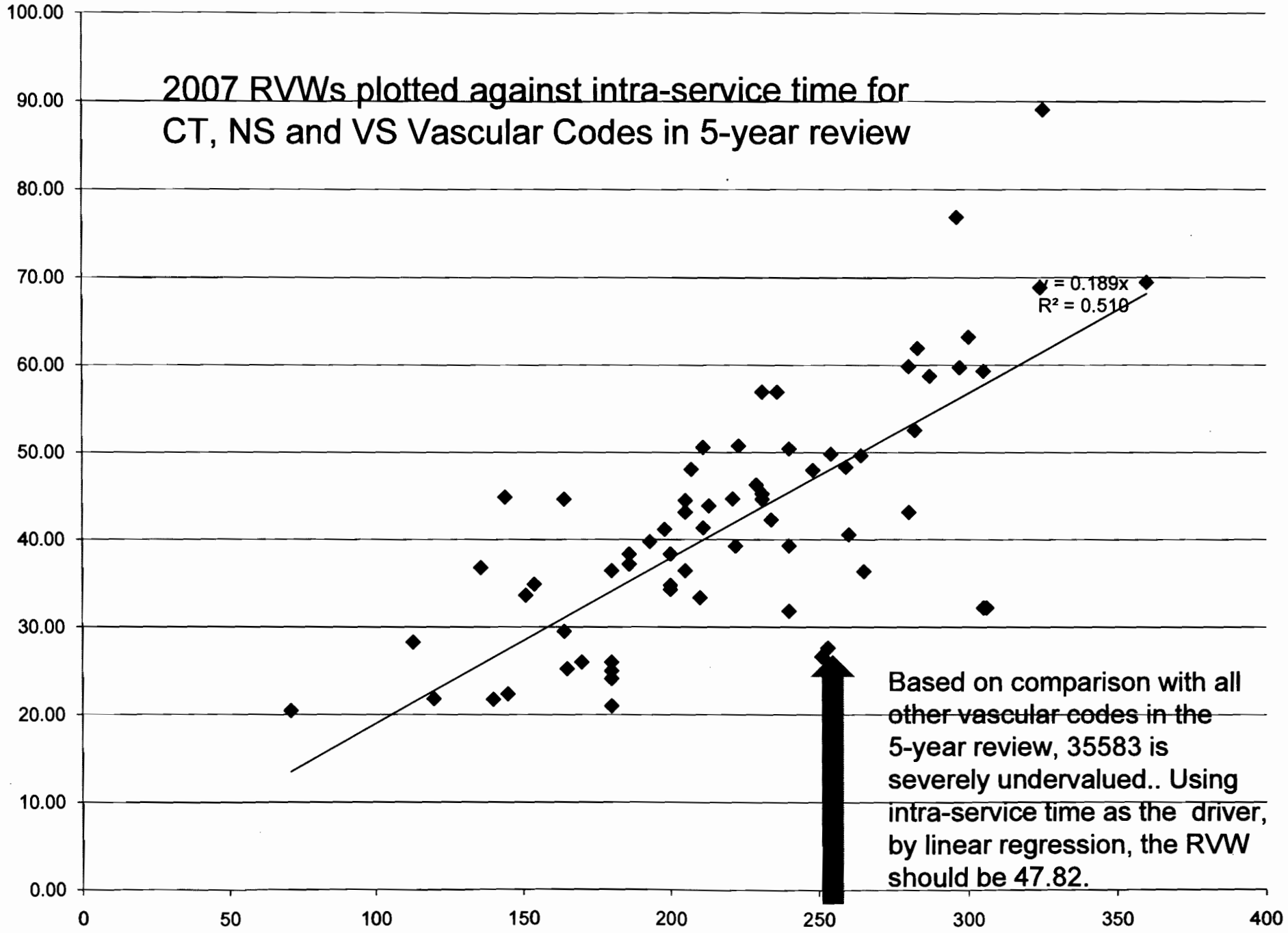
CMS/RUC IWPUTs for Vascular Surgery Bypass Codes 2000-2006

CPT Code	Short Descriptor	IWPUT
35558	BPG w vein femoral-femoral	0.065
35583	CMS Rec inappropriately places code here	0.068
35533	BPG w vein axillary-bi-femoral	0.075
35656	BPG w other than vein fem-pop	0.075
35565	BPG w vein ilio-femoral	0.076
35522	BPG w vein axillary-brachial	0.077
35521	BPG w vein axillary-femoral	0.079
35665	BPG w other than vein iliofem	0.080
35563	BPG w vein ilio-iliac	0.081
35571	BPG w vein popliteal-tibial	0.083
35510	BPG w vein carotid-brachial	0.084
35671	BPG w other than vein pop-tib	0.084
35663	BPG w other than vein ilioiliac	0.084
35587	BPG w vein insitu pop-tib	0.085
35512	BPG w vein subclavian-brachial	0.085
35666	BPG w other than vein fem-tib	0.086
35661	BPG w other than vein fem-fem	0.086
35531	BPG w vein aorto-mesenteric	0.086
35654	BPG w other than vein ax-bifem	0.089
35518	BPG w vein axillary-axillary	0.091
35583	SVS Rec Appropriately places code here	0.092
35646	BPG w other than vein aortobifem	0.092
35525	BPG w vein brachial-brachial	0.093
35636	BPG w other than vein splenorenal	0.094
35511	BPG w vein subclavian-subclavian	0.096
35526	BPG w vein aorto-subclavian	0.098
35621	BPG w other than vein ax-fem	0.100
35647	BPG w other than vein aortofem	0.101
35631	BPG w other than vein aorto-mes	0.101
35626	BPG w other than vein aorto-sub	0.104
35560	BPG w vein aorto-renal	0.107
35650	BPG w other than vein ax-ax	0.107
35536	BPG w vien splenorenal	0.120
35623	BPG w other than vein ax-pop	0.120

At the SVS recommended RVW this service would have an appropriate intensity value of 0.092

With the CMS RVW this service has an inappropriately low intensity value of only 0.068


2007 RVW plotted against
Total physician time for
CT, NS & VS Vascular cases
that were revised in 5-year review
y = 0.055x
R² = 0.913
Comparison to all other vascular codes revalued in the
5-year review indicates that 35583 is substantially undervalued.
Based on this linear regression analysis, it should have an
RVW of 32.34.
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
200
400
600
800
1000
1200
1400
1600
1800
2000


2007 RVWs plotted against intra-service time for CT, NS and VS Vascular Codes in 5-year review
y = 0.189x
R² = 0.510
Based on comparison with all other vascular codes in the 5-year review, 35583 is severely undervalued.. Using intra-service time as the driver, by linear regression, the RVW should be 47.82.
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
50
100
150
200
250
300
350
400

Based on comparisons with all other vascular codes in the just completed 5-year review, in order to correct a rank order anomaly, SVS requests and RVW of 33.70 for CPT 35583 fem-pop bypass graft using in-situ vein

[redacted]

35583 for CMS mtg May 2007			33.70
Open fem-pop with vein	Svy Data	RUC Std.	RVW
	Time	Intensity	(=time x intensity)
Pre-service eval & positioning	55	0.0224	1.23
Pre-service scrub, dress, wait	15	0.0081	0.12
Pre-service total			**1.35**
Post-service:	Time	Intensity	(=time x intensity)
Immediate post cut from 30	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
ICU 99291		4.50	0.00
ICU 99292		2.25	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	1	2.00	2.00
99232	1	1.39	1.39
99231	2	0.76	1.52
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.9	0.00
99215		2.00	0.00
99214	0	1.42	0.00
99213	2	0.92	1.84
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			**9.13**
	Time	IWPUT	INTRA-RVW
Intra-service:	253	0.092	23.21

CPT 35585 Bypass graft with vein in-situ, femoral-tibial or peroneal:

This lower extremity bypass is also performed to prevent leg amputation due to ischemic gangrene and non-healing foot ulcers.

SVS recommended RVW:	39.42
RUC recommended RVW:	32.00
CMS RVW:	30.00
2007/8 CMS RVW with new E/M:	32.22
2008 SVS rec RVW with new E/M:	41.00

NOTE: The phrase "new E/M" simply means adjustment has been made for the new work RVUs of the E/M codes that constitute the 90-day global package.

SVS Recommendation vs. CMS Proposed RVU for CPT 35585. SVS recommendation results in appropriate IWPUT intensity measure:

Rec RVU	35585		39.42
RUC time & visits	RUC data	RUC Std.	RVW
ervice:	Time	Intensity	(=time x intensity)
ervice eval & positioning	55	0.0224	1.23
ervice scrub, dress, wait	15	0.0081	0.12
ervice total			1.35
service:	Time	Intensity	(=time x intensity)
diate post	30	0.0224	0.67
equent visits:	Visit n	E/M RVW	(=n x RVW)
9291	0	4.00	0.00
9292		2.00	0.00
99296		16.00	0.00
99297		8.00	0.00
3	1	1.51	1.51
2	2	1.06	2.12
1	3	0.64	1.92
arge 99238	0	1.28	0.00
arge 99239	1	1.75	1.75
5		1.73	0.00
4	0	1.08	0.00
3	2	0.65	1.30
2	1	0.43	0.43
1		0.17	0.00
service total			9.70
	Time	IWPUT	INTRA-RVW
Intra-service:	305	0.093	28.36
Total Time:	669		

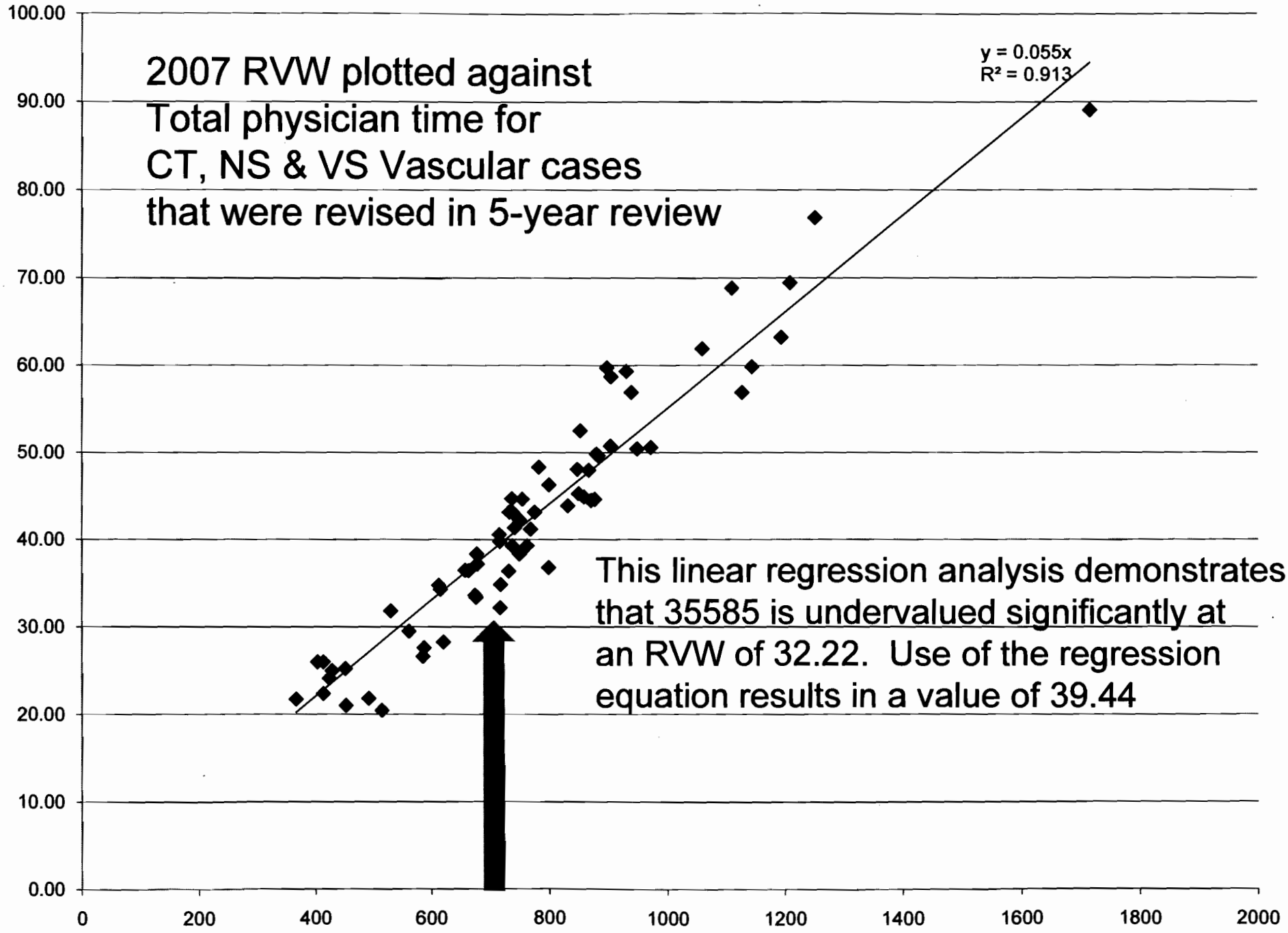
CMS Proposed RVU	35585		32.00
with RUC time & visits	RUC data	RUC Std.	RVW
Pre-service:	Time	Intensity	(=time x intensity)
Pre-service eval & positioning	55	0.0224	1.23
Pre-service scrub, dress, wait	15	0.0081	0.12
Pre-service total			1.35
Post-service:	Time	Intensity	(=time x intensity)
Immediate post	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
ICU 99291	0	4.00	0.00
ICU 99292		2.00	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	1	1.51	1.51
99232	2	1.06	2.12
99231	3	0.64	1.92
Discharge 99238	0	1.28	0.00
Discharge 99239	1	1.75	1.75
99215		1.73	0.00
99214	0	1.08	0.00
99213	2	0.65	1.30
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			9.70
	Time	IWPUT	INTRA-RVW
Intra-service:	305	0.069	20.94
Total Time:	669		

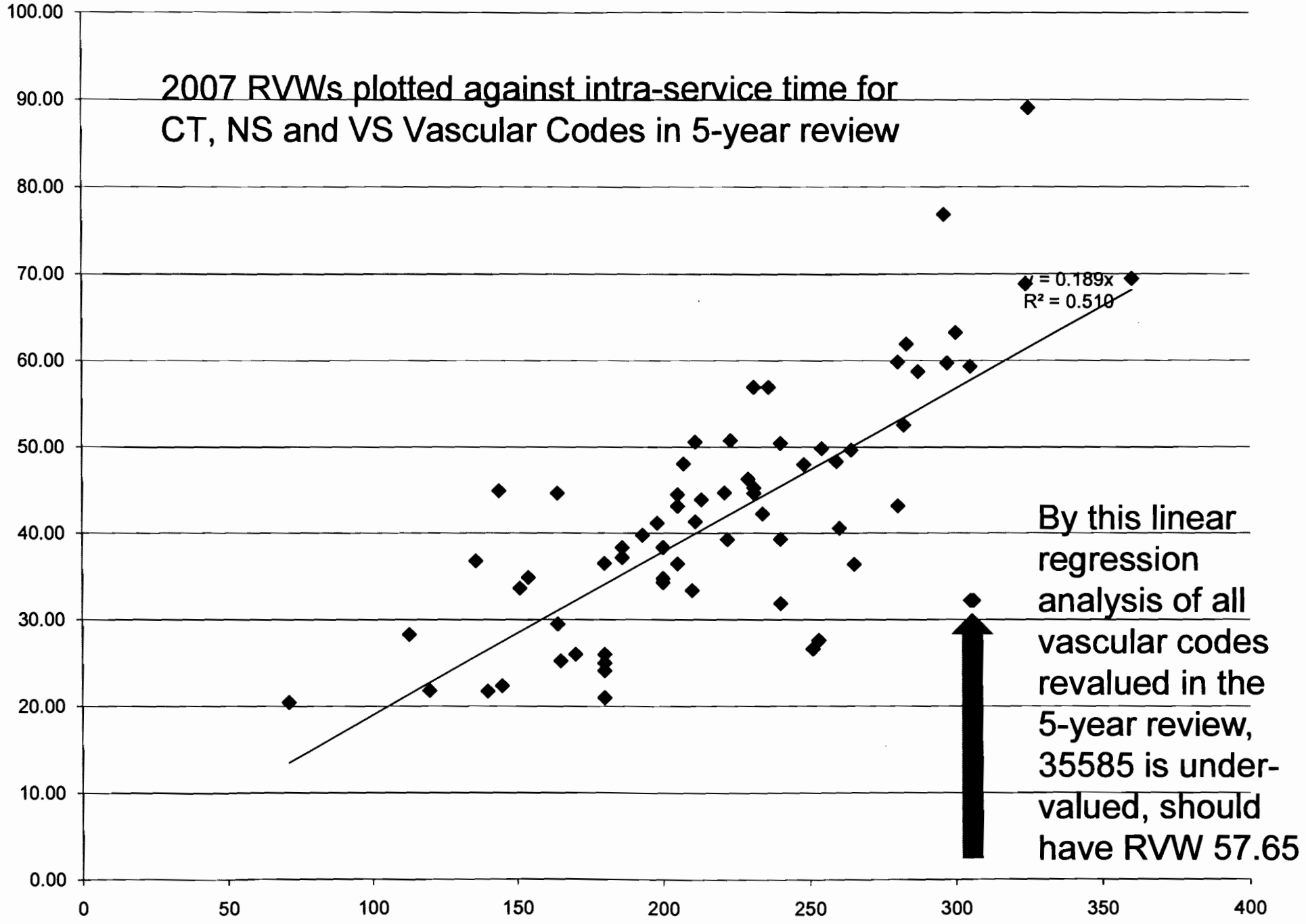
Note: These are the original 2005 SVS and 2006 CMS values, using 2005 E/Ms

CMS/RUC IWPUTs for Vascular Surgery Bypass Codes 2000-2006

CPT Code	Short Descriptor	IWPUT
35558	BPG w vein femoral-femoral	0.065
35585	CMS Rec inappropriately places code here	0.069
35533	BPG w vein axillary-bi-femoral	0.075
35656	BPG w other than vein fem-pop	0.075
35565	BPG w vein ilio-femoral	0.076
35522	BPG w vein axillary-brachial	0.077
35521	BPG w vein axillary-femoral	0.079
35665	BPG w other than vein iliofem	0.080
35563	BPG w vein ilio-iliac	0.081
35571	BPG w vein popliteal-tibial	0.083
35510	BPG w vein carotid-brachial	0.084
35671	BPG w other than vein pop-tib	0.084
35663	BPG w other than vein ilioiliac	0.084
35587	BPG w vein insitu pop-tib	0.085
35512	BPG w vein subclavian-brachial	0.085
35666	BPG w other than vein fem-tib	0.086
35661	BPG w other than vein fem-fem	0.086
35531	BPG w vein aorto-mesenteric	0.086
35654	BPG w other than vein ax-bifem	0.089
35518	BPG w vein axillary-axillary	0.091
35646	BPG w other than vein aortobifem	0.092
35585	SVS Rec Appropriately places code here	0.093
35525	BPG w vein brachial-brachial	0.093
35636	BPG w other than vein splenorenal	0.094
35511	BPG w vein subclavian-subclavian	0.096
35526	BPG w vein aorto-subclavian	0.098
35621	BPG w other than vein ax-fem	0.100
35647	BPG w other than vein aortofem	0.101
35631	BPG w other than vein aorto-mes	0.101
35626	BPG w other than vein aorto-sub	0.104
35560	BPG w vein aorto-renal	0.107
35650	BPG w other than vein ax-ax	0.107
35536	BPG w vien splenorenal	0.120
35623	BPG w other than vein ax-pop	0.120

As with the other three codes in this family, the CMS RVW resulted in an extremely low, and inappropriate intensity value for a complex distal arterial reconstruction.


2007 RVW plotted against
Total physician time for
CT, NS & VS Vascular cases
that were revised in 5-year review
y = 0.055x
R² = 0.913
This linear regression analysis demonstrates that 35585 is undervalued significantly at an RVW of 32.22. Use of the regression equation results in a value of 39.44
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
200
400
600
800
1000
1200
1400
1600
1800
2000


2007 RVWs plotted against intra-service time for CT, NS and VS Vascular Codes in 5-year review
y = 0.189x
R² = 0.510
By this linear regression analysis of all vascular codes revalued in the 5-year review, 35585 is under-valued, should have RVW 57.65
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
50
100
150
200
250
300
350
400

Based on comparison with all vascular codes that were revalued in the 5-year Review, and to correct a rank order anomaly, SVS recommends an RVW of 41.00 for CPT 35585

[redacted]			
35585 for CMS mtg May 2007			41.00
Open fem-tib in-situ	Svy Data	RUC Std.	RVW
	Time	Intensity	(=time x intensity)
Pre-service eval & positioning	55	0.0224	1.23
Pre-service scrub, dress, wait	15	0.0081	0.12
Pre-service total			1.35
Post-service:	Time	Intensity	(=time x intensity)
Immediate post cut from 30	30	0.0224	0.67
Subsequent visits:	Visit n	E/M RVW	(=n x RVW)
ICU 99291		4.50	0.00
ICU 99292		2.25	0.00
NICU 99296		16.00	0.00
NICU 99297		8.00	0.00
99233	1	2.00	2.00
99232	2	1.39	2.78
99231	3	0.76	2.28
Discharge 99238	1	1.28	1.28
Discharge 99239	0	1.9	0.00
99215		2.00	0.00
99214	0	1.42	0.00
99213	2	0.92	1.84
99212	1	0.43	0.43
99211		0.17	0.00
Post-service total			11.28
	Time	IWPUT	INTRA-RVW
Intra-service:	305	0.093	28.36

Summary of RVW Recommendations using the original data from the 5-year review, adjusted to include the current E/M work RVUs

35081 Open AAA repair with tube:	36.80
35102 Open AAA repair with bifurcated graft:	42.20
35556 Open fem-pop bypass with vein:	33.20
35566 Open fem-tibial bypass with vein:	40.20
35583 Open fem-pop bypass w/ vein in-situ:	33.70
35585 Open fem-tibial bypass w/ vein in-situ:	41.00

Submitter : **Mr. Andrew Paulin** **Date: 08/31/2007**

Organization : **Mt. San Antonio College**

Category : **Other Practitioner**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear CMS:

I am a certified athletic trainer working as an instructor and athletic trainer at a community college in southerb California
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients and student athletes.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Andrew Paulin, ATC
Athletic Trainer
Mt. San Antonio College
Walnut, CA
(909)594-5611, ext. 4878
apaulin@mtsac.edu

Submitter : Dr. Pedro de Alarcon **Date:** 08/31/2007

Organization : Univ of Illinois College of Medicine at Peoria

Category : Academic

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Regarding the proposed change to bundle CPT 93325 into other CPT codes when provided together. As a Chair of a Department of Pediatrics and on behalf of our Pediatric Cardiology Division, this is of particular concern to me because: I do not believe the appropriate process has been followed with respect to this change that is scheduled to be implemented on January 1, 2009. This new code is fully expected to address any outstanding issues relative to Medicare utilization of 93307, and has been analyzed at length by appropriate national medical societies, the CPT editorial panel, and the RUC. However, as a result of this proposed regulatory action by CMS, we are faced with resolving, in an accelerated timeframe of less than two months, an issue that directly impacts a distinctly non-Medicare population namely, pediatric cardiology practices and which is normally addressed over a multi-year period. Further, because the actions of CMS are contrary to the normal process for such changes and the resultant compressed timeframe, the specialty societies have not been able to effectively work with their membership to evaluate the proposed change in a reasoned, methodical manner (something that is in the interests of all parties). The surveys performed to set the work RVU s for almost all of the ECHO codes utilized specifically by pediatric cardiologists and affected by this proposed change were performed more than 10 years ago. Particularly among pediatric cardiologists, much needed new surveys would provide evidence that the work and risk components of the procedures that involve Doppler Color Flow Mapping have evolved to the point where the relative value of the procedures have shifted to a significantly greater work component and a lesser technology component. This shift is reflected in the development of national standards such as those present in the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) initiative to develop and implement an ECHO Laboratory accreditation process. The focus of this initiative is in process, measuring work performed and not the technology associated with the provision of echocardiography services. This echocardiography accreditation initiative will be mandated by many payors within the next year. In 1997 there were specific echocardiography codes implemented in CPT for congenital cardiac anomalies to complement the existing CPT codes for echocardiography for non congenital heart disease. The codes were developed by the CPT Editorial Panel in response to the American Academy of Pediatrics and the American College of Cardiology s request to delineate more distinctively the different services involved in assessing and performing echocardiography on infants and young children with congenital cardiac anomalies. (CPT Assistant 1997). I have significant concern with the continued approach (of which this bundling proposal is an example) of placing adult and pediatric patients in the same grouping when it comes to evaluation of the work associated with providing care to these significantly different patient populations. Because the adult cardiology population is much larger than the pediatric population, the RVU s for procedures that are common to both are established exclusively using adult patients as the basis. The work and expense associated with providing care to pediatric patients is not considered. The inaccuracies that result from this approach can be linked to anatomical differences between pediatric and adult patients (size, development, etc. - see references from the CPT Assistant below) as well as the basic issue of getting a child to be still while performing complex imaging procedures. CPT Code 93325 describes Doppler color flow velocity mapping. This service is typically performed in conjuction with another ECHO imaging study to define abnormalities as a clue to flow aberrations and to provide landmarks for positioning the Doppler cursor.

CMS-1385-P-15435-Attach-1.DOC

August 10, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1385–P
P.O. Box 8018
Baltimore, MD 21244–8018

Re. File Code: CMS–1385–P, CODING—ADDITIONAL CODES FROM 5-YEAR REVIEW

To CMS:

I am writing regarding the proposed change to bundle CPT 93325 into CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350 when provided together.

As a Chair of a Department of Pediatrics and on behalf of our Pediatric Cardiology Division, this is of particular concern to me because:

1. I do not believe the appropriate process has been followed with respect to this change that is scheduled to be implemented on January 1, 2009.

   This new code is fully expected to address any outstanding issues relative to Medicare utilization of 93307, and has been analyzed at length by appropriate national medical societies, the CPT editorial panel, and the RUC. However, as a result of this proposed regulatory action by CMS, we are faced with resolving, in an accelerated timeframe of less than two months, an issue that directly impacts a distinctly non-Medicare population – namely, pediatric cardiology practices – and which is normally addressed over a multi-year period. Further, because the actions of CMS are contrary to the normal process for such changes and the resultant compressed timeframe, the specialty societies have not been able to effectively work with their membership to evaluate the proposed change in a reasoned, methodical manner (something that is in the interests of all parties).

2. The surveys performed to set the work RVU's for almost all of the ECHO codes utilized specifically by pediatric cardiologists and affected by this proposed change were performed more than 10 years ago. Particularly among pediatric cardiologists, much needed new surveys would provide evidence that the work and risk components of the procedures that involve Doppler Color Flow Mapping have evolved to the point where the relative value of the procedures have shifted to a significantly greater work component and a lesser technology component.

   This shift is reflected in the development of national standards such as those present in the Intersocietal Commission for the Accreditation of Echocardiography Laboratories

(ICAEL) initiative to develop and implement an ECHO Laboratory accreditation process. The focus of this initiative is in process, measuring work performed and not the technology associated with the provision of echocardiography services. This echocardiography accreditation initiative will be mandated by many payors within the next year.

In 1997 there were specific echocardiography codes implemented in CPT for congenital cardiac anomalies to complement the existing CPT codes for echocardiography for non congenital heart disease. "The codes were developed by the CPT Editorial Panel in response to the American Academy of Pediatrics and the American College of Cardiology's request to delineate more distinctively the different services involved in *assessing* and *performing* echocardiography on infants and young children with congenital cardiac anomalies." (*CPT Assistant 1997).*

Consistent with this, I have significant concern with the continued approach (of which this bundling proposal is an example) of placing adult and pediatric patients in the same grouping when it comes to evaluation of the work associated with providing care to these significantly different patient populations. Because the adult cardiology population is much larger than the pediatric population, the RVU's for procedures that are common to both are established exclusively using adult patients as the basis. The work and expense associated with providing care to pediatric patients is not considered. The inaccuracies that result from this approach can be linked to anatomical differences between pediatric and adult patients (size, development, etc. - see references from the CPT Assistant below) as well as the basic issue of getting a child to be still while performing complex imaging procedures.

CPT Code 93325 describes Doppler color flow velocity mapping. This service is typically performed in *conjunction* with another echocardiography imaging study to define structural and dynamic abnormalities as a clue to flow aberrations and to provide internal anatomic landmarks necessary for positioning the Doppler cursor to record cardiovascular blood flow velocities.

Pediatric echocardiography is unique in that it is frequently necessary to use Doppler flow velocity mapping (93325) for diagnostic purposes and it forms the basis for subsequent clinical management decisions. CPT Assistant in 1997 references the uniqueness of the 93325 for the pediatric population stating that Doppler color flow velocity is "... even more critical in the neonatal period when rapid changes in pressure in the pulmonary circuit can cause significant blood flow changes, reversals of fetal shunts and delayed adaptation to neonatal life." It should also be recognized that Doppler flow velocity mapping is an essential medical service being provided to patients with congenital and non-congenital heart disease in the pediatric population.

The following vignettes will illustrate the importance of the Doppler color flow velocity mapping (93325) remaining as a separate and distinct medical service and as an add-on code (+) for pediatric echocardiography services. These are just a few examples of the many complex anatomic and physiologic issues that we as pediatric cardiologists face on a daily basis when performing echocardiograms on infants, children, and adults with complex congenital or non-congenital heart disease. These are not unusual cases for us.

Vignette 1 (*quoted from CPT Assistant 1997*) (example of Congenital Heart Disease)

"A three-day-old neonate with transposition of the great vessels was initially treated with an atrial septostomy with a planned arterial switch procedure at seven days. On the third day post Raskind balloon septostomy increasing cyanosis is seen with saturation dropping to the low 70s. A repeat transthoracic echocardiography (93304) with color flow Doppler study is performed *(color flow Doppler is coded in addition as a 93325).* The physician reviews the echocardiographic images and prepares a report. The echocardiogram shows a closed patent ductus arteriousus and a small atrial septal defect. The child is returned to the cath-lab for a repeat septostomy and prostaglandin is restarted."

Vignette II (example of non-congenital heart disease)

A two-month-old infant is referred by the pediatrician to a pediatric cardiologist for a persistent murmur in an otherwise healthy infant. The pediatric cardiologist is concerned about a patent ductus arteriousus as a possible diagnosis. A ductus arteriousus, connecting the pulmonary artery and the aorta, is an essential structure during fetal life. Normally, the ductus arteriousus closes in the first few days after birth in healthy term infants. A persistent ductus arteriousus can give rise to long-term complications and needs to be followed carefully to evaluate if further intervention is needed (medical vs. surgical). Echocardiography permits an accurate diagnosis of a patent ductus arteriousus with assessment of both the hemodynamic impact if there is a shunt. Estimated pulmonary artery pressure is obtained by Doppler imaging and can exclude other associated defects also. Color flow Doppler will be able to outline the flow of a patent ductus arteriousus from the aorta to the pulmonary artery. Color flow Doppler in this baby revealed no cardiac defects or patent ductus arteriousus and the murmur was determined to be innocent.

Vignette III (example of congenital heart disease)

An eight year-old child (or a 23-year-old young adult), with complex cyanotic congenital heart disease (functional single ventricle) is post-op completion of a fenestrated Fontan procedure several years ago. He has had a progressive decrease in saturations over the last year. There are several possible explanations and the pediatric cardiologist performs an echocardiogram to help determine the etiology. Color flow Doppler (93325) is essential to help elucidate the postoperative anatomy and blood flow patterns, but the process is complex and time-consuming involving assessment of the surgically constructed lateral tunnel or extracardiac conduit searching for a residual fenestration shunt or obstruction to flow, assessment of flow patterns through the previously surgically constructed Glenn anastomsis between the superior vena cava and pulmonary artery, assessment for obstruction to flow through the bulboventricular foramen, assessment for significant AV valve or semilunar valve insufficiency, and assessment for collateral vessels directing venous (desaturated blood) into the heart that may have developed over time. Any or all of these findings will then help dictate the next step in the care of this patient.

3. I am concerned that this change would adversely impact access to care for pediatric cardiology patients. Pediatric cardiology programs provide care not only to patients with the resources to afford private insurance, but also, to a large extent, to patients covered by Medicaid or with no coverage at all. Because a key impact of this change will be to reduce reimbursement for pediatric cardiology services across all payor groups, the resources available today that allow us to support programs that provide this much-

needed care to our patients will not be sufficient to continue to do so should the proposed change to bundle 93325 with other pediatric cardiology echocardiography codes be implemented.

Thus the effect of this change on pediatric cardiology programs throughout the country will be an increase in the need for subsidies from already resource-challenged children's hospitals and academic programs, or a significant increase in Medicaid reimbursement for the proposed bundled services, in order for pediatric cardiology patients to have the same access to care and resources that they do today.

I strongly urge CMS to withdraw the proposed change with respect to bundling 93325 with other pediatric cardiology echocardiography codes until such time as an appropriate review of all related issues can be performed, working within the prescribed process and timeframe, in order to achieve the most appropriate solution.

Thank you for your consideration of this serious matter.

Sincerely,

Submitter : **Mr. Christopher Roy** **Date: 08/31/2007**

Organization : **Via-Christi Sports Medicine**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Christoher Roy. I am an Liscensed and Certified Athletic Trainer with Via-Christi Sports Medicine. My main responsibilities are with Newman University in Wichita, Kansas and with the Wichita Wild Indoor Professional Football Team. I have a bachelors degree in Exercise Science from Wichita State University and a Masters degree in Exercise Sports Science from Southwest Texas State University.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposcd regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Christopher T. Roy M.Ed., LAT, ATC, CSCS
Athletic Trainer
Via-Christi Sports Medicine
Wichita, Kansas

Submitter : **Mrs. Anne Lamb** **Date: 08/31/2007**

Organization : **In Touch Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Mr. Kerry N. Weems Aug 31, 2007
Administrator Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

PHYSICIAN SELF-REFERRAL ISSUES

Dear Mr. Weems:

As a Physical Therapist for 28 years and an owner of a private practice, I wish to comment on the July 12 proposed 2008 physician fee schedule rule, and in particular the issue surrounding physician self-referral and the in-office ancillary services exception. I support the removal of physical therapy as a designated health service (DHS) allowable under the in-office ancillary exception of the federal physician self-referral laws.

I believe that a conflict of interest exists whenever physicians are permitted to refer to, and profit from physical therapy services in which they have a financial interest. In these arrangements physicians seek income beyond the fee for their own services and enter into arrangements that amount to voluntary, or avoidable, conflicts of interest. These types of arrangements are being marketed to physicians as passive revenue streams .

Since Stark II the number of physician-owned and chiropractic-owned physical therapy practices has rapidly increased in this state. My physical therapist-owned private practice has suffered measurable losses in the number of patients who are referred , especially from those physicians who employ their own physical therapists.

As a physical therapist professional, I oppose allowing one profession to control the marketplace of another profession. I do not believe that patients are well-served when avoidable conflicts of interest exist. My concern is that physician self-referral is a cost-driver in healthcare. This can lead to unnecessary referrals, excessive frequencies of treatment, procedures and equipment. I am also concerned about the occurrence of denials or restrictions of physical therapy. This has been reported to occur when the therapy might eliminate the need for other high cost services, such as imaging or surgery, from which the physician profits. Finally, I have concerns over the limited choice that the Medicare beneficiary might have in physical therapists. Beneficiaries have reported that they feel pressured to discontinue the relationships they have with their own physical therapist in order to receive the physical therapy that they need.

Physician self-referral is being defended as allowing physicians a greater role in the physical therapy services provided to patients. However the trend in Minnesota has been for physician-owned physical therapy clinics to take advantage of the reassignment of benefits laws to collect payment in order to avoid the incident to requirements. Either way, the physician is controlling demand and access to services and at the same time is profiting from that control.

I strongly support any efforts to eliminate abusive financing arrangements under the Stark law that are contrary to the best interest of the Medicare beneficiary. I strongly urge the CMS to remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.

On behalf of me, a physical therapist and a private practice owner, thank you for your consideration of my comments.

Submitter : **Ms. Donna Dugas** **Date: 08/31/2007**

Organization : **UPMC Sports Medicine**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Donna M. Dugas and I am a Certified Athletic Trainer. I graduated from the University of Pittsburgh and currently work for UPMC Sports Medicine in Pittsburgh. I am contracted to provide Athletic Training services to the student-athletes at Chatham University and have done so for the past twelve years. In this capacity, I evaluate injuries and provide daily treatment and rehabilitation to the varsity sports teams. Through my employer, I also have the opportunity to work alongside physicians in their offices and see patients who need injury rehabilitation, home exercise instruction for musculoskeletal issues, and fit a variety of braces to assist patients with activities of daily living.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Donna M. Dugas, ATC

UPMC Sports Medicine
Head Athletic Trainer,
Chatham University

Submitter : Dr. Robert Zwolak **Date: 08/31/2007**

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I am submitting the complete MS Word document that is the Society for Vascular Surgery comment letter. This is different from the PDF that I just sent (successfully I think) that includes only supportive data for six CPT codes still in play from the 5-year review. This is our entire NPRM Comment Letter. THANKS for your attention. I hope this works. R Zwolak, SVS

CMS-1385-P-15439-Attach-1.DOC

[redacted] SVS
SOCIETY FOR VASCULAR SURGERY

August 31, 2007

The Honorable Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1385-P
PO Box 8017
Baltimore, MD 21244–8017

RE: CMS-1385-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee schedule for Calendar Year 2008 and Other Changes to Payment Under Part B

Dear Mr. Kuhn:

On behalf of the 2,300 members of the Society for Vascular Surgery (SVS), we offer the following comments on the Proposed Rule published in the Federal Register on July 12, 2007. We will address multiple provisions under this proposal.

For 2007, our specialty endured a 6% pay-cut due to the impact of the Deficit Reduction Act (DRA) on Noninvasive vascular laboratory studies plus negative changes in physician work payments due to the budget neutrality adjustor, plus additional reductions in the PE RVUs. **Yet, again for CY 2008 our specialty is facing a reduction that is double in size to what we have lost in 2007, 12 percent.** This simply can not continue. For many vascular surgeons, over 50% of their patients are Medicare beneficiaries, due the nature of the diseases and conditions we treat. We can not sustain reductions of this magnitude year after year and not at some point be forced to reduce access to Medicare beneficiaries. We are extremely concerned that 2008 will be the year that this happens.

These decisions regarding our practices are extremely difficult and not made lightly. SVS members are deeply committed to caring for our nation's seniors, but this combination of negative impacts may simply make it impossible for us to continue to offer all services to all Medicare beneficiaries.

The SVS comments will follow in this order:

1. Continuing Codes from the Five-Year Review Open Vascular Surgery Procedures
2. DRA Proposals – Section 5102 – Proposed Adjustments for Payments for Imaging Services

3. TRHCA – Section 101(b) – PQRI general comments
4. TRHCA – Section 101(b) – PQRI SVS ESRD quality measure
5. TRHCA – Section 101(b) – PQRI diabetic podiatry measures
6. Budget Neutrality Adjustor for Work RVUs & other work RVU issues
7. Resourced-Based PE-RVUs
    a. Equipment Use Rate
    b. CPT Codes 37205 and 37206 – Direct PE Inputs for Non-facility Setting
8. Medicare Payment Policy

1. Continuing Codes from the Five-Year Review: Six open Vascular Surgery Codes

SVS would again like to thank CMS for meeting with us on May 16, 2007 regarding the six interim valued vascular surgery procedures, some of our most complex and labor-intensive open aortic aneurysm and bypass operations (CPT codes 35102, 35081, 35556, 35566, 35583, 35585), procedures that are performed to save life and limb. We felt the meeting was very productive and allowed us to present new, additional regression analysis data in addition to information from our July, 2006 comments on the 2007 proposed Medicare Physician Payment rule and our December 30, 2006 comments on the final rule for 2007.

Despite of the opinion held by CMS regarding use of NSQIP data during the five-year review process SVS used multiple other methods besides NSQIP data to arrive at our work RVU recommendations for these codes. As we discussed at the CMS meeting on 16 May, we believe the Refinement Panel did not have time to fully consider all the huge amount of data supporting the conclusion that values above the median survey results were the most appropriate for these 6 very complex open surgical procedures. With due respect for the RUC process, SVS has processed nearly 100% of the vascular surgery codes to RUC survey and analysis, and we ALMOST NEVER asked for more than the median survey value. Nevertheless, for these six very large open surgery procedures, we believe the weight of evidence developed to validate our recommendations, i.e. building blocks, crosswalk comparisons intensity analyses, and finally the regression analyses, all serve to indicate that work RVUs greater than median survey are truly indicated to fairly value the work and to avoid rank order anomalies both within vascular surgery and across the entire relativity spectrum of all surgical procedures. We strongly urge CMS to reconsider the work RVUs of these 6 codes.

For example, regarding CPT code 35102 – Open repair of abdominal aortic aneurysm requiring bifurcated graft – an intensity/IWPUT analysis conducted by SVS determined that the appropriate IWPUT vale is 0.096, the mid-point range for all aneurysms and aortic surgery that maintains the relativity within the families of vascular surgery codes. The 2007 and proposed 2008 work RVUs instead establish a totally inappropriate IWPUT of 0.074, multiples of relative steps below appropriate intensity for open aortic surgery.

SVS used four additional analyses of physician work all of which indicated valuation higher than the CMS value. As we mentioned in our previous December 30, 2006 comments, SVS is very concerned that the Refinement Panel did not have adequate opportunity to review and discuss with SVS representatives the large body of data that SVS prepared and shared with them for all six of the open, vascular surgery codes that were part of the five-year review.

Again, we felt that our meeting on May 16th was a very productive exchange of information regarding the six CPT codes in question and these various methods and outputs that we have used to construct and verify SVS' recommendations that we part of the five-year review. We look forward to some positive level of resolution when the 2008 Final Rule is published in November. As noted below, we are sending the data analysis under separate cover for reconsideration. The following are SVS recommendations for these six codes. The work RVUs have been adjusted from our 2005 RUC recommendations to reflect the changes in EM work RVUs.

	2008 NPRM	SVS Recommendation
35081 Open AAA repair	33.37	36.80
35102 Open AAA repair	36.37	42.20
35556 Open fem-pop bypass graft	26.62	33.20
35566 Open fem-tibial bypass graft	32.22	40.20
35583 Open fem-pop insitu bypass	27.62	33.70
35585 Open fem-tib insitu bypass	32.22	41.00

SVS is sending under separate cover the large compendium of data we used to arrive at work RVU recommendations for these codes. We do not take lightly the RUC survey process, and we reiterate that it is an extremely rare event when SVS recommends work RVUs higher than the RUC survey median. This is in contrast to recommendation of the 25th percentile, which we have used with some regularity when we felt the overall data analysis did not support the RUC survey median. There is a fairness issue here that comes into play. These are not high volume codes, and each requires a huge effort and substantial surgical skill with attention to detail to achieve high quality outcomes. When measured by yardsticks of data provided to support recent E/M increases and proposed Anesthesia increases, these six codes have a huge amount of hard data justifying the requested work RVUs.

During our May 16th meeting Mr. Kay and Drs. Simon and Hambrick ask that we identify the high outliers on our regression analyses. The universe of codes we analyzed included neurosurgical, cardiac and vascular codes that involve arterial surgery and that had been considered during the current 5-year review. In all, this was 68 codes. For IWPUT comparisons, the high outliers were CPT 33413, 33427, 33545, 33863 and 33945. For the regression of RVW vs. total physician time the outliers were CPT 33305, 33413, 33863 and 33877. For the regression of RVW vs. intra-service time the high outliers are CPT 33300, 33305, 33460, 33945, 33463.

2. DRA Proposals - Section 5102 – Proposed Adjustments for Payments for Imaging Services

Having now experienced almost a full year of reductions under the DRA for non-invasive vascular diagnostic studies, SVS is even more convinced that CMS having included CPT codes 93880 – 93990 and G-code 0365 on the list of imaging codes that are defined by Section 5102(b) of the DRA when in fact these studies are predominately non-imaging in nature is not appropriate and needs to be re-visited by CMS to ensure that Medicare beneficiaries have access to the highest quality, most appropriate care.

Non-invasive diagnostic vascular studies ARE NOT included in the "Radiology" section of the CPT Book by intent because they are diagnostic tests used to identify and assess the severity of arterial and venous vascular diseases and disorders, either entirely or primarily through non-imaging modalities. Although these vascular diagnostic tests use ultrasound, they were invented as applications of Doppler ultrasound, which is NOT an imaging form of ultrasound. Doppler ultrasound measures the frequency shift of sound waves that bounce off moving red blood cells. Those frequency shifts undergo analysis by the electronics in the Doppler instrument and are plotted on paper or on a computer screen as graphs of velocity. These are not pictures or images of the tissue. The velocities determine the severity of the arterial disease. For instance, in a patient with severe atherosclerosis plaque in the carotid artery, the high velocities of blood flowing through a very narrow artery correspond to a severe stenosis. The most accurate way to determine the severity of stenosis is based on these velocities, and NOT on a picture of the plaque. It is the visual display of blood flow velocity, not visual pictures of the interior of the vasculature, which are analyzed and interpreted when performing a non-invasive diagnostic vascular study.

Furthermore, noninvasive vascular lab studies have never been appropriately valued in the HOPPS APC system. Noninvasive vascular diagnostic services are performed in a wide variety of locations in different hospitals, ranging from radiology, to pulmonary medicine, to respiratory therapy, to cardiology, vascular surgery and others, lending to a huge range of cost/charge ratios. These services are low profile and seldom garner any attention by the hospital regarding the creation of appropriate charges. Thus, application of cost/charge ratio to charges in order to determine costs has never produced accurate cost numbers for this small family of tests. In fact, the Society for Vascular Ultrasound brought this to the attention of one of the very first APC Panel meetings. SVU was informed that "it all comes out in the wash for hospitals," and no corrective action was taken. Interestingly, in the CY 2008 Proposed Hospital Outpatient Prospective Payment System Rule, the proposed APC payments to hospitals for non-invasive vascular studies are flat and have been for some time, even though the conversion factor for the hospitals has been increasing approximately 3 percent per year for last few years.

However, the fact is that for office providers of these services, it does not "come out in the wash". The AMA PEAC committee considered all the

direct inputs for these services in great detail during their deliberative process. The PEAC inputs are very accurate and result in appropriate valuation for these services. Starting January 1, 2007, SVS members have endured the magnitude of these reductions, 30 – 40 percent, from PFS to APC payments and it has only hardened our resolve that the APC payments are inappropriately low.

Therefore, SVS believes that it is imperative that CMS work across divisions to address the issues we have raised. SVS would like to work with CMS regarding these definitional and data issues to achieve a workable solution.

3. TRHCA – Section 101(b) – PQRI General Comments

SVS appreciates CMS using this proposed rule in an attempt to provide greater clarity regarding the role of a consensus organization in both the measure development process and the measure approval process. SVS believes it is very important to the future of the PQRI program and the quality movement to have better, more complete definitions regarding what constitutes an appropriate venue and organizations and processes for these roles.

SVS is an active participant in many organizations including the AMA Physician Consortium, the Surgical Quality Alliance, the Fistula First Initiative, the Ambulatory Quality Alliance, and the National Quality Forum. Also, the SVS has developed and maintained for the last several years a registry regarding patient outcomes in vascular surgery.

SVS believes that it is imperative that these measures be generated for the purposes of development and then submitted/endorsed for the approval process by physician specialty societies and organizations. Being a member in all the "consensus organizations" listed above, the SVS is a supporter of these types of organizations; however, we believe it is more helpful to the process to define the characteristics of what CMS will consider an "approved" consensus organization, in addition to just giving examples, for the purposes of measure development and then a separate, distinct set of characteristics for what CMS will consider an "approved" consensus organization for the purposed of measure approval.

Because this is a dynamic process and one where additional capacity may be needed, defining characteristics and then CMS continually updating a list of organizations that meet these characteristics will enhance transparency and will enable more physician societies to participate in the process through the various organizations. We urge CMS to meet with the quality leaders of the physician societies and organizations to define the

characteristics of "approved" consensus measure development groups and consensus measure approval groups.

Need for Greater Transparency Regarding Process

We want to bring to CMS' attention that there is a need for greater transparency and a need for a real, structured governance of some of the consensus organizations, such as the AQA, and voting process for measure approval in this organization. This leads to a lack of rigorous and scientific evaluation for these measures. Also, it leads to arbitrary decisions regarding measures that may be in the 2007 program and now may not be in the 2008 program. Having physicians gear up to report measures in 2007 that may be gone in 2008 will lead to frustration, lack of robust data, and a lack of interest in participation. Thus, CMS needs to make a decision that once a measure is on the list, it will stay on the list of approved measures for at least a specific number of years, versus just six or 12 months.

Use of Medical Registry to Submit Data

SVS encourages CMS to consider participation in a physician society developed patient outcomes registry as a structural measure, even to the point that it would be considered, "a global measure" such that participation in the registry, assuming the data could be accessed by CMS, would be considered successful participation in PQRI. The type and level of data sets that are included in these patient registries can provide CMS with a level of data regarding patterns of quality care for specific indications that will never be realized with the type of reporting currently contained within the PQRI program. SVS currently operates one of two national carotid stent registries. This has been extremely useful as providers comply with data reporting requirements for percutaneous carotid artery stenting.

Given that in the future there may be instances where SVS members who participate in our registry may be reporting data that is similar to data that would also be reported under a PQRI quality measure, we wanted to bring the following concerns to CMS' attention: 1) the routine data would be free of any information that could be used to identify the patient; 2) CMS would need to work with the existing registries regarding forms and processes used for patient consent regarding how the data could be used; 3) There would have to be a way developed to export the data by individual record, allowing either physicians or patients to decide not to have their data shared with CMS; and 4) Physicians must be in control of their data at all times. That being said, the SVS is extremely interested in working with CMS regarding how we can work together on this issue.

4. TRHCA – Section 101(b) – End-Stage Renal Disease Fistula Quality Measure

Not knowing exactly when CMS received the measures listed in Table 21, SVS wishes to inform CMS that it has submitted a measure to the NQF that we believe will be endorsed prior to November 15, 2007. This measure is relevant to the Medicare population and will allow vascular surgeons to report on their role and activities as providers of native hemodialysis access for Medicare beneficiaries that are in CKD 4,5 or End Stage Renal Disease. The goal of this measure is to provide a tool by which individual surgeon effort can be gauged in terms of creating native fistulas in those CKD and ESRD patients who are appropriate candidates. The details of this measure, which is currently under final review by the NQF, are provided here. We look forward to this measure being part of the 2008 set of PQRI measures.

NQF Number: 45

Focus: Vascular Access

Measure Title: Hemodialysis Vascular Access – Surgical Decision-making to Maximize Placement of Autogenous Arterial Venous Fistula

Developer: SVS

Type Reclassified: Outcome

Setting: Ambulatory Care Hospital

Level of Analysis: Individual Clinician

Description: Percentage of patients with advanced chronic disease (CKD4 or 5) or end-stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arteriovenous fistula (AVF).

Numerator: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons OR Fistula not Performed for Patient Reasons. NOTE: This measure will be reported as the total of the three categories of numerators and also as the three numerators reported separately.

Numerator Data Collection: G8081: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons: Append modifier (1P) to G8081 to report documented circumstances that appropriately exclude patients from an

autogenous fistula. A typical medical exclusion would include clinician documented that CKD4, CKD5 or ESRD patient requiring hemodialysis vascular access was not eligible for autogenous AV fistula based on results of vein mapping. OR Fistula not Performed for Patient Reasons: Append modifier (2P) to G8081 to report documented circumstances that exclude patients for patient related reasons. For instance, clinician documented that CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access refused autogenous AV fistula following recommendation for same by provider. Autogenous is defined as the patient's own native tissue. Fistula is defined as a surgical connection established between and artery and a vein.

Case Finding: Patients eligible for inclusion are those with KDOQI Stage 4 and 5 CKD and ESRD.

Denominator: Patients with CKD4, CKD5 or End-stage renal disease who undergo open surgical placement of permanent hemodialysis access

Denominator Data Collection: ICD-9 585.3, 585.4, 585.5, 585.6 or 996.73 AND CPT 36818, 36819, 36820, 36821, 36825, or 36830

Exclusions: None

Risk Adjustment: This measure is recommended only for first-time vascular access patients, that is, all patients who have not previously undergone placement of a permanent upper extremity indwelling fistula or graft. The justification for this limitation to first-time access patients is that insufficient scientific data exists to know the target threshold for placement of native AVFs in patients who have previously undergone AVF surgery.

Data Source / Collection Instrument: Administrative and medical record data, provider data

Release / Revision Date: 2007

In Use: no

Testing: no

Conditions: Use term "autogenous" AV fistula. Remove CKD3. Clarify denominator exclusions because medical reason and pt reason included in numerator. Use separate codes and reporting for numerator categories.

5. TRHCA – Section 101(b) – Podiatric Measures Table 22 of NPRM

SVS offers its highest possible level of support to appropriately crafted quality measures aimed at preventing limb loss in diabetics.

We note that one of the measures in Table 22 of the NPRM is entitled "Peripheral Arterial Disease: Ankle Brachial Index (ABI) Measurement". Assessment for presence of peripheral arterial disease (PAD) in diabetics is crucially important, but we would potentially suggest that physical exam palpation for foot pulses might be the first appropriate step in assessment for PAD. Otherwise the broad application of ABIs in all diabetics might be considered screening, and coverage issues could become relevant. The absence of palpable pulses could be a signal that ABIs are indicated in the diabetic patient. Certainly if the diabetic arrives with a foot ulcer, diabetic foot infection, or presence of tissue gangrene, ABIs and evaluation for PAD are mandatory.

Some diabetic patients have calcified tibial arteries, a condition that renders the ABI test unreliable. In this situation, measurement of toe pressures is indicated. In summary, SVS strongly supports evaluation for PAD in diabetics as a means to reduce limb loss. We look forward to appropriately designed quality measures to accomplish that.

6. Budget Neutrality Adjustor for Work RVUs and other Work RVU issues

SVS strongly objects to the use of budget neutrality adjustors for physician work. When CMS applied a budget neutrality adjuster to the work RVUs following the first 5-year review of physician work, it caused substantial confusion among non-Medicare payers, as well as physician practices. CMS eventually acknowledged the confusion and ineffectiveness of applying the budget neutrality adjuster to the work RVUs, and the Agency eventually eliminated the problem. Now its back again. SVS understands the argument that relativity among work, PE and PLI pools should remain constant, but we believe the counter-argument holds more weight, that is that RVUs should be paid equally, regardless of work, PE or PLI origin. The outcome of the 5-year review should be shifted to the Conversion Factor because it would: (i) have less impact on other payers who use the Medicare RBRVS; (ii) be consistent with the notion that budget neutrality is mandated for monetary reasons, and since the conversion factor is the monetary multiplier in the Medicare payment formula, this is the most appropriate place to adjust for budget neutrality; and (iii) be consistent with CMS' goal of transparency in the Medicare payment system.

Anesthesia Conversion Factor upgrade

SVS agrees that Medicare payment for anesthesia services is undervalued. SVS compliments ASA and the RUC for a completing a complex analysis of anesthesia services in order to compare it to work provided by other specialties. It was certainly a

challenging task to compare services that include reimbursement for base plus time to services that are reimbursed for base or time, but not both. However, SVS is concerned about the Intensity assignment during the lowest level of Post Induction Period Procedure Anesthesia (PIPPA) being set at 0.031 work units per minute. This Intensity setting was derived from comparison with CPT code 99149, a moderate sedation service. As opposed to the lowest level of PIPPA, wherein the patient has already been induced and is stable, it is our understanding that CPT 99149 includes the initiation of moderate sedation, during which a patient undergoes transformation from awake and alert to a hoped for level of "moderate" sedation. We believe this may be more complex than the lowest level of stable PIPPA, therefore not a fully appropriate one-to-one crosswalk for lowest level PIPPA. More troublesome, however, is that there are many periods in the construct of a surgical global service wherein the baseline Intensity is substantially less than 0.031. For instance, all time spent assessing the patient in the immediate pre-op period, reviewing informed consent, assessing patient for surgical readiness, discussing case requirements with nursing and anesthesia, are all reimbursed by Medicare at 0.0224 RVUs/min, or 28% less than the proposed lowest level of PIPPA. Likewise, all immediate post-op care in the surgical package is reimbursed at the same 0.0224 RVUs/min. These services include ensuring surgical stability of the patient in the immediate post-op period, writing post-op orders, etc., again seemingly of equal intensity to lowest level PIPPA. In summary, SVS believes that an increase in Medicare reimbursement for anesthesia services is well-deserved, but if the lowest level PIPPA is set at 0.031, we believe that all pre and post surgical service should be set at the equivalent or higher level.

93325

SVS recognizes the major clinical value and importance of colorflow analysis in vascular studies such as echocardiography. Having said that, we support elimination of an add-on code for colorflow during echocardiography, as apparently now underway by ACC. In absence of that independent method, we support bundling color into the base codes as is the case in other ultrasound applications. The colorflow add-on was created decades ago when the technology was new, unique, and very expensive. Today, colorflow is a routine component of all quality echocardiography scanners. It is, therefore, difficult to justify separate payment for this service.

7. Resource-Based PE – RVUs

Equipment Use Rate

SVS agrees with CMS that the 50 percent utilization rate for medical equipment is appropriate for equipment used as part of office-based procedures. For surgical specialties, procedure specific equipment used in the office may only be in use approximately one – two days a week, depending on the service mix of a specific office.

SVS is currently participating in two different surveys that are asking questions regarding equipment use rate. In both instances, the surveys are asking there questions in such a way to be both specialty and type of equipment specific. SVS believes that these types of specialty specific surveys are important and the type of data that CMS should be considering when making code specific decisions, regarding practice expense inputs. We believe that the data coming from these two efforts will be more instructive to CMS versus generalizing the higher utilization rates found by MedPAC in their six site survey for CT and MRI imaging equipment to even all types of imaging equipment – i.e. ultrasound - or for other types of equipment. Instead, SVS hopes that CMS uses specialty and type of equipment specific data to work through this question going forward.

CPT Codes 37205 and 37206 – Direct PE Inputs for Non-facility Setting

The SVS appreciates CMS reviewing clinical literature regarding transcatheter stent placement and what is considered standard practice regarding the number of stents placed per patient, per vessel. While we agree with CMS that it is not typical, i.e. greater than 50 percent of the time that two stents would be used to maintain the vascular integrity of an initial vessel, there are instances where a patient does need two stents. Since most of these stents cost more than $1,000 each, we ask that CMS provide some guidance to the Medicare contractors regarding how the cost of a second stent, when used, may be separately billable using a HCPCS code.

8. Medicare Physician Payment Rate for 2008

In 2008, physicians and other health care practitioners whose payment rates are tied to the physician fee schedule face a 10% payment rate cut. The SVS urges CMS to work with Congress to avert this cut and ensure that physician payment updates for 2008 and subsequent years accurately reflect increases in medical practice costs.

Payments to physicians today in 2007 are essentially the same as they were six years ago in 2001. Due to the SGR, physicians now face drastic Medicare payment cuts totaling almost 40% over the next eight years. Yet, during this same time period, the Medicare Economic Index (MEI), which measures increases in medical practice costs, is expected to increase by about 20%. Physicians cannot absorb these draconian cuts.

Only physicians and other health professionals face steep cuts under this flawed payment formula. Other providers, such as nursing homes and hospitals have payment updates that reflect the cost of inflation. Further, the 10% cut in payment rates facing physicians is in stark contrast to Medicare Advantage (MA) plans, which are paid on average 112% above the cost of traditional Medicare, with a significant number of MA plans paid from 120% to more than 150% of traditional Medicare. These overpayments are shortening the life of the Medicare trust fund.

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SVS appreciates the opportunity to submit these comments and looks forward to working with CMS to implement these recommendations. Please feel free to contact Pam Phillips, Director of Health Policy and Government Relations at 703-573-7894 or PPhillips@vascularsociety.org, if we can provide further information.

Yours truly,

K. Wayne Johnston, MD
President
Society for Vascular Surgery

Robert M. Zwolak, M.D.
Robert M. Zwolak, M.D.
Chair, Health Policy Committee
Society for Vascular Surgery

Submitter : **Dr. Curtis Baysinger** **Date: 08/31/2007**

Organization : **Vanderbilt University School of Medicine**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Date: 08/31/2007**

Organization :

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Unlicensed/unskilled office staff treating patients in a POPTS and billing fully for it, POPTS keeping the "good" patients who have the best reimbursement/insurance and sending the rest to offices like ours, Remember the OIG report that found $136 million in improper payments for PT services billed by physicians durning the first 6 months alone of 2002.

Submitter : **Dr. James Buese, MD** **Date: 08/31/2007**

Organization : **Anesthesiologist**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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CMS-1385-P-15442-Attach-1.DOC

CMS-1385-P-15442-Attach-2.TXT

CMS-1385-P-15442-Attach-3.DOC

15442

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Mr. Michael DeCarlo** **Date: 08/31/2007**

Organization : **Blue Cross Blue Shield Association**

Category : **Health Plan or Association**

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

RE: File Code CMS-1385-P - PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES
----CONTINUATION OF PREVIOUS COMMENTS----
3. Integration into small physicians workflow

Eliminating the facsimile exemption may also impact physician workflow. With regard to the failsafe capability above which would require that the physician temporarily use a written prescription until the network connections are restored, there is ample industry experience showing that physieian acceptance of the e-prescribing technology is lower where the technology is unreliable or lacks teehnical support.

The other negative influence is where the system application is inconsistent. Consider, for example, restricted class II drugs: federal law requires a written prescription signed by the physician. For these prescriptions the physician must either revert to the paper prescription pad or the e-prescribing system defaults to printing a hard copy of the prescription. Eliminating the facsimile exemption would add a third scenario where the physician would need to revert to a paper prescription when the patient s pharmacy of choice is not SCRIPT capable. Simply keeping track of which pharmacies are not SCRIPT capable represents an additional workflow burden and another reason for a physician not to e-prescribe.

Recommendations

Because eliminating the facsimile exemption could have potentially serious short-run impacts on Medicare Part D accessibility for beneficiaries, physicians workflows, and health plan network business relationships and arrangements, we recommend that CMS take the following steps to minimize the impact of eliminating the facsimile prescription:

" Allow at least one calendar year for industry compliance and implementation activities prior to the effective date for elimination of the facsimile exemption (i.e., compliance not required before January 1, 2009 or later if appropriate to facilitate the adoption of products compliant with the final e-prescribing standards that will be required as of April 1, 2009).

" Allow for the continued use of facsimile prescriptions as a failsafe method of e-prescribing during emergencies or other situations where electronic data transmissions based on SCRIPT standards are not possible (including, but not limited to, internet service outages and dispenser system failures).

" Extend the compliance deadline for an additional year for small prescribers, dispensers and independent pharmacies, based on an appropriate measure of business revenue (similar to the HIPAA transaction compliance extension for small health plans).

We thank you for the opportunity to submit comments on the proposed elimination of computer generated facsimiles for Medicare Part D electronic prescribing. Again we support these efforts to encourage pharmacies and prescribers to engage in e-preseribing and encourage the agency to incorporate the recommendations we have made in these comments.

Thank you.

Sincerely,

Joel Slackman
Managing Director, Policy
Office of Policy and Representation

Submitter : **Mr. Benjamin McLain** **Date: 08/31/2007**

Organization : **St. John's Hospital**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Benjamin McLain and I supervise outpatient rehabilitation for St. John's Hospital in Springfield, IL. I have been practicing as a Certified Athletic Trainer for nearly 10 year in a variety of settings; hospital, college and high shool to with private practice physical therapy. I currently employee 6 Certified Athletic Trainers with-in this hospital setting that are at risk of losing their positions due to these proposed changes.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Benjamin McLain, MBA, ATC

Submitter : **Mr. David Colt** **Date: 08/31/2007**

Organization : **Northwest Missouri State University**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is David Colt. I am in my 27th year as the Head Athletic Trainer at Northwest Missouri State University. I also teach anatomy and physiology classes. I am currently finishing my dissertation in Educational Leadership and Policy Analysis at the University of Missouri. I have been a certified athletic trainer since 1977.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for many patients.

As an athletic trainer, I am qualified to perform and do perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas like mine, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
David E. Colt, MSEd, ATC, LAT
Head Athletic Trainer & Assistant Professor
Northwest Missouri State University

Submitter : **Wendy Hart** **Date: 08/31/2007**

Organization : **UPMC Sports Medicine**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am currently a Certified Athletic Trainer working for UPMC Sports Medicine in Pittsburgh, Pennsylvania. I have been an ATC for approximately 15 years. I received my bachelor's degree from Slippery Rock University and my master's degree from the University of Pittsburgh.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Wendy G. Hart,MS,ATC

Submitter : **Carol Pecher** **Date: 08/31/2007**

Organization : **Adams County Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Adams County Physical Therapy
10 Springs Ave
Gettysburg, PA 17325
Adams County Physical Therapy
10 Springs Ave
Gettysburg, PA 17325

August 31, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention:CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.
Re: Physician Office PT/OT Services

Dear Mr. Weems;

I am writing this letter to express my concern regarding the in-office ancillary service arrangements that have impacted the delivery of quality Physical and Occupational Therapy.

Through the in-office ancillary services exception, many new physician owned arrangements have been initiated to provide physical and occupational therapy services. This loophole that seems to have been provided to allow physicians to provide services that might not otherwise be available has turned into an additional revenue source for many physicians. Because of this, the potential for abuse exists. It is unfair for the private practice owner such as myself to have to compete for business against physicians who are able to control their own referrals.

I have personally experienced a physician removing a patient who chose my facility for the convenience and better hours and referring them back to his in-house PT, saying Who told you that you could go there. I have also experienced the potential for abuse when my own office manager was referred to an in-house PT. When she explained that their office was too far for her to drive and that she worked in a PT office, she was given a home exercise sheet and instructed to do them on your own. Numerous patients have told me how they have had to push the doctor to allow them to come to see me over the in-house or physician invested practice. I have no idea how many gave up after their first request was rejected with the statement I would really prefer you go to my therapist.

Having practiced in the same small town for 16 years (my fellow therapist for 20 years) I have developed a following of loyal patients. It is extremely disappointing to hear them tell me that they had to argue with their doctor to allow them to come to see me. Physical therapy is a very personal experience as patients need to trust their therapist s judgment as they push them to work harder. Having developed a rapport, many patients would choose to return to the same therapist rather than develop a new relationship. Physician owned arrangements often take that choice out of the hands of the patient and put in the hands of a person who has the potential to make money from that decision

I urge you to consider the impact of these in-house arrangements on not only your beneficiaries lives and outcomes, but also for the potential for overuse of physical therapy services when physicians have the ability to profit from self-referral. When so many other cutbacks have occurred to limit costs, it is hard to believe this issue has not been addressed.

Thank you for considering these comments.

Sincerely,

Carol Pecher, PT

Submitter : **Mr. Justin Eggleston** **Date: 08/31/2007**

Organization : **Lincoln North Star High School**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Justin D. Eggleston and I am a certified Athletic Trainer for a high school in Lincoln Nebraska. I am also the Vice President of the Nebraska State Athletic Trainers Association.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Justin D. Eggleston, ATC

Submitter : Dr. Cindy Trowbridge **Date:** 08/31/2007

Organization : The University of Texas at Arlington

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

August 31, 2007

Dear Sir or Madam:

My name is Dr. Cindy Trowbridge and I am an Assistant Professor and Clinical Education Coordinator for the Athletic Training Education Program at The University of Texas at Arlington. I have been a certified athletic trainer for 14 years and have practiced in a variety of settings providing quality physical medicine and rehabilitation services to many people. I have a Doctor of Philosophy degree in Exercise Science with a specialization in Physical Medicine and Rehabilitation. I was trained and educated by certified athletic trainers dedicated to the health and wellness of our population through clinical services, education, and research. Therefore, I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Cindy Trowbridge PhD, ATC, LAT, CSCS
Assistant Professor and Clinical Education Coordinator Athletic Training Education Program
Department of Kinesiology
Box 19259
The University of Texas at Arlington
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Submitter : Mr. Greg Waltner **Date:** 08/31/2007

Organization : University of California, Santa Barbara

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Greg Waltner and I am a certified Athletic Trainer currently working for the University of California, Santa Barbara. I work with the Universities Intercollegiate Athletes. I am charged with educating, evaluating, preventing, and rehabilitating my athletes about their injuries; as well as, serving as a liaison between them and other allied health professionals. I have been a nationally certified Athletic Trainer since 2004 by the National Athletic Trainer's Association. I maintain my certification through stringent continuing education requirements. I have a Bachelor's and a Master's of Science Degree in Athletic Training.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Greg Waltner, MS, ATC

Submitter : Dr. JAMES SCULLY **Date:** 08/31/2007

Organization : AMERICAN PSYCHIATRIC ASSN.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

PLEASE SEE APPENDIX 3-THIS MS WORD FILE & ASSOCIATE WITH THE BODY OF COMMENTS SUBMITTED VIA THIS SITE A FEW MINUTES AGO. DUE TO ITS SIZE, I HAD TO BREAK THE FILE INTO THREE PARTS (BODY & 3 APPENDIX FILES, APPX. 1, 2 + 3) IN ORDER TO TRANSMIT. TRIED MULTIPLE TIMES BEFORE 5 PM WHICH DID NOT GO THROUGH, SO BROKE INTO 3 APPX FILES. THANK YOU. A.F.

CMS-1385-P-15451-Attach-1.DOC

APPENDIX 3:
NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR AMBULATORY CARE JULY 2007
(pgs. 7-8)

Mental Health and Substance Use Disorders		
Major Depressive Disorder: Diagnostic Evaluation	Percentage of patients with a diagnosis of major depressive disorder who met the DSM–IV™ criteria during the visit in which the new diagnosis or recurrent episode was identified	AMA PCPI[2]
Major Depressive Disorder: Suicide Risk Assessment	Percentage of patients who had a suicide risk assessment completed at each visit	AMA PCPI[2]
New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management (b) Effective Acute Phase Treatment (c) Effective Continuation Phase Treatment	a. Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication, and who had at least three follow-up contacts with a practitioner during the 84-day (12-week) Acute Treatment Phase. b. Percentage of patients who were diagnosed with a new episode of depression, were treated with antidepressant medication and remained on an antidepressant drug during the entire 84-day Acute Treatment Phase. c. Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication and who remained on an antidepressant drug for at least 180 days.	NCQA

MEASURE TITLE	**MEASURE DESCRIPTION**	**IP OWNER[1]**
Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents	Percentage of patients newly diagnosed with attention deficit hyperactivity disorder (ADHD) whose medical record contains documentation of Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or Diagnostic and Statistical Manual for Primary Care (DSM-PC) criteria being addressed.	ICSI

Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents	Percentage of patients diagnosed with attention deficit hyperactivity disorder (ADHD) and on first-line medication whose medical record contains documentation of a follow-up visit twice a year.	ICSI
ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication.	a. *Initiation Phase:* Percentage of children 6 – 12 years of age as of the Index Prescription Episode Start Date with an ambulatory prescription dispensed for and ADHD medication and who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. *Continuation and Maintenance (C&M) Phase:* Percentage of children 6 – 12 years of age as of the Index Prescription Episode Start Date with an ambulatory prescription dispensed for ADHD medication who remained on the medication for at least 210 days and who in addition to the visit in the Initiation Phase had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ends.	NCQA
Bipolar Disorder and Major Depression: Assessment for Manic or hypomanic behaviors	Percentage of patients treated for depression who were assessed, prior to treatment, for the presence of current and/or prior manic or hypomanic behaviors.	STABLE
Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use	Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use	STABLE
Bipolar Disorder: Appraisal for risk of suicide	Percentage of patients with bipolar disorder with evidence of an initial assessment that includes an appraisal for risk of suicide.	STABLE
Bipolar Disorder: Level-of-function evaluation	Percentage of patients treated for bipolar disorder with evidence of level-of-function evaluation at the time of the initial assessment and again within 12 weeks of initiating treatment	STABLE
Bipolar Disorder: Assessment for diabetes	Percentage of patients treated for bipolar disorder who are assessed for diabetes within 16 weeks after initiating treatment with an atypical antipsychotic agent	STABLE

Initiation and Engagement of Alcohol and Other Drug Dependence Treatment a. Initiation b. Engagement	Percentage of adults aged 18 and over diagnosed with AOD abuse or dependence and receiving a related service who initiate treatment Assessment of the degree to which members engage in treatment with two additional AOD treatments within 30 days after initiating treatment.	NCQA/WC

Submitter : Mr. Jay Greissing **Date:** 08/31/2007

Organization : Plasma Protein Therapeutics Association

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached. I had trouble sending before, so please use this attached document as PPTA's official comment. Thank you.

CMS-1385-P-15452-Attach-1.PDF

19452

PPTA
Plasma Protein Therapeutics Association

August 31, 2007
Reference No.: FASC07055

Kerry Weems
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS–1385–P (Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008)

Dear Administrator Weems:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the proposed rule regarding revisions to payment policies under the Medicare physician fee schedule, published in the *Federal Register* on July 12, 2007 ("Proposed Rule").[1] As an association deeply committed to the health and safety of the patients it serves, these comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("plasma protein therapies") in the physician office setting.

PPTA is the association that represents the manufacturers of plasma protein therapies. These therapies, which include albumin, blood clotting factor, alpha-1 antitrypsin, and intravenous immunoglobulin ("IVIG"), are used to treat a variety of orphan diseases and serious medical conditions for a very small, fragile patient population in the United States. PPTA members produce more than 80 percent of the plasma protein therapies for the U.S. market and more than 60 percent of such therapies for global consumption.

Patient access to plasma protein therapies is dependent on adequate physician reimbursement for the acquisition and administration of these biologicals. Because PPTA remains very concerned that the manner in which physicians and suppliers are reimbursed for the costs they incur related to furnishing IVIG therapies is insufficient, we applaud the Centers for Medicare and Medicaid Services ("CMS") for its proposal to

[1] Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 72 Fed. Reg. 38122 (July 12, 2007).

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continue to reimburse for IVIG preadministration-related services (G0332) for calendar year ("CY") 2008 at the current reimbursement rate. PPTA further supports the agency's proposal with regard to the future publication of the blood clotting factor furnishing fee update.

I. DISCUSSION

A. BACKGROUND

PPTA remains concerned with the access difficulties afflicting more than 10,000 Medicare beneficiaries who rely on regular infusions of IVIG therapies. PPTA has consistently argued that the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") (Pub. L. No. 108-173, 117 Stat. 2066 et. seq. (2003)) led to a reimbursement shortfall for IVIG therapies in the physician office setting. The MMA instituted the market-based manufacturer's average sales price ("ASP") for payment for most drugs under Medicare Part B, including IVIG when furnished by physicians and suppliers.[2] By shifting reimbursement methodology in this site of service for IVIG from 95 percent of the average wholesale price ("AWP") to 85 percent of the AWP in 2004, and then finally to 106 percent of the ASP in 2005, the MMA significantly reduced reimbursement levels for IVIG in the physician office.[3] When the ASP methodology went into effect in the physician office in 2005,[4] some physicians were unable to continue to offer IVIG therapies to their patients in this setting because 106 percent of the ASP does not adequately reimburse providers for the acquisition of IVIG.

Both the U.S. Department of Health and Human Services ("HHS")[5] and the Immune Deficiency Foundation and ("IDF")[6] have issued recent reports that support PPTA claims that insufficient reimbursement is a leading factor in the difficulties patients face in accessing IVIG. This reimbursement shortfall resulted in patient migration from

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[2] *See* 42 U.S.C. § 1395w-3a (2007).
[3] *See* 42 U.S.C. § 1395u(o)(1)(E) (2007).
[4] *See* Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 Fed. Reg. 66236, 66299 (Nov. 15, 2004) (codified by 42 C.F.R. § 414.804 (2007)).
[5] *See* OFFICE OF THE ASS'T SEC. FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH AND HUMAN SERV., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV) (2007) [hereinafter "ASPE Report"], at 4-22 (discussing reimbursement levels and noting difficulties Medicare beneficiaries confront in finding infusion sites); *see* OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH AND HUMAN SERVS., INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (2007) [hereinafter "OIG Report"], at 15 (concluding that a significant percentage of sales of IVIG to hospitals and physicians were at prices at or above the Medicare payment rate for the third quarter of 2006).
[6] *See* IMMUNE DEFICIENCY FOUNDATION, ASSESSING THE IMPACT OF CHANGES IN REIMBURSEMENT REGULATIONS AND PRODUCT AVAILABILITY ON ACCESS TO INTRAVENOUS GAMMAGLOBULIN TREATMENT AMONG PRIMARY IMMUNE DEFICIENCY PATIENTS 17 (2006) (revealing that a significant majority of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).

the physician office to the hospital outpatient department.[7] The shift in site of service for those patients requiring IVIG has led to further access difficulties because of the allocation system for IVIG.[8] PPTA believes, however, that Medicare beneficiaries should be able to obtain IVIG therapies best suited for their individual needs in the most appropriate site of service, and more suitable reimbursement levels would effectuate such patient autonomy.

PPTA welcomes the attention given and action taken by CMS to address this very difficult patient access situation. We are especially grateful that the agency decided to grant new brand specific "Q" codes effective July 1, 2007 to four liquid IVIG therapies and two other immune globulin therapies in response to PPTA's February 21, 2007 request that IVIG products that were not on the market as of October 1, 2003 be assigned separate codes in order to be consistent with the ASP statute. PPTA further appreciates the agency's decision to implement an additional payment for IVIG preadministration-related services and the proposal to continue this payment at the current level. As we will discuss later, PPTA hopes your proposal to extend this payment through CY 2008 will be finalized. We believe such actions taken by the agency are a good first step to help improve patient access to IVIG therapies.

As the recent HHS studies illustrate, the ASP methodology does not reflect the true acquisition cost of IVIG therapies.[9] The Government Accountability Office ("GAO") has further argued that "a sufficient empirical foundation does not exist for setting the payment rate for Medicare Part B drugs at 6 percent above ASP."[10] Additionally, in a 2005 study commissioned by PPTA, The Lewin Group determined there is an 8 percent shortfall for the acquisition of IVIG in the physician office. Such analysis by HHS and GAO should provide CMS with enough support to consider a payment adjustment to the ASP plus six percent in order to address the reimbursement shortfall providers experience in acquiring this critical therapy. The analysis from The Lewin Group could be used to provide guidance on what the appropriate amount may be.

In addition to the reimbursement for the product and preadministration-related services, CMS also reimburses providers for the costs of administering the infusion of

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[7] *See, e.g.*, Ricardo Alonso-Zaldivar, *Crucial But Costly Treatment Is Drying Up With Funding: Thousands Of Elderly Patients Who Need Intravenous Antibodies Are Hurt By Medicare Cutbacks - More Pain Could Be On The Way*, L.A. TIMES, February 28, 2006, at A8 (illustrating the challenges, including shifts in sites of service, patients must overcome to receive IVIG therapies because of the Medicare reimbursement cuts).

[8] *See* ASPE Report, *supra* note 5 at 2-29.

[9] *See, e.g.* OIG Report, *supra* note 5 at 9 (demonstrating that physicians are experiencing a significant reimbursement shortfall in acquiring IVIG therapies because the majority of IVIG sales to physicians in the third quarter of 2006 by the three largest IVIG distributors are at prices exceeding the reimbursement levels for that quarter).

[10] *See Hearing on Medicare Reimbursement of Physician-Administered Drugs Before the House Comm. on Ways and Means Subcomm. on Health*, 109th Cong. (2006) (statement of A. Bruce Greenwald, Director, Health Care, GAO).

IVIG. As you know, the Current Procedural Terminology ("CPT") codes of the American Medical Association ("AMA") are used for reporting medical services and procedures, including IVIG infusions. For example, the first hour of infusing IVIG is assigned to CPT code 90765, while the second hour of infusing IVIG is assigned to CPT code 90766.[11] For each CPT code, CMS assigns relative value units ("RVUs") to services that reflect (1) physician work, such as the time, skill, and intensity it takes to provide the service, (2) practice expenses, and (3) malpractice costs.[12] After the RVUs are adjusted for geographic variations in costs by the geographic practice cost indices ("GPCI"),[13] they are then converted into a dollar payment amount by a conversion factor, which for 2007 is $37.8975.[14] According to CMS, this conversion factor is scheduled to be reduced by 9.9 percent for CY 2008.[15] Without Congressional intervention, such a reduction could further hinder patient access to IVIG and other important drugs and biologicals.

PPTA would also like to comment on the CPT codes to which IVIG is assigned. PPTA respectfully disagrees with the inadequate work RVUs that CMS assigned to CPT codes 90765 and 90766 for CY 2007, and proposes for 2008. Although the AMA's Relative Value Update Committee ("RUC") recommends RVUs to CMS, CMS ultimately decides the pertinent figures comprising each RVU. While PPTA has not completed an analysis on the work RVUs assigned to CPT codes 90765 and 90766, we respectfully contend that assigning the first and additional hours of IVIG infusion to these codes is an oversight because the work RVUs fail to account for the complexities of infusing IVIG.

The MMA called for CMS to evaluate drugs according to the complexity of administration. The resulting statutory provision requires CMS to promptly evaluate drug administration codes for physicians' services to ensure accurate reporting and billing of those services, taking into account levels of complexity of the administration and resource consumption.[16] Although IVIG infusions are more complex and resource intensive than many other types of infusions currently reported using the same drug administration CPT codes 90765 and 90766, the RUC and CMS evidently believe IVIG infusions to be of low complexity, similar to a saline infusion. The resources required to administer IVIG, however, exceed reimbursement.

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[11] *See* Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; 71 Fed. Reg. 69623, 69974 (Dec. 1, 2006).
[12] *See* 42 U.S.C. § 1395w-4(c) (2007).
[13] *See* 42 U.S.C. § 1395w-4(e).
[14] In determining the administration payment for IVIG and other Part B drugs, one must use the following equation for each CPT code as appropriate: [(RVU work x budget neutrality adjustor x GPCI work) + (RVU PE x GPCI PE) + (RVU malpractice x GPCI malpractice)] x the conversion factor.
[15] *See* Letter from Thomas A. Gustafson, Ph.D., Acting Director, Center for Medicare Management, U.S. Dep't of Health & Human Servs., to Glen M. Hackbarth, Chair, Medicare Payment Advisory Commission (Feb. 28, 2007).
[16] 42 U.S.C. § 1395w-4(c)(2)(J).

For CY 2008, until CMS and the RUC can better evaluate the costs of the administration of IVIG, PPTA urges CMS to issue two "G" codes that will provide a more accurate reimbursement payment for the administration of an IVIG infusion -- one to account for the first hour of infusion and one to be used for each additional hour of infusion. In terms of resources required, PPTA believes the infusion of IVIG is most similar to the infusion of chemotherapy drugs and issuing this temporary payment code will help alleviate any problems that may arise in providing patients with safe and effective infusions of this lifesaving therapy.

Similar to the infusion of chemotherapy, an IVIG infusion requires the presence of a trained infusion nurse to administer the infusion and to monitor the patient during the entire infusion. As you may know, the infusion of IVIG has been associated with:

- renal dysfunction;
- acute renal failure;
- osmotic nephrosis;
- thrombotic events; and
- death.

If CMS does not more accurately reimburse the administration of an IVIG infusion, patient safety could be compromised because providers may be forced to make a business decision to no longer continue to use these nurses to administer IVIG and monitor the patients receiving the infusion. The continued presence of a trained infusion nurse for the entirety of an IVIG infusion is essential to ensure that both IVIG is properly administered to Medicare beneficiaries and such patients are appropriately monitored for these adverse reactions. For example, IVIG must be administered at the minimum concentration available and the minimum rate of infusion practicable to those patients with a predisposition to acute renal failure. In addition, the nurse can monitor those patients at risk for thrombotic events, including those patients with hyperviscosity, atherosclerosis, and cardiovascular disease. PPTA implores CMS to consider these complexities and dangers associated with this infusion and, for CY 2008, assign the administration of IVIG infusion to more appropriate "G" codes.

B. CODING—PAYMENT FOR IVIG ADD-ON CODE : CMS SHOULD FINALIZE THE PROPOSAL TO CONTINUE THE SEPARATE PAYMENT FOR IVIG PREADMINISTRATION_RELATED SERVICES AND SHOULD MAKE THIS PAYMENT PERMANENT

IVIG therapies are single source, as defined by the ASP statute,[17] orphan drugs[18] that treat patients with immune deficiencies and other serious, chronic medical disorders. According to the IDF, these therapies are the only effective treatment for primary immune deficiency disease ("PIDD").[19] Currently, the FDA has approved existing IVIG therapies for six clinical indications, including treatment of: (1) PIDD; secondary immune deficiency diseases, such as (2) pediatric HIV and (3) B-cell chronic lymphocytic leukemia; (4) idiopathic thrombocytopenic purpura, which is an autoimmune bleeding disorder, (5) Kawasaki disease, and (6) bone marrow transplantation.[20] For indications such as PIDD, IVIG enhances the defective components of a patient's immunity to fight and protect against infection and complications of infection. Patients relying upon IVIG therapies usually require infusions every three to four weeks for the duration of their lives.[21]

As you know, CMS established a G-code (G0332), effective January 1, 2006, in order to address the significant resources necessary to manage inventory, locate and acquire product, reschedule infusions due to product availability and patient needs, and provide the proper therapy and dose to patients.[22] PPTA appreciates the recognition by CMS of these additional costs incurred by physicians in providing IVIG therapies to Medicare beneficiaries. We agree with the Secretary of HHS about the importance of this payment.[23]

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[17] 42 U.S.C. § 1395w-3(c)(6)(D) (2007) (specifying that a biological, which each IVIG therapy is, is a "single source drug or biological").

[18] An "orphan drug" is a drug used to treat a rare disease or condition that "affects less than 200,000 persons in the United States, or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug." *See* 21 U.S.C. § 360bb(a)(2) (2007).

[19] *See* Immune Deficiency Foundation *at* http://www.primaryimmune.org/igivreimb/igivreimb_bkgnd.htm (last visited August 12, 2007).

[20] PRIMARY IMMUNODEFICIENCY COMMITTEE OF THE AMERICAN ACADEMY OF ALLERGY, ASTHMA, AND IMMUNOLOGY, PRACTICE PAPER ON THE APPROPRIATE USE OF INTRAVENOUSLY ADMINISTERED IMMUNOGLOBULIN 6 (Jordan S. Orange, MD, PhD, ed., 2005).

[21] *Id.* at 15.

[22] 70 Fed. Reg. 70116, 70220 (Nov. 21, 2005).

[23] *See, e.g.*, Letter from Michael O. Leavitt, Secretary Dep't of Health & Human Servs., to Rep. Ellen O. Tauscher (Aug. 29, 2006) (demonstrating the agency's support for the preadministration payment in his response to a May 31st letter, which was led by Representative Joe Pitts and signed by 34 other Members of Congress, urging CMS to consider a both a payment adjustment and brand-specific reimbursement for IVIG to address its reimbursement shortfall and improve patient access to this lifesaving therapy).

The Proposed Rule would continue payment for G0332 for CY 2008 at the current reimbursement rate, which is $71 in the physician office.[24] PPTA supports the agency's proposal, which is consistent with the position of the Secretary of HHS. While PPTA is grateful for the continuation at the current rate, we ask the agency to be mindful of the access issues facing Medicare beneficiaries seeking IVIG and respectfully urge CMS to consider increasing the payment amount for G0332 for CY 2008 if CMS is unable to provide a payment adjustment to the ASP plus six percent for the product as requested in section I: A of this letter.

We note that, in the Proposed Rule, CMS expresses a concern that continuing this payment could "further distort the [IVIG] market" or create incentives for inappropriate utilization.[25] In the more than 20 months that CMS has made payments for IVIG preadministration-related services, PPTA has seen no evidence that this payment has created market distortions or incentives for inappropriate utilization. Rather, PPTA believes that without this payment, a greater number of health care providers would have discontinued providing IVIG to Medicare beneficiaries. As a result, we see no foundation for the concerns raised by CMS and urge CMS to both finalize the proposal and make the additional payment permanent.

We believe maintaining G0332 for CY 2008 and beyond, as well as the agency's recent decision to provide brand-specific reimbursement for the four liquid IVIG therapies should play a significant role in improving patient access to IVIG therapies. This provision in the Proposed Rule to continue to reimburse G0332 in CY 2008 is another example of the tremendous effort CMS has undertaken to resolve the existing IVIG access barriers faced by Medicare beneficiaries that rely on these lifesaving therapies. PPTA does request that the agency, when finalizing the continuation of the payment for preadministration-related services for IVIG in CY 2008, please include G-0332 in Addendum B as it is not currently present in that location in the Proposed Rule. We again thank you for your commitment in this area.

C. ASP ISSUES: CMS SHOULD PROVIDE MORE GUIDANCE AND REVISIONS TO ITS PROPOSAL ON BUNDLED PRICE CONCESSIONS

In the interest of reimbursing physicians as accurately as possible for all physician-administered drugs, especially IVIG therapies, PPTA appreciates the efforts taken by CMS to provide additional guidance in calculating the ASP. PPTA, however, is seeking more guidance from the agency on not only the proposed definition of bundled arrangements, but also the proposed application of this definition in calculating the ASP. We are especially concerned that one may interpret the proposed definition to include any line-item discount contract a "bundled arrangement" if such contract includes a price concession on more than one nine-digit NDC, even if such drugs are not tied

[24] 72 Fed. Reg. at 38146.
[25] *Id.*

together for the purpose of a discount. PPTA believes such a broad interpretation could actually further distort ASP calculations, rather than bring more clarity and accuracy to the process. Until more guidance is provided, PPTA urges CMS to continue to allow for manufacturers to make reasonable assumptions in accounting for price concessions in bundled arrangements in their calculation of the ASP for their products.

In response to a January 2007 report from the Medicare Payment Advisory Committee ("MedPAC"), *Report to Congress: Impact of Changes in Medicare Payments for Part B Drugs*, CMS now believes it should define bundled sales arrangements and specify the methodology for manufacturers to use in allocating price concessions earned under such arrangements in calculating the ASP. CMS had proposed addressing this issue in its CY 2007 Physician Fee Schedule proposed rule,[26] but opted against including it in its final rule last year.[27] In the absence of any specific guidance from CMS on how to allocate price concessions in such arrangements, CMS directed manufacturers to "make reasonable assumptions in its calculations of the ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices."[28] Currently, the ASP must include price concession such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates, except for the Medicaid outpatient drug rebates.[29] Bona fide service fees are not considered price concessions for the purpose of calculating the ASP.[30]

Although the flexibility to use "reasonable assumptions" has been beneficial in some instances, PPTA agrees with both MedPAC and CMS that without clear guidance on how to treat bundled sales arrangements, the ASP for some Medicare Part B drugs may be inaccurate, which could potentially drive some products from the marketplace, and possibly create a reimbursement shortfall for physicians. In the case of IVIG, such a result would be very dangerous for patients. We further support CMS' desire that any definition of bundled sales arrangements under the ASP be consistent with the definition of "bundled sales" as recently proposed and finalized for the purpose of the average manufacturer's price ("AMP"). Without more guidance and revisions to the language, however, PPTA does not believe the proposed definition and proposed application of that definition in calculating the ASP, as drafted, will further the goals of MedPAC and CMS.

In the Proposed Rule, CMS summarizes the MedPAC Report and discusses the two proposals offered by MedPAC for consideration to achieve more accurate ASP calculations. The MedPAC report recommends that the CMS clarify ASP reporting requirements for bundled products to ensure that ASP calculations allocate discounts to

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[26] 71 Fed. Reg. at 49003.
[27] 71 Fed. Reg. at 69673.
[28] *Id.* at 69675.
[29] *See* 42 C.F.R. § 414.804(a)(2)(i).
[30] *See* 42 C.F.R. § 414.804(a)(2)(ii).

reflect the transaction price for each drug.[31] MedPAC further stated that CMS should ensure any guidance it issues with regard to the allocation of discounts be "clear" and can be implemented by manufacturers "in a timely fashion."[32] If CMS were to require manufacturer's to reflect contingencies in their sales contracts, MedPAC believes the ASPs for the drugs involved in a bundling arrangement that relies on contingencies will be more accurate.[33] CMS could also require manufacturers to allocate bundled discounts in proportion to sales of each drug sold under the bundled arrangement.[34] Although the latter recommendation is most consistent with the AMP calculation, as discussed below, it may not accurately account for contingency sales, according to MedPAC.[35]

According to CMS in its final rule on the AMP, which was issued pursuant to the Deficit Reduction Act of 2005 (Pub. L. 109-171, 120 Stat. 4 (2006)), a bundled sale is "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement."[36] In accounting for such price concessions, the discounts must be "allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement."[37] When discounts are offered on multiple drugs in a bundled arrangement, however, "the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle."[38] CMS further believes that a "consistent methodology for addressing bundled sales in [both] the Medicaid and [the] Medicare Part B programs will reduce the burden and likelihood of errors for manufacturers calculating and reporting Medicaid rebate prices and ASP."[39] CMS echoes this sentiment throughout the Proposed Rule and proposes to adopt a definition for "bundled arrangements" under the ASP that is very similar to the above-mentioned definition of "bundled sales" under the AMP.[40]

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[31] *See* MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO CONGRESS: IMPACT OF CHANGES IN MEDICARE PAYMENTS FOR PART B DRUGS 9 (2007).
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *See* Medicaid Program; Prescription Drugs; Final Rule, 72 Fed. Reg. 39142, 39240 to be codified in 42 C.F.R. § 447.502.
[37] *Id.*
[38] *Id.*
[39] *See* 72 Fed. Reg. at 39159.
[40] *See* 72 Fed. Reg. at 38151.

The Proposed Rule defines a "bundled arrangement" for the purpose of the ASP to mean "an arrangement, regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), *or where the resulting discount or other price concessions are greater than those that would have been available had the drugs or biologicals sold under the bundled arrangement been purchased separately or outside of the bundled arrangement.*"[41] CMS further proposes that "the manufacturer must allocate the total value of all price concessions proportionately according to the dollar value of the units of each drug sold under a bundled arrangement."[42] If multiple drugs are discounted under a single bundled arrangement, "the aggregate value of all the discounts would be proportionately allocated across all of the drugs sold under the bundled arrangement."[43]

PPTA appreciates CMS' efforts to provide clear guidance on bundled arrangements for the purpose of calculating the ASP. We are, however, concerned that this definition of bundled arrangement, similar to the definition of bundled sale for the purpose of the AMP, could be interpreted to mean that any contract that provides for discounts on multiple products, even when those discounts are not linked in any way, would qualify as a "bundled arrangement" for the purpose of calculating the ASP. Under the italicized language quoted above, such contracts could be viewed as bundled arrangements because they contain price concessions for a nine-digit NDC that are "greater than those that would have been available had the drugs or biologicals sold under [the contract] been purchased separately or outside [the contract]." If this definition of "bundled arrangement" is finalized as proposed and without additional guidance by CMS, PPTA believes that CMS could consider <u>any</u> line-item discount contract a "bundled arrangement" if such contract includes a price concession on more than one nine-digit NDC, even if such drugs are not tied together for the purpose of a discount. PPTA envisions an excessive administrative burden on manufacturers and the agency if all GPO contracts are considered "bundled arrangements" for the purpose of calculating the ASP and requests CMS to amend the definition as appropriate to clarify that those nine-digit NDCs that are not part of a contingency arrangement in larger contracts do not fall under the definition of a bundled arrangement for the purpose of calculating the ASP.

Such a broad definition also creates complications when allocating the price concessions across all sales in the bundle as would be required by the Proposed Rule. This could be especially problematic for lagged price concessions. As you know, data on price concessions is either available at the time of purchase of a product, or on a

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[41] *Id.* (emphasis added).
[42] *Id.*
[43] *Id.*

lagged basis. If the data on these price concessions are lagged, then the manufacturer is required to estimate costs attributable to these price concessions using the required estimation methodology.[44] A definition of bundled arrangement that requires reallocation of discounts that do not involve any contingencies, particularly where those discounts otherwise are not lagged, could be read to require the treatment of these discounts as lagged and not includable in the estimation methodology until the performance period for the bundled arrangement is completed, because only then will the universe of sales involved in the bundle be known so that the discounts can be allocated proportionately based on the sales involved in the bundle as the proposed rule requires. Without more guidance on how to reallocate lagged price concessions in transactions that would qualify as "bundled arrangements," it appears manufacturers would be required to reallocate all the price concessions, both lagged and non-lagged, across the entire universe of sales included in the arrangement, which could be one quarter, unless the sales contract specifies a longer or shorter duration. PPTA urges CMS to provide more guidance to clarify how to reallocate lagged price concessions in order to further the agency's goal of receiving the most accurate ASP calculations by manufacturers.

Because, under Section 1847A(d) of the Social Security Act, the AMP may be used as an alternative payment methodology for Part B drugs, PPTA further believes that definition of "bundled sales" for the purpose of the AMP and "bundled arrangements" for the purpose of the ASP should be consistent. The Proposed Rule, however, includes in the definition of a "bundled arrangement" as examples of a "performance requirement" both "purchasing patterns" and "prior purchases," neither of which are included in the definition of "bundled sales." In the interest of consistency and less administrative burden for manufacturers, PPTA respectfully urges you to remove "purchasing patterns" and "prior purchases" as possible conditions for bundling arrangements in calculating the ASP.

D. ASP ISSUES: PPTA SUPPORTS THE DECISION BY CMS TO DISCONTINUE PUBLISHING THE ANNUAL BLOOD CLOTTING FACTOR FURNISHING FEE UPDATE IN THE ANNUAL PHYSICIAN FEE SCHEDULE RULE, BUT INSTEAD POST THE RELEVANT INFORMATION ON THE CMS WEBSITE

As you know, the MMA established a furnishing fee for blood clotting factor,[45] which is currently $0.152.[46] We believe this furnishing fee has been instrumental in preserving patient access to blood clotting factor in the physician office since the ASP plus six percent went into effect in 2005. PPTA supports CMS' decision in the Proposed Rule, consistent with the Social Security Act,[47] to increase this payment according to the annual consumer price index for medical care ending in June 2007.

[44] *See* 42 C.F.R. § 414.804(a)(3).
[45] *See* 42 U.S.C. § 1395u(o)(5).
[46] *See* 71 Fed. Reg. at 69680.
[47] 42 U.S.C. § 1395u(o)(5)(C).

We further support the agency's proposal that, beginning in CY 2009, CMS will announce the blood clotting furnishing fee update using the applicable program instructions and posting on the CMS Web site.

CMS determined it is not necessary to announce the furnishing fee update as part of the rulemaking process because: (1) the timing of the rulemaking process makes it impossible to release the blood clotting factor furnishing fee for the upcoming year in the proposed rule because the annual CPI information for medical care is not available when CMS issues its proposed rule; and (2) the blood clotting factor furnishing fee is determined by statute and the CPI for medical care cannot be affected by the rulemaking process so it is not imperative that this information is released in such a manner. Moreover, removing the blood clotting factor furnishing fee update from the rulemaking process and issuing it through program instructions will expedite receipt of this information by the necessary stakeholders, who currently must wait until the issuance of the final rule, which is several months after the information could be made available. PPTA fully agrees with this rationale on how to proceed for CY 2009, and looks forward to the issuance of the blood clotting factor furnishing fee for CY 2008 in the forthcoming final rule for the physician fee schedule.

E. ASP ISSUES: CMS MUST BE CAUTIOUS IN CONSIDERING WHETHER IT IS APPROPRIATE TO APPLY THE WAMP AND AMP THRESHOLD IN REIMBURSING IVIG"

Under the ASP statute, if the OIG finds that the ASP for a product exceeds the widely available market price ("WAMP") or the AMP by a percentage threshold, the OIG informs CMS and the agency, in the next quarter, shall replace the ASP amount with the lesser of the WAMP or 103 percent of the AMP.[48] The OIG must conduct studies, which can include surveys, to determine the WAMP.[49] In the Proposed Rule, CMS proposes to continue to set the WAMP and AMP threshold at 5 percent for CY 2008.[50] While PPTA does not oppose this threshold generally, we caution CMS that any decision to apply this statutory provision to the reimbursement of IVIG could exacerbate existing difficulties a fragile patient population is experiencing in attempting to access these therapies in the physician office. Because, as the two recent studies by HHS has confirmed,[51] reimbursement for the acquisition of IVIG at 106 percent of the ASP is inadequate, any reduction from that reimbursement level would be devastating to these patients who rely upon these lifesaving therapies.

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[48] 42 U.S.C. § 1395w-3a(d)(3).
[49] 42 U.S.C. § 1395w-3a(d)(1).
[50] 72 Fed. Reg. at 38152.
[51] *See* discussion, *supra* at Section I:A.

II. CONCLUSION

PPTA appreciates the opportunity to comment on the Proposed Rule. Again, we are especially grateful for your decision to continue to reimburse temporary code G0332. We urge CMS to consider carefully these comments, particularly those related to IVIG access. Many beneficiaries depend on this therapy and reimbursement should not impede their access to this necessary treatment. Please contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Julie Birkofer
Vice President, North America

Submitter : **Dr. Greg Lind** **Date: 08/31/2007**

Organization : **Dr. Greg Lind**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

To Whom It May Concern:

I am writing in support of increased payments for anesthesiologists under Medicare as proposed by CMS.

For roughly 15 years HCFA and CMS has undervalued the work of anesthesiologists as they have cared for senior citizens and the disabled under Medicare. As you may know, the initial work of Hsaio (et al) that evaluated physician work under RBRVS (resource based relative value scale) methodology never included anesthesiology.

The result has been an arbitrary and extremely low conversion factor that has contributed to the unsustainable inflation of health insurance premiums through the inevitable cost-shifting. More importantly, the existing CF has contributed to access to care problems. This has been documented in a variety of studies across the country and in Montana (Montana Medical Association 2006 survey on Medicaid).

In the 21st century, anesthesiologists will do the job of caring for an aging population, with more co-morbidities for increasingly complex surgical procedures. Please support the CMS proposal for increased value for work by anesthesiologists.

Sincerely,

Greg Lind, MD
7383 Highline Ct
Missoula, MT 59808
406-542-5195

Submitter : Mr. Michael S. O'Shea MS,ATC,CSCS **Date:** 08/31/2007

Organization : South Bay Sports

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer working directly with patients in a sports Physical Therapy Clinic, South Bay Sports and Preventive Medicine Associates, INC. ALong with other Physical Therapists and PT Assistants, we provide rehabiliation to several patients a day. I hold a Masters of Science degress from CSU, Sacramento and am a nationally certified athletic trainer with NATA, as well as a nationally certified strength and conditioning specialist througth the NSCA. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Michael S. O'Shea MS,ATC,CSCS

Submitter : **Dr. Jeff Baeuerle** **Date: 08/31/2007**

Organization : **American Society of Anesthesiologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Anesthesia Coding and Payment,

Dear Sirs: Please consider the $4.00 increase per unit in anesthesia reimbursement,

Submitter : **Ms. Marina Pascali** **Date: 08/31/2007**

Organization : **Phytel**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15456-Attach-1.DOC

File Code: CMS-1385-P

Issue Identifier: TRHCA –Section 101(b): PQRI
Subsection: d. Addressing a Mechanism for Submission of Data on Quality Measures Via a Medical Registry or Electronic Health Record

Comments Submitted by: Phytel

As CMS reviews different data submission options for registry-based reporting of PQRI data, Phytel would like to share the experience we have in providing PQRI data from a patient registry and urge CMS to include data submission options that do not require claims information.

Today, Phytel is delivering CPT II codes and ICD-9 codes from a patient registry to a client who is then including this information on the Medicare claims that are submitted for PQRI 2007. All of the data that we are currently providing is available in our registry and has not required significant revisions to either our data feeds or data storage requirements.

Phytel supports CMS' exploration of alternative methods for PQRI reporting and believes that registry-based reporting could provide a more streamlined option for providers and vendors to deliver the necessary information to CMS.

Of the five data submission options under consideration, Phytel believes it is critical that CMS retain and test options 2 or 3 as part of the 2008 evaluation of whether and how to implement the use of registries for the reporting of quality data.

Claims Data: Options 4 and 5
The level of claims detail required for data submission under options 4 and 5 is truly at the transactional level. This type of information is provided on the claims submission process that is currently in place. According to the provided definition of a registry, a registry is really designed to summarize information, to roll up information from a detailed transactional level so that the data can be analyzed, managed and manipulated at an aggregate level. Requiring detailed claims data at the transactional level from a clinical registry does not take advantage of the benefits that a registry offers.

Insurance Data: Options 1 and 5
Options 1 and 5 require that the registry submit the beneficiary's HIC number. Since insurance information is not always available in health registries, this may require a change for many registries to collect this data. For those registries that currently extract information from claims data this will not be a hindrance.

Clinical Data: Options 2 and 3
Options 2 and 3 require that registries submit clinical data. Clinical data and the handling of clinical data is a core competency of any health registry. Requiring registries to report on clinical data is certainly within their capabilities and would not require significant changes to their overall structure and content. Including one of these options in the 2008 evaluation is critical. Phytel is already using their patient registry to deliver this information for 2007 PQRI reporting.

Phytel appreciates the opportunity to comment on CMS' proposed data submission options and looks forward to making further contributions to the improvement of the quality of patient care.

About Phytel

Phytel is the leading provider of solutions that enable physicians to anticipate patient care needs, motivate patient compliance, activate evidence-based standards of care, improve practice efficiency and measurably increase practice profitability. J. D. Smiley, M.D. founded the company in 1996 to provide physicians with tools for better managing patient-physician communications and care-related activities. Phytel provides a complete suite of integrated technology solutions for an affordable monthly subscription fee. Phytel interfaces with practice management, EMR and other clinical data systems to automate processes and communications for physician practices. As a hosted solution, there is no equipment to purchase and nothing to buy. Phytel is passionate about helping physicians, and providing a solid return on investment.

Contact

Marina Pascali
Director of Clinical Products
14900 Landmark Blvd. Suite 240
Dallas, TX 75254
tel: 214.750.9922 ext.102
fax: 214.750.9296
marina.pascali@phytel.com

Submitter : Dr. Sarah Webb **Date:** 08/31/2007

Organization : Propath Labs

Category : Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

8/31/07

To: CMS
Re: Physician Self-Referral Provisions of CMS-1385-P

I am a pathologist practicing in a community hospital in the Dallas Fort Worth metroplex. Our area is one of the epicenters of the pod/condo labs and various other arrangements whereby non-pathologists profit from pathology billing. We have seen blatant evidence of overutilization from this practice. For example, when my pathology group provided the anatomic pathology for our local urology group, they used to perform two prostate biopsies per patient, and we rarely ordered expensive immunostains. Now that the urology group has formed a condo lab so that they profit from pathology billing, they now perform 12 biopsies per patient and order immunostains frequently. The gastroenterology group in our area (the largest GI group in the U.S.), is in the process of setting up an arrangement where they would profit from anatomic pathology. I expect to see a similar increase in their utilization. Such abuses are clearly in violation of the Stark law and a detriment to the Medicare program.

I support the expansion of the anti-mark-up rule to purchased pathology interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. I appreciate CMS undertaking this review and urge you to make the necessary revisions to protect patients and our Medicare system.

Sincerely,

Sarah Webb, M.D.
Pathologist
Propath Labs
Bedford, TX 76022
sarahwcbb@texashealth.org

Submitter : Mrs. Debora Salhus **Date:** 08/31/2007

Organization : Courage Center

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

CORF Issues

CORF Issues

We would like to respond to the proposed CORF changes as they relate to Social and Psychological Services.

We agree that the treatment plan should be related to and address the specific disability and/or medical diagnosis and the adjustment to the disability. However it should also address pyschological or social issues which were created by or exacerbated by their physical condition. It may be necessary for these issues to be addressed independently or following discharge from other CORF services (such as OT,PT, Speech). Ongoing and episodic treatment by a licensed provider may be necessary to ensure continued progress in resolving social and emotional problems that may have an adverse effect on their ability to make progress or live independently. We are concerned that the proposed wording would restrict access to social and psychological services to a period of time which an individual is receiving other CORF services and it would not recognize the need for these services as an independent or stand alone service.

The recommended qualifications to provide these services should be inclusive of a licensed psychologist at a Masters or PhD level or a LICSW.

Regarding the limitation of CPT codes to 96150-96154, the intent of the treatment may be more accurately described with another CPT code, and therefore we find it potentially restrictive to not be able to code to the highest specificity.

We appreciate the opportunity to provide comments on this important issue. If you have further questions you may contact me.

Respectfully,

Deb Salhus
Sr. Director, Medical Rehabilitation Services
763-520-0424
debs@courage.org

Submitter : Ms. Kimberly Belcher **Date:** 08/31/2007

Organization : PRORehab

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dir Sir or Madam,

I am a certified licensed Athletic Trainer and my name is Kim Belcher. I work for PRORehab,p.c. in Washington , Missouri. I am the sports medicine director for the entire company. We have 18 privately owned outpatient clinics throughout the metropolitan area, including two facilities in IL. Our sports medicine program consist of 15 full time certified Athletic Trainers covering 13 school contracts and multiple club teams.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

As an athltiec trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. Statc law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is suppossed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to recieve those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertainent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day to day health care needs of their patients. I respectfully request that you withdrawl the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sinccely,

Kim Belcher, ATC

Submitter : **Mr. Todd John** **Date: 08/31/2007**

Organization : **Southwest Baptist University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

BRIEF INTRO ABOUT SELF ie. Where you work, what you do, education, certification, etc.

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While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Sincerely,

Todd John, MA ATC/L

Submitter : **Mr. MIchael Barnish** **Date: 08/31/2007**

Organization : **Trinity Orthopaedics**

Category : **Other Health Care Professional**

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam:

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Sincerely,

Mike Barnish, MS, ATC, CSCS

Submitter : Mrs. Val Veitengruber **Date:** 08/31/2007

Organization : SonoSite, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

15462

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Yohannes Getachew **Date:** 08/31/2007

Organization : Geisinger

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to inerease anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Ageney is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to signifieant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia serviees. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Yohannes Getachew

Submitter : LINDA JAMES **Date:** 08/31/2007

Organization : ST. VINCENT HOSPITAL

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Dr. Wayne Leimbach** **Date: 08/31/2007**

Organization : **Oklahoma Heart Institute**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15465-Attach-1.DOC

CMS-1385-P-15465-Attach-2.TXT

15465

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951..

Submitter : Dr. Jose Rivera **Date:** 08/31/2007

Organization : Pain Management Center of Paducah

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Attachment

154606

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Robert Zwolak **Date:** 08/31/2007

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

SVS comment on TRHCA PQRI has three parts, general comments on process, details of an End-stage renal disease outcomes measure that is under final review by NQF, and supportive observations regarding the Podiatry measures to assess diabetics for the possibility of peripheral arterial disease. Please see sections 3,4 and 5 of the enclosed SVS NPRM comment letter. thanks

CMS-1385-P-15467-Attach-1.DOC

1514-07

SOCIETY FOR VASCULAR SURGERY

August 31, 2007

The Honorable Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1385-P
PO Box 8017
Baltimore, MD 21244–8017

RE: CMS-1385-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee schedule for Calendar Year 2008 and Other Changes to Payment Under Part B

Dear Mr. Kuhn:

On behalf of the 2,300 members of the Society for Vascular Surgery (SVS), we offer the following comments on the Proposed Rule published in the Federal Register on July 12, 2007. We will address multiple provisions under this proposal.

For 2007, our specialty endured a 6% pay-cut due to the impact of the Deficit Reduction Act (DRA) on Noninvasive vascular laboratory studies plus negative changes in physician work payments due to the budget neutrality adjustor, plus additional reductions in the PE RVUs. **Yet, again for CY 2008 our specialty is facing a reduction that is double in size to what we have lost in 2007, 12 percent.** This simply can not continue. For many vascular surgeons, over 50% of their patients are Medicare beneficiaries, due the nature of the diseases and conditions we treat. We can not sustain reductions of this magnitude year after year and not at some point be forced to reduce access to Medicare beneficiaries. We are extremely concerned that 2008 will be the year that this happens.

These decisions regarding our practices are extremely difficult and not made lightly. SVS members are deeply committed to caring for our nation's seniors, but this combination of negative impacts may simply make it impossible for us to continue to offer all services to all Medicare beneficiaries.

The SVS comments will follow in this order:

1. Continuing Codes from the Five-Year Review Open Vascular Surgery Procedures
2. DRA Proposals – Section 5102 – Proposed Adjustments for Payments for Imaging Services

3. TRHCA – Section 101(b) – PQRI general comments
4. TRHCA – Section 101(b) – PQRI SVS ESRD quality measure
5. TRHCA – Section 101(b) – PQRI diabetic podiatry measures
6. Budget Neutrality Adjustor for Work RVUs & other work RVU issues
7. Resourced-Based PE-RVUs
    a. Equipment Use Rate
    b. CPT Codes 37205 and 37206 – Direct PE Inputs for Non-facility Setting
8. Medicare Payment Policy

1. Continuing Codes from the Five-Year Review: Six open Vascular Surgery Codes

SVS would again like to thank CMS for meeting with us on May 16, 2007 regarding the six interim valued vascular surgery procedures, some of our most complex and labor-intensive open aortic aneurysm and bypass operations (CPT codes 35102, 35081, 35556, 35566, 35583, 35585), procedures that are performed to save life and limb. We felt the meeting was very productive and allowed us to present new, additional regression analysis data in addition to information from our July, 2006 comments on the 2007 proposed Medicare Physician Payment rule and our December 30, 2006 comments on the final rule for 2007.

Despite of the opinion held by CMS regarding use of NSQIP data during the five-year review process SVS used multiple other methods besides NSQIP data to arrive at our work RVU recommendations for these codes. As we discussed at the CMS meeting on 16 May, we believe the Refinement Panel did not have time to fully consider all the huge amount of data supporting the conclusion that values above the median survey results were the most appropriate for these 6 very complex open surgical procedures. With due respect for the RUC process, SVS has processed nearly 100% of the vascular surgery codes to RUC survey and analysis, and we ALMOST NEVER asked for more than the median survey value. Nevertheless, for these six very large open surgery procedures, we believe the weight of evidence developed to validate our recommendations, i.e. building blocks, crosswalk comparisons intensity analyses, and finally the regression analyses, all serve to indicate that work RVUs greater than median survey are truly indicated to fairly value the work and to avoid rank order anomalies both within vascular surgery and across the entire relativity spectrum of all surgical procedures. We strongly urge CMS to reconsider the work RVUs of these 6 codes.

For example, regarding CPT code 35102 – Open repair of abdominal aortic aneurysm requiring bifurcated graft – an intensity/IWPUT analysis conducted by SVS determined that the appropriate IWPUT vale is 0.096, the mid-point range for all aneurysms and aortic surgery that maintains the relativity within the families of vascular surgery codes. The 2007 and proposed 2008 work RVUs instead establish a totally inappropriate IWPUT of 0.074, multiples of relative steps below appropriate intensity for open aortic surgery.

SVS used four additional analyses of physician work all of which indicated valuation higher than the CMS value. As we mentioned in our previous December 30, 2006 comments, SVS is very concerned that the Refinement Panel did not have adequate opportunity to review and discuss with SVS representatives the large body of data that SVS prepared and shared with them for all six of the open, vascular surgery codes that were part of the five-year review.

Again, we felt that our meeting on May 16th was a very productive exchange of information regarding the six CPT codes in question and these various methods and outputs that we have used to construct and verify SVS' recommendations that we part of the five-year review. We look forward to some positive level of resolution when the 2008 Final Rule is published in November. As noted below, we are sending the data analysis under separate cover for reconsideration. The following are SVS recommendations for these six codes. The work RVUs have been adjusted from our 2005 RUC recommendations to reflect the changes in EM work RVUs.

	2008 NPRM	SVS Recommendation
35081 Open AAA repair	33.37	36.80
35102 Open AAA repair	36.37	42.20
35556 Open fem-pop bypass graft	26.62	33.20
35566 Open fem-tibial bypass graft	32.22	40.20
35583 Open fem-pop insitu bypass	27.62	33.70
35585 Open fem-tib insitu bypass	32.22	41.00

SVS is sending under separate cover the large compendium of data we used to arrive at work RVU recommendations for these codes. We do not take lightly the RUC survey process, and we reiterate that it is an extremely rare event when SVS recommends work RVUs higher than the RUC survey median. This is in contrast to recommendation of the 25th percentile, which we have used with some regularity when we felt the overall data analysis did not support the RUC survey median. There is a fairness issue here that comes into play. These are not high volume codes, and each requires a huge effort and substantial surgical skill with attention to detail to achieve high quality outcomes. When measured by yardsticks of data provided to support recent E/M increases and proposed Anesthesia increases, these six codes have a huge amount of hard data justifying the requested work RVUs.

During our May 16th meeting Mr. Kay and Drs. Simon and Hambrick ask that we identify the high outliers on our regression analyses. The universe of codes we analyzed included neurosurgical, cardiac and vascular codes that involve arterial surgery and that had been considered during the current 5-year review. In all, this was 68 codes. For IWPUT comparisons, the high outliers were CPT 33413, 33427, 33545, 33863 and 33945. For the regression of RVW vs. total physician time the outliers were CPT 33305, 33413, 33863 and 33877. For the regression of RVW vs. intra-service time the high outliers are CPT 33300, 33305, 33460, 33945, 33463.

2. DRA Proposals - Section 5102 – Proposed Adjustments for Payments for Imaging Services

Having now experienced almost a full year of reductions under the DRA for non-invasive vascular diagnostic studies, SVS is even more convinced that CMS having included CPT codes 93880 – 93990 and G-code 0365 on the list of imaging codes that are defined by Section 5102(b) of the DRA when in fact these studies are predominately non-imaging in nature is not appropriate and needs to be re-visited by CMS to ensure that Medicare beneficiaries have access to the highest quality, most appropriate care.

Non-invasive diagnostic vascular studies ARE NOT included in the "Radiology" section of the CPT Book by intent because they are diagnostic tests used to identify and assess the severity of arterial and venous vascular diseases and disorders, either entirely or primarily through non-imaging modalities. Although these vascular diagnostic tests use ultrasound, they were invented as applications of Doppler ultrasound, which is NOT an imaging form of ultrasound. Doppler ultrasound measures the frequency shift of sound waves that bounce off moving red blood cells. Those frequency shifts undergo analysis by the electronics in the Doppler instrument and are plotted on paper or on a computer screen as graphs of velocity. These are not pictures or images of the tissue. The velocities determine the severity of the arterial disease. For instance, in a patient with severe atherosclerosis plaque in the carotid artery, the high velocities of blood flowing through a very narrow artery correspond to a severe stenosis. The most accurate way to determine the severity of stenosis is based on these velocities, and NOT on a picture of the plaque. It is the visual display of blood flow velocity, not visual pictures of the interior of the vasculature, which are analyzed and interpreted when performing a non-invasive diagnostic vascular study.

Furthermore, noninvasive vascular lab studies have never been appropriately valued in the HOPPS APC system. Noninvasive vascular diagnostic services are performed in a wide variety of locations in different hospitals, ranging from radiology, to pulmonary medicine, to respiratory therapy, to cardiology, vascular surgery and others, lending to a huge range of cost/charge ratios. These services are low profile and seldom garner any attention by the hospital regarding the creation of appropriate charges. Thus, application of cost/charge ratio to charges in order to determine costs has never produced accurate cost numbers for this small family of tests. In fact, the Society for Vascular Ultrasound brought this to the attention of one of the very first APC Panel meetings. SVU was informed that "it all comes out in the wash for hospitals," and no corrective action was taken. Interestingly, in the CY 2008 Proposed Hospital Outpatient Prospective Payment System Rule, the proposed APC payments to hospitals for non-invasive vascular studies are flat and have been for some time, even though the conversion factor for the hospitals has been increasing approximately 3 percent per year for last few years.

However, the fact is that for office providers of these services, it does not "come out in the wash". The AMA PEAC committee considered all the

direct inputs for these services in great detail during their deliberative process. The PEAC inputs are very accurate and result in appropriate valuation for these services. Starting January 1, 2007, SVS members have endured the magnitude of these reductions, 30 – 40 percent, from PFS to APC payments and it has only hardened our resolve that the APC payments are inappropriately low.

Therefore, SVS believes that it is imperative that CMS work across divisions to address the issues we have raised. SVS would like to work with CMS regarding these definitional and data issues to achieve a workable solution.

3. TRHCA – Section 101(b) – PQRI General Comments

SVS appreciates CMS using this proposed rule in an attempt to provide greater clarity regarding the role of a consensus organization in both the measure development process and the measure approval process. SVS believes it is very important to the future of the PQRI program and the quality movement to have better, more complete definitions regarding what constitutes an appropriate venue and organizations and processes for these roles.

SVS is an active participant in many organizations including the AMA Physician Consortium, the Surgical Quality Alliance, the Fistula First Initiative, the Ambulatory Quality Alliance, and the National Quality Forum. Also, the SVS has developed and maintained for the last several years a registry regarding patient outcomes in vascular surgery.

SVS believes that it is imperative that these measures be generated for the purposes of development and then submitted/endorsed for the approval process by physician specialty societies and organizations. Being a member in all the "consensus organizations" listed above, the SVS is a supporter of these types of organizations; however, we believe it is more helpful to the process to define the characteristics of what CMS will consider an "approved" consensus organization, in addition to just giving examples, for the purposes of measure development and then a separate, distinct set of characteristics for what CMS will consider an "approved" consensus organization for the purposed of measure approval.

Because this is a dynamic process and one where additional capacity may be needed, defining characteristics and then CMS continually updating a list of organizations that meet these characteristics will enhance transparency and will enable more physician societies to participate in the process through the various organizations. We urge CMS to meet with the quality leaders of the physician societies and organizations to define the

characteristics of "approved" consensus measure development groups and consensus measure approval groups.

Need for Greater Transparency Regarding Process

We want to bring to CMS' attention that there is a need for greater transparency and a need for a real, structured governance of some of the consensus organizations, such as the AQA, and voting process for measure approval in this organization. This leads to a lack of rigorous and scientific evaluation for these measures. Also, it leads to arbitrary decisions regarding measures that may be in the 2007 program and now may not be in the 2008 program. Having physicians gear up to report measures in 2007 that may be gone in 2008 will lead to frustration, lack of robust data, and a lack of interest in participation. Thus, CMS needs to make a decision that once a measure is on the list, it will stay on the list of approved measures for at least a specific number of years, versus just six or 12 months.

Use of Medical Registry to Submit Data

SVS encourages CMS to consider participation in a physician society developed patient outcomes registry as a structural measure, even to the point that it would be considered, "a global measure" such that participation in the registry, assuming the data could be accessed by CMS, would be considered successful participation in PQRI. The type and level of data sets that are included in these patient registries can provide CMS with a level of data regarding patterns of quality care for specific indications that will never be realized with the type of reporting currently contained within the PQRI program. SVS currently operates one of two national carotid stent registries. This has been extremely useful as providers comply with data reporting requirements for percutaneous carotid artery stenting.

Given that in the future there may be instances where SVS members who participate in our registry may be reporting data that is similar to data that would also be reported under a PQRI quality measure, we wanted to bring the following concerns to CMS' attention: 1) the routine data would be free of any information that could be used to identify the patient; 2) CMS would need to work with the existing registries regarding forms and processes used for patient consent regarding how the data could be used; 3) There would have to be a way developed to export the data by individual record, allowing either physicians or patients to decide not to have their data shared with CMS; and 4) Physicians must be in control of their data at all times. That being said, the SVS is extremely interested in working with CMS regarding how we can work together on this issue.

4. TRHCA – Section 101(b) – End-Stage Renal Disease Fistula Quality Measure

Not knowing exactly when CMS received the measures listed in Table 21, SVS wishes to inform CMS that it has submitted a measure to the NQF that we believe will be endorsed prior to November 15, 2007. This measure is relevant to the Medicare population and will allow vascular surgeons to report on their role and activities as providers of native hemodialysis access for Medicare beneficiaries that are in CKD 4,5 or End Stage Renal Disease. The goal of this measure is to provide a tool by which individual surgeon effort can be gauged in terms of creating native fistulas in those CKD and ESRD patients who are appropriate candidates. The details of this measure, which is currently under final review by the NQF, are provided here. We look forward to this measure being part of the 2008 set of PQRI measures.

NQF Number: 45

Focus: Vascular Access

Measure Title: Hemodialysis Vascular Access – Surgical Decision-making to Maximize Placement of Autogenous Arterial Venous Fistula

Developer: SVS

Type Reclassified: Outcome

Setting: Ambulatory Care Hospital

Level of Analysis: Individual Clinician

Description: Percentage of patients with advanced chronic disease (CKD4 or 5) or end-stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arteriovenous fistula (AVF).

Numerator: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons OR Fistula not Performed for Patient Reasons. NOTE: This measure will be reported as the total of the three categories of numerators and also as the three numerators reported separately.

Numerator Data Collection: G8081: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons: Append modifier (1P) to G8081 to report documented circumstances that appropriately exclude patients from an

autogenous fistula. A typical medical exclusion would include clinician documented that CKD4, CKD5 or ESRD patient requiring hemodialysis vascular access was not eligible for autogenous AV fistula based on results of vein mapping. OR Fistula not Performed for Patient Reasons: Append modifier (2P) to G8081 to report documented circumstances that exclude patients for patient related reasons. For instance, clinician documented that CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access refused autogenous AV fistula following recommendation for same by provider. Autogenous is defined as the patient's own native tissue. Fistula is defined as a surgical connection established between and artery and a vein.

Case Finding: Patients eligible for inclusion are those with KDOQI Stage 4 and 5 CKD and ESRD.

Denominator: Patients with CKD4, CKD5 or End-stage renal disease who undergo open surgical placement of permanent hemodialysis access

Denominator Data Collection: ICD-9 585.3, 585.4, 585.5, 585.6 or 996.73 AND CPT 36818, 36819, 36820, 36821, 36825, or 36830

Exclusions: None

Risk Adjustment: This measure is recommended only for first-time vascular access patients, that is, all patients who have not previously undergone placement of a permanent upper extremity indwelling fistula or graft. The justification for this limitation to first-time access patients is that insufficient scientific data exists to know the target threshold for placement of native AVFs in patients who have previously undergone AVF surgery.

Data Source / Collection Instrument: Administrative and medical record data, provider data

Release / Revision Date: 2007

In Use: no

Testing: no

Conditions: Use term "autogenous" AV fistula. Remove CKD3. Clarify denominator exclusions because medical reason and pt reason included in numerator. Use separate codes and reporting for numerator categories.

5. TRHCA – Section 101(b) – Podiatric Measures Table 22 of NPRM

SVS offers its highest possible level of support to appropriately crafted quality measures aimed at preventing limb loss in diabetics.

We note that one of the measures in Table 22 of the NPRM is entitled "Peripheral Arterial Disease: Ankle Brachial Index (ABI) Measurement". Assessment for presence of peripheral arterial disease (PAD) in diabetics is crucially important, but we would potentially suggest that physical exam palpation for foot pulses might be the first appropriate step in assessment for PAD. Otherwise the broad application of ABIs in all diabetics might be considered screening, and coverage issues could become relevant. The absence of palpable pulses could be a signal that ABIs are indicated in the diabetic patient. Certainly if the diabetic arrives with a foot ulcer, diabetic foot infection, or presence of tissue gangrene, ABIs and evaluation for PAD are mandatory.

Some diabetic patients have calcified tibial arteries, a condition that renders the ABI test unreliable. In this situation, measurement of toe pressures is indicated. In summary, SVS strongly supports evaluation for PAD in diabetics as a means to reduce limb loss. We look forward to appropriately designed quality measures to accomplish that.

6. Budget Neutrality Adjustor for Work RVUs and other Work RVU issues

SVS strongly objects to the use of budget neutrality adjustors for physician work. When CMS applied a budget neutrality adjuster to the work RVUs following the first 5-year review of physician work, it caused substantial confusion among non-Medicare payers, as well as physician practices. CMS eventually acknowledged the confusion and ineffectiveness of applying the budget neutrality adjuster to the work RVUs, and the Agency eventually eliminated the problem. Now its back again. SVS understands the argument that relativity among work, PE and PLI pools should remain constant, but we believe the counter-argument holds more weight, that is that RVUs should be paid equally, regardless of work, PE or PLI origin. The outcome of the 5-year review should be shifted to the Conversion Factor because it would: (i) have less impact on other payers who use the Medicare RBRVS; (ii) be consistent with the notion that budget neutrality is mandated for monetary reasons, and since the conversion factor is the monetary multiplier in the Medicare payment formula, this is the most appropriate place to adjust for budget neutrality; and (iii) be consistent with CMS' goal of transparency in the Medicare payment system.

Anesthesia Conversion Factor upgrade

SVS agrees that Medicare payment for anesthesia services is undervalued. SVS compliments ASA and the RUC for a completing a complex analysis of anesthesia services in order to compare it to work provided by other specialties. It was certainly a

challenging task to compare services that include reimbursement for base plus time to services that are reimbursed for base or time, but not both. However, SVS is concerned about the Intensity assignment during the lowest level of Post Induction Period Procedure Anesthesia (PIPPA) being set at 0.031 work units per minute. This Intensity setting was derived from comparison with CPT code 99149, a moderate sedation service. As opposed to the lowest level of PIPPA, wherein the patient has already been induced and is stable, it is our understanding that CPT 99149 includes the initiation of moderate sedation, during which a patient undergoes transformation from awake and alert to a hoped for level of "moderate" sedation. We believe this may be more complex than the lowest level of stable PIPPA, therefore not a fully appropriate one-to-one crosswalk for lowest level PIPPA. More troublesome, however, is that there are many periods in the construct of a surgical global service wherein the baseline Intensity is substantially less than 0.031. For instance, all time spent assessing the patient in the immediate pre-op period, reviewing informed consent, assessing patient for surgical readiness, discussing case requirements with nursing and anesthesia, are all reimbursed by Medicare at 0.0224 RVUs/min, or 28% less than the proposed lowest level of PIPPA. Likewise, all immediate post-op care in the surgical package is reimbursed at the same 0.0224 RVUs/min. These services include ensuring surgical stability of the patient in the immediate post-op period, writing post-op orders, etc., again seemingly of equal intensity to lowest level PIPPA. In summary, SVS believes that an increase in Medicare reimbursement for anesthesia services is well-deserved, but if the lowest level PIPPA is set at 0.031, we believe that all pre and post surgical service should be set at the equivalent or higher level.

93325

SVS recognizes the major clinical value and importance of colorflow analysis in vascular studies such as echocardiography. Having said that, we support elimination of an add-on code for colorflow during echocardiography, as apparently now underway by ACC. In absence of that independent method, we support bundling color into the base codes as is the case in other ultrasound applications. The colorflow add-on was created decades ago when the technology was new, unique, and very expensive. Today, colorflow is a routine component of all quality echocardiography scanners. It is, therefore, difficult to justify separate payment for this service.

7. Resource-Based PE – RVUs

Equipment Use Rate

SVS agrees with CMS that the 50 percent utilization rate for medical equipment is appropriate for equipment used as part of office-based procedures. For surgical specialties, procedure specific equipment used in the office may only be in use approximately one – two days a week, depending on the service mix of a specific office.

SVS is currently participating in two different surveys that are asking questions regarding equipment use rate. In both instances, the surveys are asking there questions in such a way to be both specialty and type of equipment specific. SVS believes that these types of specialty specific surveys are important and the type of data that CMS should be considering when making code specific decisions, regarding practice expense inputs. We believe that the data coming from these two efforts will be more instructive to CMS versus generalizing the higher utilization rates found by MedPAC in their six site survey for CT and MRI imaging equipment to even all types of imaging equipment – i.e. ultrasound - or for other types of equipment. Instead, SVS hopes that CMS uses specialty and type of equipment specific data to work through this question going forward.

CPT Codes 37205 and 37206 – Direct PE Inputs for Non-facility Setting

The SVS appreciates CMS reviewing clinical literature regarding transcatheter stent placement and what is considered standard practice regarding the number of stents placed per patient, per vessel. While we agree with CMS that it is not typical, i.e. greater than 50 percent of the time that two stents would be used to maintain the vascular integrity of an initial vessel, there are instances where a patient does need two stents. Since most of these stents cost more than $1,000 each, we ask that CMS provide some guidance to the Medicare contractors regarding how the cost of a second stent, when used, may be separately billable using a HCPCS code.

8. Medicare Physician Payment Rate for 2008

In 2008, physicians and other health care practitioners whose payment rates are tied to the physician fee schedule face a 10% payment rate cut. The SVS urges CMS to work with Congress to avert this cut and ensure that physician payment updates for 2008 and subsequent years accurately reflect increases in medical practice costs.

Payments to physicians today in 2007 are essentially the same as they were six years ago in 2001. Due to the SGR, physicians now face drastic Medicare payment cuts totaling almost 40% over the next eight years. Yet, during this same time period, the Medicare Economic Index (MEI), which measures increases in medical practice costs, is expected to increase by about 20%. Physicians cannot absorb these draconian cuts.

Only physicians and other health professionals face steep cuts under this flawed payment formula. Other providers, such as nursing homes and hospitals have payment updates that reflect the cost of inflation. Further, the 10% cut in payment rates facing physicians is in stark contrast to Medicare Advantage (MA) plans, which are paid on average 112% above the cost of traditional Medicare, with a significant number of MA plans paid from 120% to more than 150% of traditional Medicare. These overpayments are shortening the life of the Medicare trust fund.

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SVS appreciates the opportunity to submit these comments and looks forward to working with CMS to implement these recommendations. Please feel free to contact Pam Phillips, Director of Health Policy and Government Relations at 703-573-7894 or PPhillips@vascularsociety.org, if we can provide further information.

Yours truly,

K. Wayne Johnston, MD
President
Society for Vascular Surgery

Robert M. Zwolak, M.D.
Robert M. Zwolak, M.D.
Chair, Health Policy Committee
Society for Vascular Surgery

Submitter : **Dr. Wolf Vogel** **Date: 08/31/2007**

Organization : **M.A.A., P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Wolf A. Vogel, M.D.
9 Rock House Rd.
Easton, CT 06612

Submitter : Mr. Ernie Quinlisk **Date:** 08/31/2007

Organization : Precision Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am the sole owner of a physical therapy practice, that includes two other physical therapists. Over the years, a large percentage of our business came from orthopedic surgeons. In fact, I treated a surgeon and some family members. Since most of the surgeons now refer to on-site physical therapy clinics, our referrals have virtually dried up. In fact, the only time we get a referral from an orthopedist now is if the patient specifically requests to come to our office. According to a few patients, their request was met with opposition from the surgeon too. My logical assumption is that we were getting consistent referrals in the past for the quality of our work, solid communication and timely appointments. Since we literally do not get any referrals from these offices now, I can only assume that money is the motivating factor.

Submitter : DENNIS JAMES **Date:** 08/31/2007

Organization : MRL RAILROAD

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Date: 08/31/2007**

Organization :

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Katie Templeton

Submitter : Mr. Seth Fibraio **Date:** 08/31/2007

Organization : Cornerstone Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15472-Attach-1.DOC

1542

CORNERSTONE PHYSICAL THERAPY, INC.

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08/31/2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Physician Self-Referral Issues

Dear Mr. Weems,

This letter is to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exceptions. I am the CEO of Cornerstone Physical Therapy, Inc. located in Tranquility and Clark, New Jersey and have been a therapist for over six years. My company was started almost four years ago and is an outpatient orthopedic clinic specializing in spinal and sports injuries. Over this time, I have witnessed multiple accounts of physicians abusing the current regulations and using loopholes to self refer patients to their practice, which is the reason for this letter.

Physical therapy is and has been for a long time a separate entity from physicians. In over thirty nine states we have direct access, which allows a physical therapist to see patients without a physician referral. This shows that physical therapy is autonomous and does not require physician direction in order to provide quality service. Also, in the majority of physician-owned practices I have been involved with, at no time is the physician anywhere near the area where physical therapy services are being provided. This dispels the notion that there is an advantage to a physician being present during a physical therapy treatment.

Physician owned practices send exclusively to their own practice with no regard to what is more beneficial to the patient. We have a physician owned practice with multiple locations in the Sussex and Warren county area. Their physical therapy clinic is in Sparta, New Jersey and in some cases they make patients drive from Belvidere, New

Jersey up to Sparta, New Jersey which is about a 45 minute drive. There are at least four other clinics between these two areas not including my own that could service these patients. For the patient it is much easier to go to a clinic close to their work or home, but the physician gives them no choice.

Before I opened my clinic in 2003, I worked for a physician owned practice in Hackettstown, New Jersey. There were multiple occurrences of arguments between myself and the physician and his administrative staff concerning the number of visits a patient was to be scheduled. The prescription, no matter how well the patient was doing was three times a week for four weeks and they wanted him or her scheduled for that amount. When I refused, it always became a source of arguments. There were even a couple of instances where I had to refuse to treat a patient because he had either met all his goals, or met maximum potential and the doctor wanted to send him back for more therapy.

We have an orthopedic group the next town over from our office that regularly referred us patients even though there was another physical therapy clinic next store to them. When the company (Healthsouth) pulled out, they opened their own clinic and now no longer send us patients even though our services have not changed.

Finally, another orthopedic practice in Hackettstown, New Jersey just purchased a building and renovated it to make a medical center with multiple disciplines. They approached my company to rent space from them. The price per square foot was approximately 15-20% higher than the going rate for the area. When I attempted to negotiate the rate the e-mail that was sent back replied that the cost is not negotiable and they will go with a physical therapy clinic that would be willing to pay the rate. Now, the physician practice only refers to this clinic.

As you can see, there is significant abuse of the system as it is currently written. Physicians use their ability to refer out for physical therapy services as a leverage to put additional money into their pocket. They do not use their better judgment to send patients to clinics based upon the patient receiving quality care, but on the judgment on which facility they will make a profit off of. This clouds the judgment process of the physician and should be seriously reconsidered. By keeping not only physical therapy, but all rehabilitation services separate from the physicans, we can be more certain the physician and the therapists are working together for the better care of patients. I would strongly urge the CMS to remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws. Thank you for taking the time to take my comments into consideration. If you need to contact me, please contact me at 908-684-1241.

Respectfully,
Seth Fibraio, MPT, MTC, CSCS
CEO

Submitter : Mr. Rick Loutsch **Date:** 08/31/2007

Organization : CNOS

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am an Athletic Trainer with CNOS in Dakota Dunes, SD, a large physician owned clinic specializing in Orthopaedics, Neurology, and Sports Medicine. As a certified athletic trainer I provide athletic training services to several area high schools and colleges under the supervision of an orthopaedic surgeon. I hold a B.S. degree as well as a M.S. degree in exercise science from the University of Iowa. I am certified by the Board of Certification and Licensed to practice athletic training in both the State of Iowa and South Dakota.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Rick Loutsch, MS, ATC, LAT

Submitter : **Dr. Yogesh Malla** **Date: 08/31/2007**

Organization : **Pain Management Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Attachement

CMS-1385-P-15474-Attach-1.DOC

15474

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05	Interventional Pain Management Physicians

	(Non-Facility)	- 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Ray Lane
81 Lakeview Drive
Paducah, KY 42001

Submitter : **Jim Kimbal** **Date: 08/31/2007**

Organization : **Self**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
I am an Athletic Trainer both certified and licensed, a Massage Therapist both certified and licensed and a Certified Strength and Conditioning Specialist. I have a B.S. degree and just over 3000 hours of professional medical continuing education that both enables and support licensing and certification. I work closely with sponsoring physicians and physical therapists in the hospital outpatient clinics and in out reach programs which provide medical coverage to sporting events. In our rural setting many of the patients I serve would not receive the same level of care or any care at all without the niche that I occupy.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules would create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Jim R Kimbal, BS, LAT, ATC, LMT, NCTMB, CSCS.

Submitter : **Ms. Barbara Vogel** **Date: 08/31/2007**

Organization : **Ms. Barbara Vogel**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : Ms. SUSAN HITE **Date:** 08/31/2007

Organization : BERKS CARDIOLOGIST LTD

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

As a nurse practitioner in the field of cardiology, I feel very strongly about the proposed Revisions to the Payment Policies Under the Physicians Fee Schedule. These revisions threaten the ability of our specialty to continue to service the aging population. Costs for providing care have continued to increase while reimbursement (as you propose) is decreasing. PLease work with Congress to find a permanent solution to the Flawed Sustainable Growth Rate.

Submitter : Dr. charles minehart **Date:** 08/31/2007

Organization : Berks cardiology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

While you have granted increases in all areas of Federal Financing including your own salaries, funding the war effort,and areas of human services,you have created and environment where we are dependent on Medicare and therefore dependent on your reimbursement rules. Our survival is totally dependent on your decision making. While our cost of providing care is increasing, your reimbursment for our professional services is declining. This continued decline in reimbursment is non sustainable. Services will begin to deteriorate.

We beg you not to enact these draconian cut backs.There is no more fat in our processing. Come see how we process a many patients as possible to provide adequate service and make ends meet.

Continued Medicare will eventually cause the collapse of private fee for service medicine. That may not effect your plan butit will effect the average American.

Submitter : **Date: 08/31/2007**

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Brad Mehl

Submitter : **Dr. Ronald Hill** **Date: 08/31/2007**

Organization : **Dr. Ronald Hill**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

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Thank you for your consideration of this serious matter.

Ronald C. Hill MD

Submitter : **Date: 08/31/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Carla Templeton

Submitter : **Date: 08/31/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Kurt Templeton

Submitter : Mrs. Michelle Shamash **Date:** 08/31/2007

Organization : Dynamic Hand Therapy

Category : Occupational Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am writing as an Occupational Therapist and as a private OT clinic owner. In the past several years, several large physician-owned practices are opening PT/OT clinics within their practices in the Chicago area. Patients are directed to be seen in any of these physician-owned clinics. We have occasional patients that learn their rights and have chosen to be seen in clinics of their choice. Upon leaving these clinics and starting therapy with us, we have heard complaints of patients being seen for very brief treatment sessions with no specialized one-on-one care. We have had patients complain that they are being seen for fewer visits than had been recommended by the physician because the clinic is too busy to provide these appointments. The patients are not given the option to find more convenient or appropriate options. Some physician owned practices do not refer their hand therapy patients for more specialized eare. They keep these patients in their clinic with a general therapist in order to bill for their treatment. These patients are losing a window of opportunity to be treated with the expertise that they deserve and need. The patients are sometimes being seen in clinics that are not under the same roof as the referring physician (although it is affiliated with that large physician group).

Patients are unaware of their rights to choose a therapist of their choice. It is a situation that is detrimental to the patient as well as private clinics where our goals are to provide quality and specialized care to our patients.

Physicians are in the position where they are able to order services for their medicare patients that may be unnecessary in order to bill their therapy services.

As therapists that are not affiliated with our referring physicians, we are able to make objective recommendations and monitor the true need for therapy services.

This problem has become increasingly problematic in the Chicagoland area as physicians band together to create large physician groups who own physical and occupational therapy clinics.

Please review this situation and ereate a check and balance system to monitor this problem.

Thank You, Michelle Shamash, OTR/L, CHT

Submitter : Mrs. Val Veitengruber **Date:** 08/31/2007

Organization : SonoSite, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15484-Attach-1.PDF

15484

SonoSite

August 31, 2007

Herb Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 security Boulevard
Baltimore, MD 21244-1850

RE: [CMS-1385-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 and Other Changes to Payment Under Part B

Dear Acting Administrator Kuhn:

SonoSite, Inc., appreciates the opportunity to comment on CMS-1385-P, the Proposed Rule for the 2008 Medicare Physician Fee Schedule (MPFS). SonoSite is a manufacturer of high quality, portable ultrasound systems located in Bothell, Washington. SonoSite manufactures and markets ultrasound systems that provide complete diagnostic ultrasound studies and are optimized for use at the point of care. SonoSite's products are used in physician offices and other sites of care, such as hospitals and free-standing imaging facilities, to provide a wide variety of diagnostic and guidance ultrasound services.

Sonosite appreciates the opportunity to provide CMS with detailed comments regarding our concerns with the proposed rule and looks forward to continuing to work with CMS in the upcoming year on:

- Resource-Based Practice Expense (PE) Relative Value Units (RVUs)
  - Imaging Equipment Usage
  - Imaging Equipment Interest Rate
- Additional Codes for the 5-Year Review of Work RVUs
- Physician Self-Referral

I. Resource-Based PE RVUs

A. Issue: Discussion of Equipment Usage Percentage

Background

In the proposed MPFS rule, the Centers for Medicare and Medicaid Services (CMS) requests comments for alternative percentages and approaches that differentially classify equipment into mutually exclusive categories with category-specific usage rate assumptions.

Currently, CMS utilizes a 50 percent utilization rate for all equipment. In the proposed rule, no proposals are made to revise the formula. CMS cites insufficient empirical data to justify changing the equipment utilization rate.

Supporting Information

Utilization rates of equipment vary dramatically by equipment type. This is because of the practice model of the physicians who are the most frequent users of the equipment. Within the large category of imaging equipment for example, the utilization rate of ultrasound equipment is likely to be quite different from the utilization rate of MRI equipment because of the practice patterns of the specialties that are each modality's respective main users. Ultrasound, more than most other imaging modalities, is integrated into the clinical care of specialties whose primary occupation is direct patient care. Therefore, the use rate of ultrasound equipment, is lower than that of other modalities used primarily by physicians whose principal occupation is imaging, such as radiologists. This is supported by a 2005 study by the Lewin Group[1] that found that whereas radiologists performed approximately 85% of certain CT studies and slightly less than 70% of certain MRI studies billed to the physician fee schedule in 2003, radiologists supplied a very low percentage of ultrasound studies submitted to the Medicare program. In that study, radiologists supplied less than one percent of echocardiograms, about one-quarter of all non-invasive vascular studies, and less than 50% of other ultrasound studies. This data makes it clear that were CMS to move forward on any sort of data collection effort to ascertain the true equipment use rates, it would need to make sure that the different physician specialties were included in the data sample in accordance with their use of the equipment being assessed.

In the June 2006 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) surveyed providers in six markets (Boston; Miami; Greenville, South Carolina; Minneapolis; Phoenix; and Orange County, California) that performed MRI and CT services on Medicare beneficiaries to examine whether certain imaging equipment is used more than 50 percent of the time. MedPAC's survey indicated that providers in those six markets used MRI and CT machines significantly more than 50 percent of the time they were open for business. However, the intent of the survey was not to establish with statistical significance the actual use rate of imaging equipment. Rather, the survey was intended to determine whether this information was obtainable using a survey methodology. According to MedPAC's comments on the survey in their April 19, 2006 MedPAC meeting, "This survey is a first step...It was not nationally representative and it was not designed to determine equipment use rates. Its intent was to assess the feasibility of getting use rate data from the survey... ***I do want to caution that***

[1] An Analysis of the Use of Ultrasound Imaging Services in the Medicare Program. The Lewin Group, 2005.

this survey is not representative [of] anything." (Emphasis added. P. 237 and 242 of April 19, 2006 MedPAC meeting transcript).

Recommendation for Equipment Usage

As a result of this information, SonoSite supports the need to distinguish between categories of equipment in order to reflect usage rate differentials and believes that within imaging equipment, the appropriate mutually exclusive categories are defined around the type of imaging technology that is used to provide the service. In short, SonoSite supports the use of separate equipment use rates for the different imaging modalities in order to accurately reflect the costs of providing services using the different types of equipment.

To support the selection of the different use rates for the different imaging modalities, we recommend that use rate data be gathered by imaging modality and that physician specialties and sites of service (physician office or imaging center) should be included in data collection in such a way as to reflect their proportion in the claims data for the individual imaging modalities. For now, in the absence of such data, SonoSite strongly agrees with CMS's decision to maintain the equipment utilization rate at 50 percent.

B. Issue: Equipment Interest Rate

Background

In the proposed rule, CMS makes reference to the possibility of revising the equipment interest rate used in determining payment rates for physicians. After reviewing the Small Business Administration (SBA) data on loans and applicable interest rates, CMS found that interest rates were comparable to the current equipment interest rate utilized in the payment rate-setting methodology.

Supporting Evidence

Data from KeyCorp's Healthcare Equipment Finance arm, indicates that the interest rate available to physicians to purchase equipment was, as of May 2006 in the range of 9 – 11%[2]. KeyCorp is one of the nation's largest bank-based financial services companies and has been providing financing to the entire range of healthcare providers including medical doctors, clinics, group practices and hospitals for over 20 years.

KeyCorp indicates that in 2006 the historically low interest rate environment began to change resulting in the rates identified above for the second half of 2006. Recent queries show those rates remaining in place currently.

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[2]Letter from Reid Lukes, Business Development, National Accounts, Key Equipment Finance, Healthcare, May 11, 2006

Recommendation

SonoSite agrees with CMS's proposal to maintain the equipment interest rate at 11 percent.

II. Additional Codes from 5-Year Review

Issue: Coding – Bundling of 93325

Background

In the proposed PFS rule, the Centers for Medicare and Medicaid Services (CMS) expresses the intent to bundle CPT code +93325 (Doppler echocardiography color flow velocity mapping) into CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, +93320, +93321, and 93350. As justification for this proposal, CMS states that color flow Doppler is "intrinsic to the performance" of all echocardiography services.

Supporting Information.

Color flow Doppler contributes to a more accurate diagnosis and appropriate selection for either surgical or medical interventions. As a result, according to a study commissioned by the American College of Cardiology and the American Society of Echocardiography, color flow Doppler is routinely performed in conjunction with CPT code 93307. However, this study also found that in less then 50% of the cases where the other echocardiography services are performed color flow Doppler is also performed.

The proposal to bundle CPT code +93325 in all echocardiography services is inconsistent with the RUC process for evaluation of relative values. Furthermore, the proposal of bundling +93325 into the base echocardiography codes without a corresponding increase in the RVU's of those codes, fails to recognize the resources used to provide color flow Doppler. Under CMS' proposal, the practice expense value associated with color flow Doppler including both the sonographer time and the equipment time is not added into any of the "base" echocardiography services listed above. The payment for these additional resources would effectively be removed by this proposal.

Recommendation for Color Flow Doppler

SonoSite asks CMS to set aside this bundling proposal and reconsider the RUC 5-Year Review workgroup recommendation. We believe that the review of CPT code +93325 by the CPT Editorial Panel and the application by ACC for the establishment of a new code that incorporates +93325 with 93307 is a reasonable course at this time. This approach will appropriately address the utilization of color flow Doppler with the transthoracic echocardiography services while maintaining the ability for physicians to add on color flow Doppler to the other base echocardiography services as needed.

III. Physician Self Referral Provisions

A. Issue: In-Office Ancillary Exception

Background

SonoSite welcomes the opportunity to comment as requested in the proposed rule regarding potential changes to the in-office ancillary services exception. That exception, allows physicians to self refer for Designated Health Services (DHS) they provide in their own office that are necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office. In the proposed rule CMS requests comments specifically on whether non-specialist physicians should qualify for the in-office ancillary services exception and be able to refer patients for services provided on equipment they themselves own.

Supporting Information.

According to Section 70 of Chapter 5 of the Internet Only Manual (IOM) 100-01, entitled, "Medicare General Information, eligibility and Entitlement, physicians are defined in the following manner:

> *"Physician means doctor of medicine, doctor of osteopathy (including osteopathic Practitioner), doctor of dental surgery or dental medicine (within the limitations in subsection §70.2), doctor of podiatric medicine (within the limitations in subsection §70.3), or doctor of optometry (within the limitations of subsection §70.5), and, with respect to certain specified treatment, a doctor of chiropractic legally authorized to practice by a State in which he/she performs this function."*

This definition does not discuss whether a physician is a specialist or a non-specialist. Indeed, it would be difficult to define a specialist versus a non-specialist using the generic two-digit specialty codes for the purposes of determining whether a physician was eligible to provide DHS under the in office ancillary services exception. For example, would a board certified general surgeon, specially trained in the diagnosis and treatment of breast disease, including ultrasound, be deemed a specialist or a non-specialist for the purposes of qualifying for the in-office ancillary services exception? Board certification in general surgery implies specialization, but in all surgery, not just one specific anatomical area or body system where a condition could be diagnosed or treated using a DHS. Even more troubling would be the consideration of the family practice physician who provides obstetrical services. By all accounts, a family practice physician is not considered a specialist. Yet, that family practice physician may be thoroughly trained and more than competent to provide obstetrical ultrasound to his pregnant patients.

Recommendation for In-Office Ancillary Exception

SonoSite believes that no further definition of a physician with regard to level of specialization and the resulting eligibility for the in-office ancillary services exception is

appropriate. Such a move would only serve to arbitrarily limit the practice of certain physicians based on their specialty alone, regardless of their competence in providing certain designated health services and the appropriateness of those services to their practice. Modification of such rules could have a tremendous impact to both patient access and unnecessarily infringe upon certain physicians' scope of practice.

***

SonoSite, Inc. appreciates the opportunity to provide comments on this proposed rule. If SonoSite can provide CMS with additional information regarding this matter, please do not hesitate to contact me at 425-951-1205 or irene.plenefisch@sonosite.com.

Sincerely,

Irene Plenefisch
Director, Payer and External Relations

Submitter : **Dr. Victoria Base-Smith** **Date: 08/31/2007**

Organization : **American Association Nurse Anesthetists**

Category : **Other Practitioner**

Issue Areas/Comments

Background

Background

August 31, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES

Dear Administrator:
I am member #42857 of the American Association of Nurse Anesthetists (AANA. Please accept this plea in support of the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Because of the extremely valuable anesthesia care we provide Medicare must increase the anesthesia conversion factor (CF) by 15% in 2008. Passage of this proposal will ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

Sincerely,
Victoria Base-Smith Ph.D. CRNA,MSN,CCRN
Associate Professor Nurse Anesthesia, University of Cincinnati
Chief Anesthetist, Veterans Administration Medical Center
4719 Fields Ertel Rd.
Cincinnati, Ohio 45241

Submitter : Mr. Ricardo Fontg **Date:** 08/31/2007

Organization : Vincent Fontg

Category : Attorney/Law Firm

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See attachment

CMS-1385-P-15486-Attach-1.PDF

15486

V F H

VINCENT | FONTG | HANSEN | LLC

August 31, 2007

VIA ELECTRONIC MAIL

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems,

On behalf of numerous health care clients who provide services to Medicare beneficiaries, we want to formally offer and submit these comments on the Proposed Rule CMS-1385-P, "*Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008*" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007. We have limited our comments to the issue of "Unit-of-Service (Per Click) Payments in Space and Equipment Leases" (herein referred to as "Per Click Arrangements").

We sincerely appreciate your staff's ongoing efforts to administer and improve the payment compliance system for physician reimbursement, and support your efforts to stem abusive practices while at the same time ensuring access to services and new technologies for beneficiaries, and ensuring adequate and fair compensation for physician providers.

Background - Proposed Rule

Section 1877(e)(1) of the Social Security Act (the "Act") provides an exception to the prohibition of physician referrals for space and equipment leases, provided that certain requirements are met. Among the requirements, which are incorporated in 42 C.F.R. §411.357(a) and (b), are that the lease be commercially reasonable even if no referrals were made between the parties, and that the rental charges be set in advance, be consistent with market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. The Act also requires that the lease arrangement meet such other requirements as the Secretary of Health and Human Services (the "Secretary") may impose by regulation as needed to safeguard against program or patient abuse.

In the Proposed Rule, you have indicated that there is concern that Per Click Arrangements may be structured so that a physician is rewarded for each referral he or she makes for designated health services ("DHS"). Though you have not expressly indicated so in the Proposed Rule, our reading and interpretation of the Proposed Rule indicates that you are referring to an individual physician, as opposed to an entity in which a group of physicians (and potentially other parties) come together to invest in equipment or medical space.

You specifically indicated that such Per Click Arrangements could take the form of a physician leasing equipment that he or she owns to a hospital, and receiving a per-use (per-click) fee each time a patient is referred by the individual physician owner to the hospital for the use of the equipment. You also expressed concern about arrangements where the physician is the lessee and rents space or equipment from a hospital or other DHS entity on a per-click basis. For purposes of this comment letter, however, we are limiting our proposed comments and discussion in instances where an individual physician or a group of physicians (through an entity joint venture) may act as lessors of equipment or space in Per Click Arrangements.

We find it notable that your review, as stated in the Proposed Rule, of the legislative history with respect to the exception for space and equipment leases concluded that Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals. However, despite these findings, you are proposing that space and equipment leases may not include unit-of-service based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity. You have requested this change to the existing regulations because you believe that such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee.

Comments

We strongly believe that, if adopted, the Proposed Rule would greatly and negatively impact the structure of arrangement that are now permissible and common today in the health care industry. Without regard to whether a particular physician has over-utilized the system, the Proposed Rule would potentially force a substantial number of arrangements to be terminated or restructured, potentially resulting in substantial and irreparable financial harm to individual physicians who may have significant personal obligations with respect to equipment or medical space that they have purchased or financed, but would have no ability to lease such equipment or space to an entity lessee under the Proposed Rule. As you know, counsel in these transactions routinely requires the arrangements to be modified or terminated in the event there is a change in laws or regulations; consequently, physicians and other health care entities would need to restructure and probably eliminate completely many Per Click Arrangements.

The Proposed Rule would also impact numerous collaborative arrangements between physicians and local community hospitals, where the only ability for a hospital to secure needed medical equipment to provide services to the community is to enter into a joint venture with a

physician for the purchase of medical equipment. While it is not clear under the Proposed Rule how these arrangements would be addressed, a possible reading of the rule would certainly render such arrangements illegal. We believe, however, that these risk sharing arrangements are the type of collaborations that are positive for Medicare beneficiaries and should not be prohibited by the Proposed Rule, if adopted.

An additional important clarification is that the Proposed Rule, though it refers to physician lessors, does not clearly articulate whether it also applies to physician joint ventures that act as lessors. We first feel that it is critical to clearly state in any rule that may be enacted by your office that it does not apply to any physician joint venture entities that come together for the purpose of acting as lessors on equipment or space leasing arrangements, provided the existing requirements of Section 1877(e)(1) of the Act, and the existing regulations promulgated thereunder, are met. While it is feasible that an individual physician may me incentivized to increase the number of his or her referrals to an entity lessee, we find it that there is little incentive to over utilize the Medicare system in instances when an individual physician holds only a small stake in a joint venture entity. The logic in this regard is that any referral by a physician who has a stake in a lessor joint venture would produce little personal gain in relation to his or her interest in the entity.

Conclusion

Thank you for the opportunity to comment on the Proposed Rule. As we have noted, our fear is there could be substantial financial hardships to providers that are caught up in the enactment of the Proposed Rule but who historically have not over-utilized DHS in any way. Moreover, unless CMS clarifies that parameters of Per Click Arrangements, there could also be substantial risk of confusion among providers as to the arrangements in which they can enter, and whether those arrangements are permitted under the rule. We strongly recommend that CMS make necessary clarifications to the Proposed Rule to address these issues so that physicians desiring to enter into otherwise permitted arrangements can have clarity on the legality of a proposed transaction and can be appropriately and fairly compensated for providing services, and in doing so preserve patient access.

Please do not hesitate to contact us if your office has any questions or comments regarding the matters addressed in this letter.

Sincerely,

RICARDO E. FONTG

REF:mmm

Submitter : Dr. Robert Zwolak **Date:** 08/31/2007

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

Coding--Reduction In TC For Imaging Services

Coding--Reduction In TC For Imaging Services

The Society for Vascular Surgery believes that non-invasive vascular diagnostic studies should not fall under the "imaging" provisions of the DRA Section 5102 because these studies primarily collect Doppler based ultrasound information that is not imaging. We therefore request removal of the following codes from the DRA-affected imaging services: 93880, 93886, 93888, 93925, 93926, 93930, 93931, 93970, 93971, 93975, 93976, 93979, 93990. For full details, please see Section 2 of our comment letter, which is attached.

CMS-1385-P-15487-Attach-1.DOC

15487

SOCIETY FOR VASCULAR SURGERY

August 31, 2007

The Honorable Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1385-P
PO Box 8017
Baltimore, MD 21244–8017

RE: CMS-1385-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee schedule for Calendar Year 2008 and Other Changes to Payment Under Part B

Dear Mr. Kuhn:

On behalf of the 2,300 members of the Society for Vascular Surgery (SVS), we offer the following comments on the Proposed Rule published in the Federal Register on July 12, 2007. We will address multiple provisions under this proposal.

For 2007, our specialty endured a 6% pay-cut due to the impact of the Deficit Reduction Act (DRA) on Noninvasive vascular laboratory studies plus negative changes in physician work payments due to the budget neutrality adjustor, plus additional reductions in the PE RVUs. **Yet, again for CY 2008 our specialty is facing a reduction that is double in size to what we have lost in 2007, 12 percent.** This simply can not continue. For many vascular surgeons, over 50% of their patients are Medicare beneficiaries, due the nature of the diseases and conditions we treat. We can not sustain reductions of this magnitude year after year and not at some point be forced to reduce access to Medicare beneficiaries. We are extremely concerned that 2008 will be the year that this happens.

These decisions regarding our practices are extremely difficult and not made lightly. SVS members are deeply committed to caring for our nation's seniors, but this combination of negative impacts may simply make it impossible for us to continue to offer all services to all Medicare beneficiaries.

The SVS comments will follow in this order:

1. Continuing Codes from the Five-Year Review Open Vascular Surgery Procedures
2. DRA Proposals – Section 5102 – Proposed Adjustments for Payments for Imaging Services

3. TRHCA – Section 101(b) – PQRI general comments
4. TRHCA – Section 101(b) – PQRI SVS ESRD quality measure
5. TRHCA – Section 101(b) – PQRI diabetic podiatry measures
6. Budget Neutrality Adjustor for Work RVUs & other work RVU issues
7. Resourced-Based PE-RVUs
    a. Equipment Use Rate
    b. CPT Codes 37205 and 37206 – Direct PE Inputs for Non-facility Setting
8. Medicare Payment Policy

1. Continuing Codes from the Five-Year Review: Six open Vascular Surgery Codes

SVS would again like to thank CMS for meeting with us on May 16, 2007 regarding the six interim valued vascular surgery procedures, some of our most complex and labor-intensive open aortic aneurysm and bypass operations (CPT codes 35102, 35081, 35556, 35566, 35583, 35585), procedures that are performed to save life and limb. We felt the meeting was very productive and allowed us to present new, additional regression analysis data in addition to information from our July, 2006 comments on the 2007 proposed Medicare Physician Payment rule and our December 30, 2006 comments on the final rule for 2007.

Despite of the opinion held by CMS regarding use of NSQIP data during the five-year review process SVS used multiple other methods besides NSQIP data to arrive at our work RVU recommendations for these codes. As we discussed at the CMS meeting on 16 May, we believe the Refinement Panel did not have time to fully consider all the huge amount of data supporting the conclusion that values above the median survey results were the most appropriate for these 6 very complex open surgical procedures. With due respect for the RUC process, SVS has processed nearly 100% of the vascular surgery codes to RUC survey and analysis, and we ALMOST NEVER asked for more than the median survey value. Nevertheless, for these six very large open surgery procedures, we believe the weight of evidence developed to validate our recommendations, i.e. building blocks, crosswalk comparisons intensity analyses, and finally the regression analyses, all serve to indicate that work RVUs greater than median survey are truly indicated to fairly value the work and to avoid rank order anomalies both within vascular surgery and across the entire relativity spectrum of all surgical procedures. We strongly urge CMS to reconsider the work RVUs of these 6 codes.

For example, regarding CPT code 35102 – Open repair of abdominal aortic aneurysm requiring bifurcated graft – an intensity/IWPUT analysis conducted by SVS determined that the appropriate IWPUT vale is 0.096, the mid-point range for all aneurysms and aortic surgery that maintains the relativity within the families of vascular surgery codes. The 2007 and proposed 2008 work RVUs instead establish a totally inappropriate IWPUT of 0.074, multiples of relative steps below appropriate intensity for open aortic surgery.

SVS used four additional analyses of physician work all of which indicated valuation higher than the CMS value. As we mentioned in our previous December 30, 2006 comments, SVS is very concerned that the Refinement Panel did not have adequate opportunity to review and discuss with SVS representatives the large body of data that SVS prepared and shared with them for all six of the open, vascular surgery codes that were part of the five-year review.

Again, we felt that our meeting on May 16th was a very productive exchange of information regarding the six CPT codes in question and these various methods and outputs that we have used to construct and verify SVS' recommendations that we part of the five-year review. We look forward to some positive level of resolution when the 2008 Final Rule is published in November. As noted below, we are sending the data analysis under separate cover for reconsideration. The following are SVS recommendations for these six codes. The work RVUs have been adjusted from our 2005 RUC recommendations to reflect the changes in EM work RVUs.

	2008 NPRM	SVS Recommendation
35081 Open AAA repair	33.37	36.80
35102 Open AAA repair	36.37	42.20
35556 Open fem-pop bypass graft	26.62	33.20
35566 Open fem-tibial bypass graft	32.22	40.20
35583 Open fem-pop insitu bypass	27.62	33.70
35585 Open fem-tib insitu bypass	32.22	41.00

SVS is sending under separate cover the large compendium of data we used to arrive at work RVU recommendations for these codes. We do not take lightly the RUC survey process, and we reiterate that it is an extremely rare event when SVS recommends work RVUs higher than the RUC survey median. This is in contrast to recommendation of the 25th percentile, which we have used with some regularity when we felt the overall data analysis did not support the RUC survey median. There is a fairness issue here that comes into play. These are not high volume codes, and each requires a huge effort and substantial surgical skill with attention to detail to achieve high quality outcomes. When measured by yardsticks of data provided to support recent E/M increases and proposed Anesthesia increases, these six codes have a huge amount of hard data justifying the requested work RVUs.

During our May 16th meeting Mr. Kay and Drs. Simon and Hambrick ask that we identify the high outliers on our regression analyses. The universe of codes we analyzed included neurosurgical, cardiac and vascular codes that involve arterial surgery and that had been considered during the current 5-year review. In all, this was 68 codes. For IWPUT comparisons, the high outliers were CPT 33413, 33427, 33545, 33863 and 33945. For the regression of RVW vs. total physician time the outliers were CPT 33305, 33413, 33863 and 33877. For the regression of RVW vs. intra-service time the high outliers are CPT 33300, 33305, 33460, 33945, 33463.

2. DRA Proposals - Section 5102 – Proposed Adjustments for Payments for Imaging Services

Having now experienced almost a full year of reductions under the DRA for non-invasive vascular diagnostic studies, SVS is even more convinced that CMS having included CPT codes 93880 – 93990 and G-code 0365 on the list of imaging codes that are defined by Section 5102(b) of the DRA when in fact these studies are predominately non-imaging in nature is not appropriate and needs to be re-visited by CMS to ensure that Medicare beneficiaries have access to the highest quality, most appropriate care.

Non-invasive diagnostic vascular studies ARE NOT included in the "Radiology" section of the CPT Book by intent because they are diagnostic tests used to identify and assess the severity of arterial and venous vascular diseases and disorders, either entirely or primarily through non-imaging modalities. Although these vascular diagnostic tests use ultrasound, they were invented as applications of Doppler ultrasound, which is NOT an imaging form of ultrasound. Doppler ultrasound measures the frequency shift of sound waves that bounce off moving red blood cells. Those frequency shifts undergo analysis by the electronics in the Doppler instrument and are plotted on paper or on a computer screen as graphs of velocity. These are not pictures or images of the tissue. The velocities determine the severity of the arterial disease. For instance, in a patient with severe atherosclerosis plaque in the carotid artery, the high velocities of blood flowing through a very narrow artery correspond to a severe stenosis. The most accurate way to determine the severity of stenosis is based on these velocities, and NOT on a picture of the plaque. It is the visual display of blood flow velocity, not visual pictures of the interior of the vasculature, which are analyzed and interpreted when performing a non-invasive diagnostic vascular study.

Furthermore, noninvasive vascular lab studies have never been appropriately valued in the HOPPS APC system. Noninvasive vascular diagnostic services are performed in a wide variety of locations in different hospitals, ranging from radiology, to pulmonary medicine, to respiratory therapy, to cardiology, vascular surgery and others, lending to a huge range of cost/charge ratios. These services are low profile and seldom garner any attention by the hospital regarding the creation of appropriate charges. Thus, application of cost/charge ratio to charges in order to determine costs has never produced accurate cost numbers for this small family of tests. In fact, the Society for Vascular Ultrasound brought this to the attention of one of the very first APC Panel meetings. SVU was informed that "it all comes out in the wash for hospitals," and no corrective action was taken. Interestingly, in the CY 2008 Proposed Hospital Outpatient Prospective Payment System Rule, the proposed APC payments to hospitals for non-invasive vascular studies are flat and have been for some time, even though the conversion factor for the hospitals has been increasing approximately 3 percent per year for last few years.

However, the fact is that for office providers of these services, it does not "come out in the wash". The AMA PEAC committee considered all the

direct inputs for these services in great detail during their deliberative process. The PEAC inputs are very accurate and result in appropriate valuation for these services. Starting January 1, 2007, SVS members have endured the magnitude of these reductions, 30 – 40 percent, from PFS to APC payments and it has only hardened our resolve that the APC payments are inappropriately low.

Therefore, SVS believes that it is imperative that CMS work across divisions to address the issues we have raised. SVS would like to work with CMS regarding these definitional and data issues to achieve a workable solution.

3. TRHCA – Section 101(b) – PQRI General Comments

SVS appreciates CMS using this proposed rule in an attempt to provide greater clarity regarding the role of a consensus organization in both the measure development process and the measure approval process. SVS believes it is very important to the future of the PQRI program and the quality movement to have better, more complete definitions regarding what constitutes an appropriate venue and organizations and processes for these roles.

SVS is an active participant in many organizations including the AMA Physician Consortium, the Surgical Quality Alliance, the Fistula First Initiative, the Ambulatory Quality Alliance, and the National Quality Forum. Also, the SVS has developed and maintained for the last several years a registry regarding patient outcomes in vascular surgery.

SVS believes that it is imperative that these measures be generated for the purposes of development and then submitted/endorsed for the approval process by physician specialty societies and organizations. Being a member in all the "consensus organizations" listed above, the SVS is a supporter of these types of organizations; however, we believe it is more helpful to the process to define the characteristics of what CMS will consider an "approved" consensus organization, in addition to just giving examples, for the purposes of measure development and then a separate, distinct set of characteristics for what CMS will consider an "approved" consensus organization for the purposed of measure approval.

Because this is a dynamic process and one where additional capacity may be needed, defining characteristics and then CMS continually updating a list of organizations that meet these characteristics will enhance transparency and will enable more physician societies to participate in the process through the various organizations. We urge CMS to meet with the quality leaders of the physician societies and organizations to define the

characteristics of "approved" consensus measure development groups and consensus measure approval groups.

Need for Greater Transparency Regarding Process

We want to bring to CMS' attention that there is a need for greater transparency and a need for a real, structured governance of some of the consensus organizations, such as the AQA, and voting process for measure approval in this organization. This leads to a lack of rigorous and scientific evaluation for these measures. Also, it leads to arbitrary decisions regarding measures that may be in the 2007 program and now may not be in the 2008 program. Having physicians gear up to report measures in 2007 that may be gone in 2008 will lead to frustration, lack of robust data, and a lack of interest in participation. Thus, CMS needs to make a decision that once a measure is on the list, it will stay on the list of approved measures for at least a specific number of years, versus just six or 12 months.

Use of Medical Registry to Submit Data

SVS encourages CMS to consider participation in a physician society developed patient outcomes registry as a structural measure, even to the point that it would be considered, "a global measure" such that participation in the registry, assuming the data could be accessed by CMS, would be considered successful participation in PQRI. The type and level of data sets that are included in these patient registries can provide CMS with a level of data regarding patterns of quality care for specific indications that will never be realized with the type of reporting currently contained within the PQRI program. SVS currently operates one of two national carotid stent registries. This has been extremely useful as providers comply with data reporting requirements for percutaneous carotid artery stenting.

Given that in the future there may be instances where SVS members who participate in our registry may be reporting data that is similar to data that would also be reported under a PQRI quality measure, we wanted to bring the following concerns to CMS' attention: 1) the routine data would be free of any information that could be used to identify the patient; 2) CMS would need to work with the existing registries regarding forms and processes used for patient consent regarding how the data could be used; 3) There would have to be a way developed to export the data by individual record, allowing either physicians or patients to decide not to have their data shared with CMS; and 4) Physicians must be in control of their data at all times. That being said, the SVS is extremely interested in working with CMS regarding how we can work together on this issue.

4. TRHCA – Section 101(b) – End-Stage Renal Disease Fistula Quality Measure

Not knowing exactly when CMS received the measures listed in Table 21, SVS wishes to inform CMS that it has submitted a measure to the NQF that we believe will be endorsed prior to November 15, 2007. This measure is relevant to the Medicare population and will allow vascular surgeons to report on their role and activities as providers of native hemodialysis access for Medicare beneficiaries that are in CKD 4,5 or End Stage Renal Disease. The goal of this measure is to provide a tool by which individual surgeon effort can be gauged in terms of creating native fistulas in those CKD and ESRD patients who are appropriate candidates. The details of this measure, which is currently under final review by the NQF, are provided here. We look forward to this measure being part of the 2008 set of PQRI measures.

NQF Number: 45

Focus: Vascular Access

Measure Title: Hemodialysis Vascular Access – Surgical Decision-making to Maximize Placement of Autogenous Arterial Venous Fistula

Developer: SVS

Type Reclassified: Outcome

Setting: Ambulatory Care Hospital

Level of Analysis: Individual Clinician

Description: Percentage of patients with advanced chronic disease (CKD4 or 5) or end-stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arteriovenous fistula (AVF).

Numerator: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons OR Fistula not Performed for Patient Reasons. NOTE: This measure will be reported as the total of the three categories of numerators and also as the three numerators reported separately.

Numerator Data Collection: G8081: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons: Append modifier (1P) to G8081 to report documented circumstances that appropriately exclude patients from an

autogenous fistula. A typical medical exclusion would include clinician documented that CKD4, CKD5 or ESRD patient requiring hemodialysis vascular access was not eligible for autogenous AV fistula based on results of vein mapping. OR Fistula not Performed for Patient Reasons: Append modifier (2P) to G8081 to report documented circumstances that exclude patients for patient related reasons. For instance, clinician documented that CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access refused autogenous AV fistula following recommendation for same by provider. Autogenous is defined as the patient's own native tissue. Fistula is defined as a surgical connection established between and artery and a vein.

Case Finding: Patients eligible for inclusion are those with KDOQI Stage 4 and 5 CKD and ESRD.

Denominator: Patients with CKD4, CKD5 or End-stage renal disease who undergo open surgical placement of permanent hemodialysis access

Denominator Data Collection: ICD-9 585.3, 585.4, 585.5, 585.6 or 996.73 AND CPT 36818, 36819, 36820, 36821, 36825, or 36830

Exclusions: None

Risk Adjustment: This measure is recommended only for first-time vascular access patients, that is, all patients who have not previously undergone placement of a permanent upper extremity indwelling fistula or graft. The justification for this limitation to first-time access patients is that insufficient scientific data exists to know the target threshold for placement of native AVFs in patients who have previously undergone AVF surgery.

Data Source / Collection Instrument: Administrative and medical record data, provider data

Release / Revision Date: 2007

In Use: no

Testing: no

Conditions: Use term "autogenous" AV fistula. Remove CKD3. Clarify denominator exclusions because medical reason and pt reason included in numerator. Use separate codes and reporting for numerator categories.

5. TRHCA – Section 101(b) – Podiatric Measures Table 22 of NPRM

SVS offers its highest possible level of support to appropriately crafted quality measures aimed at preventing limb loss in diabetics.

We note that one of the measures in Table 22 of the NPRM is entitled "Peripheral Arterial Disease: Ankle Brachial Index (ABI) Measurement". Assessment for presence of peripheral arterial disease (PAD) in diabetics is crucially important, but we would potentially suggest that physical exam palpation for foot pulses might be the first appropriate step in assessment for PAD. Otherwise the broad application of ABIs in all diabetics might be considered screening, and coverage issues could become relevant. The absence of palpable pulses could be a signal that ABIs are indicated in the diabetic patient. Certainly if the diabetic arrives with a foot ulcer, diabetic foot infection, or presence of tissue gangrene, ABIs and evaluation for PAD are mandatory.

Some diabetic patients have calcified tibial arteries, a condition that renders the ABI test unreliable. In this situation, measurement of toe pressures is indicated. In summary, SVS strongly supports evaluation for PAD in diabetics as a means to reduce limb loss. We look forward to appropriately designed quality measures to accomplish that.

6. Budget Neutrality Adjustor for Work RVUs and other Work RVU issues

SVS strongly objects to the use of budget neutrality adjustors for physician work. When CMS applied a budget neutrality adjuster to the work RVUs following the first 5-year review of physician work, it caused substantial confusion among non-Medicare payers, as well as physician practices. CMS eventually acknowledged the confusion and ineffectiveness of applying the budget neutrality adjuster to the work RVUs, and the Agency eventually eliminated the problem. Now its back again. SVS understands the argument that relativity among work, PE and PLI pools should remain constant, but we believe the counter-argument holds more weight, that is that RVUs should be paid equally, regardless of work, PE or PLI origin. The outcome of the 5-year review should be shifted to the Conversion Factor because it would: (i) have less impact on other payers who use the Medicare RBRVS; (ii) be consistent with the notion that budget neutrality is mandated for monetary reasons, and since the conversion factor is the monetary multiplier in the Medicare payment formula, this is the most appropriate place to adjust for budget neutrality; and (iii) be consistent with CMS' goal of transparency in the Medicare payment system.

Anesthesia Conversion Factor upgrade

SVS agrees that Medicare payment for anesthesia services is undervalued. SVS compliments ASA and the RUC for a completing a complex analysis of anesthesia services in order to compare it to work provided by other specialties. It was certainly a

challenging task to compare services that include reimbursement for base plus time to services that are reimbursed for base or time, but not both. However, SVS is concerned about the Intensity assignment during the lowest level of Post Induction Period Procedure Anesthesia (PIPPA) being set at 0.031 work units per minute. This Intensity setting was derived from comparison with CPT code 99149, a moderate sedation service. As opposed to the lowest level of PIPPA, wherein the patient has already been induced and is stable, it is our understanding that CPT 99149 includes the initiation of moderate sedation, during which a patient undergoes transformation from awake and alert to a hoped for level of "moderate" sedation. We believe this may be more complex than the lowest level of stable PIPPA, therefore not a fully appropriate one-to-one crosswalk for lowest level PIPPA. More troublesome, however, is that there are many periods in the construct of a surgical global service wherein the baseline Intensity is substantially less than 0.031. For instance, all time spent assessing the patient in the immediate pre-op period, reviewing informed consent, assessing patient for surgical readiness, discussing case requirements with nursing and anesthesia, are all reimbursed by Medicare at 0.0224 RVUs/min, or 28% less than the proposed lowest level of PIPPA. Likewise, all immediate post-op care in the surgical package is reimbursed at the same 0.0224 RVUs/min. These services include ensuring surgical stability of the patient in the immediate post-op period, writing post-op orders, etc., again seemingly of equal intensity to lowest level PIPPA. In summary, SVS believes that an increase in Medicare reimbursement for anesthesia services is well-deserved, but if the lowest level PIPPA is set at 0.031, we believe that all pre and post surgical service should be set at the equivalent or higher level.

93325

SVS recognizes the major clinical value and importance of colorflow analysis in vascular studies such as echocardiography. Having said that, we support elimination of an add-on code for colorflow during echocardiography, as apparently now underway by ACC. In absence of that independent method, we support bundling color into the base codes as is the case in other ultrasound applications. The colorflow add-on was created decades ago when the technology was new, unique, and very expensive. Today, colorflow is a routine component of all quality echocardiography scanners. It is, therefore, difficult to justify separate payment for this service.

7. Resource-Based PE – RVUs

Equipment Use Rate

SVS agrees with CMS that the 50 percent utilization rate for medical equipment is appropriate for equipment used as part of office-based procedures. For surgical specialties, procedure specific equipment used in the office may only be in use approximately one – two days a week, depending on the service mix of a specific office.

SVS is currently participating in two different surveys that are asking questions regarding equipment use rate. In both instances, the surveys are asking there questions in such a way to be both specialty and type of equipment specific. SVS believes that these types of specialty specific surveys are important and the type of data that CMS should be considering when making code specific decisions, regarding practice expense inputs. We believe that the data coming from these two efforts will be more instructive to CMS versus generalizing the higher utilization rates found by MedPAC in their six site survey for CT and MRI imaging equipment to even all types of imaging equipment – i.e. ultrasound - or for other types of equipment. Instead, SVS hopes that CMS uses specialty and type of equipment specific data to work through this question going forward.

CPT Codes 37205 and 37206 – Direct PE Inputs for Non-facility Setting

The SVS appreciates CMS reviewing clinical literature regarding transcatheter stent placement and what is considered standard practice regarding the number of stents placed per patient, per vessel. While we agree with CMS that it is not typical, i.e. greater than 50 percent of the time that two stents would be used to maintain the vascular integrity of an initial vessel, there are instances where a patient does need two stents. Since most of these stents cost more than $1,000 each, we ask that CMS provide some guidance to the Medicare contractors regarding how the cost of a second stent, when used, may be separately billable using a HCPCS code.

8. Medicare Physician Payment Rate for 2008

In 2008, physicians and other health care practitioners whose payment rates are tied to the physician fee schedule face a 10% payment rate cut. The SVS urges CMS to work with Congress to avert this cut and ensure that physician payment updates for 2008 and subsequent years accurately reflect increases in medical practice costs.

Payments to physicians today in 2007 are essentially the same as they were six years ago in 2001. Due to the SGR, physicians now face drastic Medicare payment cuts totaling almost 40% over the next eight years. Yet, during this same time period, the Medicare Economic Index (MEI), which measures increases in medical practice costs, is expected to increase by about 20%. Physicians cannot absorb these draconian cuts.

Only physicians and other health professionals face steep cuts under this flawed payment formula. Other providers, such as nursing homes and hospitals have payment updates that reflect the cost of inflation. Further, the 10% cut in payment rates facing physicians is in stark contrast to Medicare Advantage (MA) plans, which are paid on average 112% above the cost of traditional Medicare, with a significant number of MA plans paid from 120% to more than 150% of traditional Medicare. These overpayments are shortening the life of the Medicare trust fund.

+++

SVS appreciates the opportunity to submit these comments and looks forward to working with CMS to implement these recommendations. Please feel free to contact Pam Phillips, Director of Health Policy and Government Relations at 703-573-7894 or PPhillips@vascularsociety.org, if we can provide further information.

Yours truly,

K. Wayne Johnston, MD
President
Society for Vascular Surgery

Robert M. Zwolak, M.D.
Robert M. Zwolak, M.D.
Chair, Health Policy Committee
Society for Vascular Surgery

Submitter : Dr. JAMES SCULLY **Date:** 08/31/2007

Organization : AMERICAN PSYCHIATRIC ASSN.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

SEE THE ATTACHED .PDF FILE, WHICH IS APPENDIX 2 FOR THE COMMENTS FILED EARLIER TODAY. I HAVE SPENT ABOUT TWO HOURS TRYING TO FILE THE COMMENTS AND ATTACHMENTS, THEN FOUND THEY HAD TO BE BROKEN INTO MULTIPLE FILES TO DO SO. THE COMMENTS, APPX 1 AND APPX 3 HAVE ALREADY BEEN FILED ONLINE. PLEASE ASSOCIATE THIS APPX 3 WITH THE BODY OF THE COMMENTS AND APPXS 1 AND 2, THANK YOU. A.F.

CMS-1385-P-15488-Attach-1.PDF

ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

August 11, 2006

Armed Forces Epidemiological Board

MEMORANDUM FOR The Honorable William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs

SUBJECT: Traumatic Brain Injury in Military Service Members – 2006-02

1. In keeping with the Armed Forces Epidemiology Board's (AFEB) mission providing independent scientific advice on matters concerning operational programs, policy development, and research needs for the prevention of disease and injury and promotion of health, the AFEB has reviewed evidence regarding the acute and long-term health implications of traumatic brain injury (TBI) in military service members and has developed recommendations on how DoD should approach TBI prevention, medical management, and future research.

2. Based on scientific literature including those documents identified in the Board's citations and other reports indicating that blast-related events compose a substantial number of combat injuries in the war on terrorism, and due to concerns regarding the long-term consequences of repeated concussion on military service members, the Board requested and received a series of briefings and a panel discussion on traumatic brain injury during a closed session at the March 6, 2006 AFEB meeting at Fort Detrick, MD.

3. Traumatic brain injury is a major public health concern and a cause of death and life-long disability in the United States, with an estimated 1.5 million Americans sustaining a TBI yearly (NCIPC, Report to Congress 2003). There is increasing evidence that clinically and pathophysiologically relevant neurologic injury occurs after even mild traumatic brain injury (MTBI) or concussion, and may have long term neurologic sequela (NCIPC, Report to Congress 2003, Bazarian 2006). Mild traumatic brain injury (MTBI) has been recognized by Congress as a public health issue in the past. In response to this concern, Congress passed the *Children's Health Act of 2000* to which the CDC responded by recommending appropriate methodological strategies to obtain data on the incidence and prevalence of MTBI (NCIPC, Report to Congress 2003).

4. Various agencies within the Department have taken commendable steps to address TBI. The Board is aware of recent activities by the Assistant Secretary of Defense for Health Affairs in this important area. The Board specifically commends the Army and the Marine Corps for recognizing TBI as a significant health and operational concern and for implementing changes in mission tactics, enhancements in traumatic care, and research into improvements in body armor. Many of these processes, however, are aimed at reducing the most severe forms and clinical consequences of TBI. There remains a need to better understand the unique characteristics of blast-associated TBI and to reduce the health risk and complications from mild or moderate forms of brain injury.

5. While the efforts of these various agencies are noteworthy, it appears to the Board that the DoD lacks a system-wide approach for proper identification, management, and surveillance for individuals who sustain a TBI, in particular mild TBI/concussion. It is timely for the DoD to be a leader in

Encl 3

tackling the issue of TBI, given our current wartime challenges. With a primary goal of delivering the highest standard of care to our military forces, a DOD-wide consensus of care, to include a standardized method of on-the-field concussion assessment, is necessary. In addition, a standardized follow-up utilizing appropriate clinical assessment techniques to recognize neurologic and behavioral effects of TBI following acute injury is important. Such advancement will enable the initiation and improvement of prevention strategies, patient management and surveillance, and basic and clinical research.

Recommendation:

6. The Board believes, based on its review, that DoD would benefit from a systematic policy-driven approach to the prevention, medical assessment, and management of traumatic brain injury in military service members. The main focus of the activities should concentrate on prevention activities in the combat theater, to include 1) improved personal protective equipment, 2) standard methods of acute injury on-the-field concussion/traumatic brain injury assessment, 3) effective disposition assessment regarding when and if a service member who has sustained a TBI event should return to duty, 4) efficient and effective documentation of acute injury and disposition assessment, and blast related events in theater to better inform senior leadership, improve the collection of TBI/blast related clinical information and help in the formulation of future research questions, 5) systematic follow-up assessment and medical management for service members suspected of having or with a known TBI event, and 6) education of service members and their families, unit commanders and fellow service members, and any individuals in a position to encounter and care for soldiers at risk for a TBI during or after military service.

7. While the primary focus should be on TBI prevention, assessment, and medical management in the combat theater, DoD should continue some form of post-deployment screening to help ensure that those who remain impaired or are suffering persistent TBI-related health problems are identified for follow-up care. This is recommended because mild to moderate TBI symptoms can be subtle with no apparent stigmata. However, TBI may markedly decrease performance, placing the injured service member, his/her fellow service members, and future missions in jeopardy. Ideally, when combat theater-level activities and documentation collection processes are fully in place, the Department may consider phasing out post-deployment screening. However, given the recognized difficulties in data collection and health care delivery in a combat environment, post-deployment screening would provide an additional safety net for those with persistent or previously unreported TBI symptoms. Consideration should be given to establishing a cohort of combat-theater service members for follow-up after deployment for incidence of health effects related to blast injury.

8. The Board wishes to stress that the primary focus of post-deployment screening is to help identify those requiring additional medical evaluation and subsequent therapy. There is a temptation to over-estimate the epidemiological value of information from screening instruments and to imply injury or illness rates from these data. The Department should guard against this temptation as well as inferring mild or moderate TBI clinical classification based solely on self-reported information.

9. Consideration should also be given to implementation of a baseline screening tool to enhance the utility of post-injury formal neuropsychological testing. Such a tool would be most effective if implemented upon entry into military service. At a minimum, implementing baseline testing should be considered pre-deployment and in military occupations at high risk for blast or impact injury.

10. The Board strongly recommends the Department consider forming a consensus panel comprised of front line and first level health care providers, and individuals with expert knowledge and specialty training in the care of TBI, (such as neurologists and neurosurgeons, physiatrists, psychiatrists, rehabilitation specialists, experts in the evaluation of evidence-based medicine and epidemiologists) to address the above recommendations. DoD should consider including Veterans Affairs representatives on the consensus panel to address access and availability of rehabilitation services in the DoD and VA systems for military personnel and veterans with mild to moderate to severe TBI.

11. The Board also recognizes that traumatic brain injury events also occur in other military environments, particularly some forms of training. The lessons learned in the combat theater would assist in the prevention and medical management of TBI in training exercises and other at risk environments.

12. The Board strongly advocates for additional TBI research, particularly as it relates to blast associated events. The majority of concussion related information and guidelines currently available are the result of research on impact events, particularly from sports related activities. There is considerable uncertainty as to how well these guidelines apply to blast related concussion. Further research is needed to fill current information gaps, help guide patient care, and potentially reduce long-term disability. In particular, the long term impact of repeated mild or moderate blast-related traumatic brain injuries over short periods of time requires further study.

Gregory A. Poland, M.D.
President

Wayne M. Lednar, M.D., Ph.D.
Chair, Occupational and
Environmental Health Subcommittee

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SUBJECT: Traumatic Brain Injury in Military Service Members - 2006-02

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AFEB

SUBJECT: Traumatic Brain Injury in Military Service Members - 2006-02

CITATIONS

Aubry M, Cantu R, Dvorak J, et. al. Summary and Agreement Statement of the First International Conference on Concussion in Sport, Vienna 2001. Phys & Sport Med 2002;30(2):57-62 (also co-published in Br J Sports Med 2002;36:3-7 and Clin J Sports Med 2002;12:6-12).

Bazarian JJ, Blyth B, Cimpello L. *Bench to Bedside*: Evidence for Brain Injury after Concussion – Looking beyond the Computed Tomography Scan. Acad Emerg Med.2006;13:199-214.

Boake C, Francisco GE, Ivanhoe CB, Kothari S. Brain Injury Rehabilitation. in *Physical Medicine and Rehabilitation* 2nd Ed. Braddom RL (ed.) Saunders, Indianapolis, IN 2000 pp.1106-1107

Center for Disease Control: National Center for Injury Prevention and Control. *Heads Up: Concussion in High School Sports* http://www.cdc.gov/ncipc/tbi/Coaches_Tool_Kit.htm http://www.cdc.gov/ncipc/pub-res/pubs.htm

Heck J, Rosa R. Evaluating Mild Head Injuries. Incorporating the Standardized Assessment of Concussion. Sports Med Update 2001;15(2):46-52.

Institute of Medicine Report. Gulf War and Health: Updated Literature Review of Sarin Description An IOM committee conducted an updated review of scientific evidence regarding statistical associations between diseases and exposure to sarin. www.iom.edu/CMS/3793/16393.aspx

King NS. Post-Concussion Syndrome: Clarity Amid the Controversy? Br J Psychiatry 2003;183:276-278.

McCrory P, Johnston K, Meeuwisse W, et. al. Summary and Agreement Statement of the 2nd International Conference on concussion in Sport, Prague 2004. Clin J Sport Med. 2005;15(2):48-55.

National Center for Injury Prevention and Control. *Report to Congress on Mild Traumatic Brain Injury in the United States: Steps to Prevent a Serious Public Health Problem.* Atlanta, GA: Centers for Disease Control and Prevention: 2003.

Ponsford J, Willmott C, Rothwell A, et. al. Impact of Early Intervention on Outcome Following Mild Head Injury in Adults. J Neurol Neurosurg Psychiatry 2002;71:330-332.

Ryan LM, Warden DL. Post Concussion Syndrome. Int Rev Psychiatry. 2003;15(4):310-316.

Team Physician Consensus Statement. *Concussion (Mild Traumatic Brain Injury) and the Team Physician: A Consensus Statement.* Med Sci Sports Exerc. 2005;37(11):2012-2016.

Theye F, Mueller KA. "Heads Up": Concussions in High School Sports (review). Clin Med & Research 2004;2(3):165-171.

States General Accounting Office. *Disabled Veterans Care: Better Data and More ıtability Needed to Adequately Assess Care.* Report to the Ranking Democratic Member, ittee on Veterans' Affairs, House of Representatives, GAO/HEHS-00-57. 2000.

Submitter : Dr. MICHAEL HOVLAND **Date:** 08/31/2007

Organization : ANESTHESIA PARTNERS

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

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Submitter : **Mr. Michael Karegeannes** **Date: 08/31/2007**

Organization : **Freedom Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P

CMS-1385-P-15490-Attach-1.DOC

15490

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Physician Self-referral issues

Dr. Mr. Weems:

I am a physical therapist who has been working as a PT for17 years. I have been in private practice in Milwaukee, Wisconsin for 13 of those years. I would like to comment on the July 12th proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

The company for which I own and work takes pride in seeking out and hiring very well-educated, experienced therapists who provide exceptional care. With declining reimbursement and limited visits with both Medicare and other insurers it has become increasingly difficult financially, for us to provide the high level of patient care our patients are used to. To compound the problem, we have physician groups reaping the financial rewards of referring patients to therapy practices they own instead of therapy practices that may provide superior and more cost-effective care. This is possible due to the "in-office ancillary services exception" to the Stark Law, as physical therapy is currently considered a "designated health service (DHS)". In some cases, these patients are not even being seen by PT's, but instead by PTA's and ATC's under the physician's direction. This needs to stop.

Generally speaking, physical therapy services are provided on a repetitive basis. That said, it is no more convenient for the patient to receive PT services 2-3 times per week in the physician's office than to attend an independent physical therapy location. Furthermore, physician-direct supervision is not necessary to administer physical therapy services. In fact, an increasing number of physician-owned physical therapy clinics are using the reassignment of benefits laws to collect payment in order to circumvent "incident-to" requirements.

REAL AND POTENTIAL EFFECTS OF POPTS ON CONSUMERS

1. **Conflict of Interest:**

- Once a physical therapist is employed by a physician or physician group, a conflict of interest exists, in which the best interests of the patient or client may be compromised for financial gain by the physician owner.
- Having a financial interest in other services to which a physician refers a client may cloud the physician's judgment as to the need for the referral, as well as the length of treatment required.
- Similarly, the physical therapist employed by a physician may face pressure to evaluate and treat all patients referred by the physician, without regard to the patient's needs.
- **The consumer is likely unaware of any conflict of interest, assuming no conflict of interest exists when the service is provided within the physician's office.**
- Physician associations have argued that self-referral to a physician-employed physical therapist is not a conflict of interest by labeling physical therapy as an "ancillary service", one provided "incident to" physician practice. **However, the suggestion that physical therapy is not a separate profession is clearly wrong.**

2. **Loss of Consumer Choice:** In addition to inherent conflicts of interest that exist within POPTS, physician referral to services within his/her office, or to those with whom he/she may have a financial interest, limits the consumer's right to choose his/her physical therapist. The consumer may not recognize this loss of choice, as no other option is offered. **Observation of the fiduciary responsibility between physician and patient is vital to preserving both consumer choice and the autonomous practice of the physical therapist.**

3. **Economic and Financial Harm:** The harm done by POPTS is not merely a matter of principle or abstract ethics. Health policy researchers have provided data demonstrating specific harms from conflict of interest in physical therapy referrals. Studies have demonstrated that POPTS arrangements have a significant adverse economic impact on consumers, third-party payers, and physical therapists. Multiple research studies validate the concerns many have regarding the "referral for profit" that occurs within physician-owned physical therapy services.

SUPPORTING RESEARCH

In August of 1991, the state of Florida Health Care Cost Containment Study — a survey of 3,000 health care facilities — was published. This study concluded that physical therapy referral for profit results in major over utilization of services:

1. Physician-owned physical therapy facilities provide 62% more patient visits per full-time physical therapist, when compared with non-physician-owned clinics.
2. The patients referred have 43% more treatments (therapeutic exercise, ultrasound, etc.), when compared with non-physician-owned clinics.

The Mitchell and Scott study in *JAMA* showed similar results. The findings of this study are as follows.

1. Visits per patient were 39% to 45% higher when compared with non- physician-owned clinics.
2. Gross and net revenue per patient was 30% to 40% higher.

3. Licensed physical therapists and physical therapist assistants employed in non-physician-owned clinics spent approximately 60% more time per visit treating patients.
4. Physician-owned clinics also generated more of their revenue from patients with well-paying insurance, strongly suggesting that "cherry picking" of patients is a common POPTS practice.

In 1992, the William M. Mercer Co studied California Worker Compensation Programs. The results of this study are as follows

1. The study found that if an injured worker received initial treatment from a physician with ownership interest in physical therapy services, that patient received a referral to physical therapy 66% of the time.
2. If, on the other hand, the injured worker received initial treatment from a physician with no ownership interest in physical therapy services, the patient was referred to physical therapy 32% of the time, less than half the frequency of physician-owned clinics.
3. This study concluded that financial incentives played a major role in decisions. The added incentive for physicians with ownership interests in physical therapy services was $233 million per year in California alone.

A 2004 APTA survey on POPTS reported that more than 80 percent of the responding therapists encountered situations in which physicians retained patients within their own practices, rather than referring patients to other physical therapy providers.

Charles Magistro, former APTA President, characterized POPTS as, **"A CANCER EATING AWAY AT THE ETHICAL, MORAL AND FINANCIAL FIBER OF OUR PROFESSION."**

Thank you for your consideration of my comments. I hope these comments have helped to highlight the abusive-nature of physician-owned physical therapy services and support PT services removal from permitted services under the in-office ancillary exception.

Sincerely,

Michael Karegeannes Owner/PT, MHSc, LAT, MTC, CFC
Freedom Physical Therapy Services, S.C.
www.freedompt.com
mkaregeannes@freedompt.com
1-414-352-2082

Submitter : **Dr. Debra Jones** **Date: 08/31/2007**

Organization : **St. Vincent Healthcare**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie v. Norwalk, Esq
Acting Administrator
CMS
Attn: CMS-1385-P
Re: Anesthesia Codin

Dear Ms. Norwalk,

I am writing in strong support of the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. While I understand that this is a very complicated issue, I am grateful that the Agency has recognized the significant undervaluation of anesthesia services and is taking steps to address the problem. The current Medicare payment for anesthesia services, at only $16.19 per unit, is simply not enough to cover the cost of caring for our nation's Medicare patients. Anesthesiologists are therefore being forced out of communities with disproportionately high Medicare populations, creating an unsustainable situation. This puts patients at risk.
To assure that our patients have access to expert anesthesiology medical care, it is essential that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration in this very serious matter.

Respectfully,
Debra G. Jones, MD

Submitter : **Dr. Silver Dwinell** **Date: 08/31/2007**

Organization : **American Sociaty of Anesthesiologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I, Silver C. Dwinell, MD, am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am extremely grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a HUGE payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does NOT cover the cost of caring for our nation s seniors, and is creating an UNSUSTAINABLE system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I, Silver C. Dwinell, MD, support full implementation of the RUC 's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is IMPERATIVE that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC. The time for change is long past-due.

Thank you for your consideration of this serious matter.

Silver C. Dwinell, MD

Submitter : Dr. CHARLES PROBERT **Date:** 08/31/2007

Organization : ANESTHESIA PARTNERS

Category : Physician

Issue Areas/Comments

GENERAL

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Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter : **Tina Lepley** **Date: 08/31/2007**

Organization : **Atlanta Center for Athletes**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Tina Lepley and I am a NATA certified athletic trainer and Georgia licensed athletic trainer. Since receiving my BA in sports medicine and becoming certified, I have continued my education by attending many educational courses to improve my skills and provide my clients the best possible services.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Tina L. Lepley, ATC

Submitter : **Dr. William McNiece** **Date: 08/31/2007**

Organization : **Dr. William McNiece**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

August 27, 2007

Dear Ms. Norwalk:

For more than ten years, the clinical work of anesthesiologists has been undervalued by the RBRVS in comparison to the clinical work of other medical specialties. Interestingly, the insurance industry has long recognized this severe undervaluing of anesthesiologist s work as unique among all the medical specialties. Payment levels for anesthesiologists are separated out in negotiations since a uniform percent of Medicaid payment levels that works for all other specialties would simply be unacceptable for clinical work by anesthesiologists.

The RUC in its current evaluation recommends an increase in Medicare payment of nearly $4.00 per unit. Clearly, this is a recommendation that should be fully implemented and I fully support the RUC recommendation. While it does not completely fix the existing undervaluation of anesthesiologists clinical services, it will be an important step forward.

Beyond the level of unit value, the Medicare payment system clearly undervalues the medical services of academic anesthesiologists in comparison to those services of all other academic physicians. The effect of the fifty percent reduction in the already low payment to academic anesthesiologists when there is any overlap of any portion of an anesthetic has been to severely hobble academic anesthesiology departments. This fifty percent reduction applies to no other group of academic physicians. It is these academic anesthesiology departments on which we depend to educate the next generation of anesthesiologists to care for patients including those who are Medicare recipients.

I should note that Medicare payments do not directly affect me to any significant degree as I am a pediatric anesthesiologist. However, I do have an eighty-eight year old mother for whom I want expert anesthesiology care to be available. I believe the persistent Medicare undervaluation of the medical care provided by anesthesiologists does not bode well for the continuing availability of those services.

Sincerely,

William McNiece, M.D.
4311 Broadway St.
Indianapolis, IN 46205

Submitter : Dr. Roger Mattison **Date:** 08/31/2007

Organization : Dr. Roger Mattison

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I support the revision of anesthesia reimbursement in the CMS proposal. Presently anesthesiology services are undervalued relative to other physicians and to the critical nature of the work we perform for our medicare patients. We are near a crisis in the care of our elderly population and realistically valuing anesthesia care may avert it.
RRoger Mattison, MD

Submitter : Dr. Robert Zwolak **Date:** 08/31/2007

Organization : Society for Vascular Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

The previous SVS submission included information on 6 vascular codes that are still a concern for us. SVS has three other short comments regarding 5-year review. These include a request to eliminate the budget neutrality adjustor, a comment on anesthesia conversion factor upgrade, and a common on CPT 93325 colorflow add-on. Please see section 6 of our comment letter for details. Thanks.

CMS-1385-P-15497-Attach-1.DOC

[redacted] SVS
SOCIETY FOR VASCULAR SURGERY

August 31, 2007

The Honorable Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1385-P
PO Box 8017
Baltimore, MD 21244–8017

RE: CMS-1385-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee schedule for Calendar Year 2008 and Other Changes to Payment Under Part B

Dear Mr. Kuhn:

On behalf of the 2,300 members of the Society for Vascular Surgery (SVS), we offer the following comments on the Proposed Rule published in the Federal Register on July 12, 2007. We will address multiple provisions under this proposal.

For 2007, our specialty endured a 6% pay-cut due to the impact of the Deficit Reduction Act (DRA) on Noninvasive vascular laboratory studies plus negative changes in physician work payments due to the budget neutrality adjustor, plus additional reductions in the PE RVUs. **Yet, again for CY 2008 our specialty is facing a reduction that is double in size to what we have lost in 2007, 12 percent.** This simply can not continue. For many vascular surgeons, over 50% of their patients are Medicare beneficiaries, due the nature of the diseases and conditions we treat. We can not sustain reductions of this magnitude year after year and not at some point be forced to reduce access to Medicare beneficiaries. We are extremely concerned that 2008 will be the year that this happens.

These decisions regarding our practices are extremely difficult and not made lightly. SVS members are deeply committed to caring for our nation's seniors, but this combination of negative impacts may simply make it impossible for us to continue to offer all services to all Medicare beneficiaries.

The SVS comments will follow in this order:

1. Continuing Codes from the Five-Year Review Open Vascular Surgery Procedures
2. DRA Proposals – Section 5102 – Proposed Adjustments for Payments for Imaging Services

3. TRHCA – Section 101(b) – PQRI general comments
4. TRHCA – Section 101(b) – PQRI SVS ESRD quality measure
5. TRHCA – Section 101(b) – PQRI diabetic podiatry measures
6. Budget Neutrality Adjustor for Work RVUs & other work RVU issues
7. Resourced-Based PE-RVUs
    a. Equipment Use Rate
    b. CPT Codes 37205 and 37206 – Direct PE Inputs for Non-facility Setting
8. Medicare Payment Policy

1. Continuing Codes from the Five-Year Review: Six open Vascular Surgery Codes

SVS would again like to thank CMS for meeting with us on May 16, 2007 regarding the six interim valued vascular surgery procedures, some of our most complex and labor-intensive open aortic aneurysm and bypass operations (CPT codes 35102, 35081, 35556, 35566, 35583, 35585), procedures that are performed to save life and limb. We felt the meeting was very productive and allowed us to present new, additional regression analysis data in addition to information from our July, 2006 comments on the 2007 proposed Medicare Physician Payment rule and our December 30, 2006 comments on the final rule for 2007.

Despite of the opinion held by CMS regarding use of NSQIP data during the five-year review process SVS used multiple other methods besides NSQIP data to arrive at our work RVU recommendations for these codes. As we discussed at the CMS meeting on 16 May, we believe the Refinement Panel did not have time to fully consider all the huge amount of data supporting the conclusion that values above the median survey results were the most appropriate for these 6 very complex open surgical procedures. With due respect for the RUC process, SVS has processed nearly 100% of the vascular surgery codes to RUC survey and analysis, and we ALMOST NEVER asked for more than the median survey value. Nevertheless, for these six very large open surgery procedures, we believe the weight of evidence developed to validate our recommendations, i.e. building blocks, crosswalk comparisons intensity analyses, and finally the regression analyses, all serve to indicate that work RVUs greater than median survey are truly indicated to fairly value the work and to avoid rank order anomalies both within vascular surgery and across the entire relativity spectrum of all surgical procedures. We strongly urge CMS to reconsider the work RVUs of these 6 codes.

For example, regarding CPT code 35102 – Open repair of abdominal aortic aneurysm requiring bifurcated graft – an intensity/IWPUT analysis conducted by SVS determined that the appropriate IWPUT vale is 0.096, the mid-point range for all aneurysms and aortic surgery that maintains the relativity within the families of vascular surgery codes. The 2007 and proposed 2008 work RVUs instead establish a totally inappropriate IWPUT of 0.074, multiples of relative steps below appropriate intensity for open aortic surgery.

SVS used four additional analyses of physician work all of which indicated valuation higher than the CMS value. As we mentioned in our previous December 30, 2006 comments, SVS is very concerned that the Refinement Panel did not have adequate opportunity to review and discuss with SVS representatives the large body of data that SVS prepared and shared with them for all six of the open, vascular surgery codes that were part of the five-year review.

Again, we felt that our meeting on May 16th was a very productive exchange of information regarding the six CPT codes in question and these various methods and outputs that we have used to construct and verify SVS' recommendations that we part of the five-year review. We look forward to some positive level of resolution when the 2008 Final Rule is published in November. As noted below, we are sending the data analysis under separate cover for reconsideration. The following are SVS recommendations for these six codes. The work RVUs have been adjusted from our 2005 RUC recommendations to reflect the changes in EM work RVUs.

	2008 NPRM	SVS Recommendation
35081 Open AAA repair	33.37	36.80
35102 Open AAA repair	36.37	42.20
35556 Open fem-pop bypass graft	26.62	33.20
35566 Open fem-tibial bypass graft	32.22	40.20
35583 Open fem-pop insitu bypass	27.62	33.70
35585 Open fem-tib insitu bypass	32.22	41.00

SVS is sending under separate cover the large compendium of data we used to arrive at work RVU recommendations for these codes. We do not take lightly the RUC survey process, and we reiterate that it is an extremely rare event when SVS recommends work RVUs higher than the RUC survey median. This is in contrast to recommendation of the 25th percentile, which we have used with some regularity when we felt the overall data analysis did not support the RUC survey median. There is a fairness issue here that comes into play. These are not high volume codes, and each requires a huge effort and substantial surgical skill with attention to detail to achieve high quality outcomes. When measured by yardsticks of data provided to support recent E/M increases and proposed Anesthesia increases, these six codes have a huge amount of hard data justifying the requested work RVUs.

During our May 16th meeting Mr. Kay and Drs. Simon and Hambrick ask that we identify the high outliers on our regression analyses. The universe of codes we analyzed included neurosurgical, cardiac and vascular codes that involve arterial surgery and that had been considered during the current 5-year review. In all, this was 68 codes. For IWPUT comparisons, the high outliers were CPT 33413, 33427, 33545, 33863 and 33945. For the regression of RVW vs. total physician time the outliers were CPT 33305, 33413, 33863 and 33877. For the regression of RVW vs. intra-service time the high outliers are CPT 33300, 33305, 33460, 33945, 33463.

2. DRA Proposals - Section 5102 – Proposed Adjustments for Payments for Imaging Services

Having now experienced almost a full year of reductions under the DRA for non-invasive vascular diagnostic studies, SVS is even more convinced that CMS having included CPT codes 93880 – 93990 and G-code 0365 on the list of imaging codes that are defined by Section 5102(b) of the DRA when in fact these studies are predominately non-imaging in nature is not appropriate and needs to be re-visited by CMS to ensure that Medicare beneficiaries have access to the highest quality, most appropriate care.

Non-invasive diagnostic vascular studies ARE NOT included in the "Radiology" section of the CPT Book by intent because they are diagnostic tests used to identify and assess the severity of arterial and venous vascular diseases and disorders, either entirely or primarily through non-imaging modalities. Although these vascular diagnostic tests use ultrasound, they were invented as applications of Doppler ultrasound, which is NOT an imaging form of ultrasound. Doppler ultrasound measures the frequency shift of sound waves that bounce off moving red blood cells. Those frequency shifts undergo analysis by the electronics in the Doppler instrument and are plotted on paper or on a computer screen as graphs of velocity. These are not pictures or images of the tissue. The velocities determine the severity of the arterial disease. For instance, in a patient with severe atherosclerosis plaque in the carotid artery, the high velocities of blood flowing through a very narrow artery correspond to a severe stenosis. The most accurate way to determine the severity of stenosis is based on these velocities, and NOT on a picture of the plaque. It is the visual display of blood flow velocity, not visual pictures of the interior of the vasculature, which are analyzed and interpreted when performing a non-invasive diagnostic vascular study.

Furthermore, noninvasive vascular lab studies have never been appropriately valued in the HOPPS APC system. Noninvasive vascular diagnostic services are performed in a wide variety of locations in different hospitals, ranging from radiology, to pulmonary medicine, to respiratory therapy, to cardiology, vascular surgery and others, lending to a huge range of cost/charge ratios. These services are low profile and seldom garner any attention by the hospital regarding the creation of appropriate charges. Thus, application of cost/charge ratio to charges in order to determine costs has never produced accurate cost numbers for this small family of tests. In fact, the Society for Vascular Ultrasound brought this to the attention of one of the very first APC Panel meetings. SVU was informed that "it all comes out in the wash for hospitals," and no corrective action was taken. Interestingly, in the CY 2008 Proposed Hospital Outpatient Prospective Payment System Rule, the proposed APC payments to hospitals for non-invasive vascular studies are flat and have been for some time, even though the conversion factor for the hospitals has been increasing approximately 3 percent per year for last few years.

However, the fact is that for office providers of these services, it does not "come out in the wash". The AMA PEAC committee considered all the

direct inputs for these services in great detail during their deliberative process. The PEAC inputs are very accurate and result in appropriate valuation for these services. Starting January 1, 2007, SVS members have endured the magnitude of these reductions, 30 – 40 percent, from PFS to APC payments and it has only hardened our resolve that the APC payments are inappropriately low.

Therefore, SVS believes that it is imperative that CMS work across divisions to address the issues we have raised. SVS would like to work with CMS regarding these definitional and data issues to achieve a workable solution.

3. TRHCA – Section 101(b) – PQRI General Comments

SVS appreciates CMS using this proposed rule in an attempt to provide greater clarity regarding the role of a consensus organization in both the measure development process and the measure approval process. SVS believes it is very important to the future of the PQRI program and the quality movement to have better, more complete definitions regarding what constitutes an appropriate venue and organizations and processes for these roles.

SVS is an active participant in many organizations including the AMA Physician Consortium, the Surgical Quality Alliance, the Fistula First Initiative, the Ambulatory Quality Alliance, and the National Quality Forum. Also, the SVS has developed and maintained for the last several years a registry regarding patient outcomes in vascular surgery.

SVS believes that it is imperative that these measures be generated for the purposes of development and then submitted/endorsed for the approval process by physician specialty societies and organizations. Being a member in all the "consensus organizations" listed above, the SVS is a supporter of these types of organizations; however, we believe it is more helpful to the process to define the characteristics of what CMS will consider an "approved" consensus organization, in addition to just giving examples, for the purposes of measure development and then a separate, distinct set of characteristics for what CMS will consider an "approved" consensus organization for the purposed of measure approval.

Because this is a dynamic process and one where additional capacity may be needed, defining characteristics and then CMS continually updating a list of organizations that meet these characteristics will enhance transparency and will enable more physician societies to participate in the process through the various organizations. We urge CMS to meet with the quality leaders of the physician societies and organizations to define the

characteristics of "approved" consensus measure development groups and consensus measure approval groups.

Need for Greater Transparency Regarding Process

We want to bring to CMS' attention that there is a need for greater transparency and a need for a real, structured governance of some of the consensus organizations, such as the AQA, and voting process for measure approval in this organization. This leads to a lack of rigorous and scientific evaluation for these measures. Also, it leads to arbitrary decisions regarding measures that may be in the 2007 program and now may not be in the 2008 program. Having physicians gear up to report measures in 2007 that may be gone in 2008 will lead to frustration, lack of robust data, and a lack of interest in participation. Thus, CMS needs to make a decision that once a measure is on the list, it will stay on the list of approved measures for at least a specific number of years, versus just six or 12 months.

Use of Medical Registry to Submit Data

SVS encourages CMS to consider participation in a physician society developed patient outcomes registry as a structural measure, even to the point that it would be considered, "a global measure" such that participation in the registry, assuming the data could be accessed by CMS, would be considered successful participation in PQRI. The type and level of data sets that are included in these patient registries can provide CMS with a level of data regarding patterns of quality care for specific indications that will never be realized with the type of reporting currently contained within the PQRI program. SVS currently operates one of two national carotid stent registries. This has been extremely useful as providers comply with data reporting requirements for percutaneous carotid artery stenting.

Given that in the future there may be instances where SVS members who participate in our registry may be reporting data that is similar to data that would also be reported under a PQRI quality measure, we wanted to bring the following concerns to CMS' attention: 1) the routine data would be free of any information that could be used to identify the patient; 2) CMS would need to work with the existing registries regarding forms and processes used for patient consent regarding how the data could be used; 3) There would have to be a way developed to export the data by individual record, allowing either physicians or patients to decide not to have their data shared with CMS; and 4) Physicians must be in control of their data at all times. That being said, the SVS is extremely interested in working with CMS regarding how we can work together on this issue.

4. TRHCA – Section 101(b) – End-Stage Renal Disease Fistula Quality Measure

Not knowing exactly when CMS received the measures listed in Table 21, SVS wishes to inform CMS that it has submitted a measure to the NQF that we believe will be endorsed prior to November 15, 2007. This measure is relevant to the Medicare population and will allow vascular surgeons to report on their role and activities as providers of native hemodialysis access for Medicare beneficiaries that are in CKD 4,5 or End Stage Renal Disease. The goal of this measure is to provide a tool by which individual surgeon effort can be gauged in terms of creating native fistulas in those CKD and ESRD patients who are appropriate candidates. The details of this measure, which is currently under final review by the NQF, are provided here. We look forward to this measure being part of the 2008 set of PQRI measures.

NQF Number: 45

Focus: Vascular Access

Measure Title: Hemodialysis Vascular Access – Surgical Decision-making to Maximize Placement of Autogenous Arterial Venous Fistula

Developer: SVS

Type Reclassified: Outcome

Setting: Ambulatory Care Hospital

Level of Analysis: Individual Clinician

Description: Percentage of patients with advanced chronic disease (CKD4 or 5) or end-stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arteriovenous fistula (AVF).

Numerator: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons OR Fistula not Performed for Patient Reasons. NOTE: This measure will be reported as the total of the three categories of numerators and also as the three numerators reported separately.

Numerator Data Collection: G8081: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons: Append modifier (1P) to G8081 to report documented circumstances that appropriately exclude patients from an

autogenous fistula. A typical medical exclusion would include clinician documented that CKD4, CKD5 or ESRD patient requiring hemodialysis vascular access was not eligible for autogenous AV fistula based on results of vein mapping. OR Fistula not Performed for Patient Reasons: Append modifier (2P) to G8081 to report documented circumstances that exclude patients for patient related reasons. For instance, clinician documented that CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access refused autogenous AV fistula following recommendation for same by provider. Autogenous is defined as the patient's own native tissue. Fistula is defined as a surgical connection established between and artery and a vein.

Case Finding: Patients eligible for inclusion are those with KDOQI Stage 4 and 5 CKD and ESRD.

Denominator: Patients with CKD4, CKD5 or End-stage renal disease who undergo open surgical placement of permanent hemodialysis access

Denominator Data Collection: ICD-9 585.3, 585.4, 585.5, 585.6 or 996.73 AND CPT 36818, 36819, 36820, 36821, 36825, or 36830

Exclusions: None

Risk Adjustment: This measure is recommended only for first-time vascular access patients, that is, all patients who have not previously undergone placement of a permanent upper extremity indwelling fistula or graft. The justification for this limitation to first-time access patients is that insufficient scientific data exists to know the target threshold for placement of native AVFs in patients who have previously undergone AVF surgery.

Data Source / Collection Instrument: Administrative and medical record data, provider data

Release / Revision Date: 2007

In Use: no

Testing: no

Conditions: Use term "autogenous" AV fistula. Remove CKD3. Clarify denominator exclusions because medical reason and pt reason included in numerator. Use separate codes and reporting for numerator categories.

5. TRHCA – Section 101(b) – Podiatric Measures Table 22 of NPRM

SVS offers its highest possible level of support to appropriately crafted quality measures aimed at preventing limb loss in diabetics.

We note that one of the measures in Table 22 of the NPRM is entitled "Peripheral Arterial Disease: Ankle Brachial Index (ABI) Measurement". Assessment for presence of peripheral arterial disease (PAD) in diabetics is crucially important, but we would potentially suggest that physical exam palpation for foot pulses might be the first appropriate step in assessment for PAD. Otherwise the broad application of ABIs in all diabetics might be considered screening, and coverage issues could become relevant. The absence of palpable pulses could be a signal that ABIs are indicated in the diabetic patient. Certainly if the diabetic arrives with a foot ulcer, diabetic foot infection, or presence of tissue gangrene, ABIs and evaluation for PAD are mandatory.

Some diabetic patients have calcified tibial arteries, a condition that renders the ABI test unreliable. In this situation, measurement of toe pressures is indicated. In summary, SVS strongly supports evaluation for PAD in diabetics as a means to reduce limb loss. We look forward to appropriately designed quality measures to accomplish that.

6. Budget Neutrality Adjustor for Work RVUs and other Work RVU issues

SVS strongly objects to the use of budget neutrality adjustors for physician work. When CMS applied a budget neutrality adjuster to the work RVUs following the first 5-year review of physician work, it caused substantial confusion among non-Medicare payers, as well as physician practices. CMS eventually acknowledged the confusion and ineffectiveness of applying the budget neutrality adjuster to the work RVUs, and the Agency eventually eliminated the problem. Now its back again. SVS understands the argument that relativity among work, PE and PLI pools should remain constant, but we believe the counter-argument holds more weight, that is that RVUs should be paid equally, regardless of work, PE or PLI origin. The outcome of the 5-year review should be shifted to the Conversion Factor because it would: (i) have less impact on other payers who use the Medicare RBRVS; (ii) be consistent with the notion that budget neutrality is mandated for monetary reasons, and since the conversion factor is the monetary multiplier in the Medicare payment formula, this is the most appropriate place to adjust for budget neutrality; and (iii) be consistent with CMS' goal of transparency in the Medicare payment system.

Anesthesia Conversion Factor upgrade

SVS agrees that Medicare payment for anesthesia services is undervalued. SVS compliments ASA and the RUC for a completing a complex analysis of anesthesia services in order to compare it to work provided by other specialties. It was certainly a

challenging task to compare services that include reimbursement for base plus time to services that are reimbursed for base or time, but not both. However, SVS is concerned about the Intensity assignment during the lowest level of Post Induction Period Procedure Anesthesia (PIPPA) being set at 0.031 work units per minute. This Intensity setting was derived from comparison with CPT code 99149, a moderate sedation service. As opposed to the lowest level of PIPPA, wherein the patient has already been induced and is stable, it is our understanding that CPT 99149 includes the initiation of moderate sedation, during which a patient undergoes transformation from awake and alert to a hoped for level of "moderate" sedation. We believe this may be more complex than the lowest level of stable PIPPA, therefore not a fully appropriate one-to-one crosswalk for lowest level PIPPA. More troublesome, however, is that there are many periods in the construct of a surgical global service wherein the baseline Intensity is substantially less than 0.031. For instance, all time spent assessing the patient in the immediate pre-op period, reviewing informed consent, assessing patient for surgical readiness, discussing case requirements with nursing and anesthesia, are all reimbursed by Medicare at 0.0224 RVUs/min, or 28% less than the proposed lowest level of PIPPA. Likewise, all immediate post-op care in the surgical package is reimbursed at the same 0.0224 RVUs/min. These services include ensuring surgical stability of the patient in the immediate post-op period, writing post-op orders, etc., again seemingly of equal intensity to lowest level PIPPA. In summary, SVS believes that an increase in Medicare reimbursement for anesthesia services is well-deserved, but if the lowest level PIPPA is set at 0.031, we believe that all pre and post surgical service should be set at the equivalent or higher level.

93325

SVS recognizes the major clinical value and importance of colorflow analysis in vascular studies such as echocardiography. Having said that, we support elimination of an add-on code for colorflow during echocardiography, as apparently now underway by ACC. In absence of that independent method, we support bundling color into the base codes as is the case in other ultrasound applications. The colorflow add-on was created decades ago when the technology was new, unique, and very expensive. Today, colorflow is a routine component of all quality echocardiography scanners. It is, therefore, difficult to justify separate payment for this service.

7. Resource-Based PE – RVUs

Equipment Use Rate

SVS agrees with CMS that the 50 percent utilization rate for medical equipment is appropriate for equipment used as part of office-based procedures. For surgical specialties, procedure specific equipment used in the office may only be in use approximately one – two days a week, depending on the service mix of a specific office.

SVS is currently participating in two different surveys that are asking questions regarding equipment use rate. In both instances, the surveys are asking there questions in such a way to be both specialty and type of equipment specific. SVS believes that these types of specialty specific surveys are important and the type of data that CMS should be considering when making code specific decisions, regarding practice expense inputs. We believe that the data coming from these two efforts will be more instructive to CMS versus generalizing the higher utilization rates found by MedPAC in their six site survey for CT and MRI imaging equipment to even all types of imaging equipment – i.e. ultrasound - or for other types of equipment. Instead, SVS hopes that CMS uses specialty and type of equipment specific data to work through this question going forward.

CPT Codes 37205 and 37206 – Direct PE Inputs for Non-facility Setting

The SVS appreciates CMS reviewing clinical literature regarding transcatheter stent placement and what is considered standard practice regarding the number of stents placed per patient, per vessel. While we agree with CMS that it is not typical, i.e. greater than 50 percent of the time that two stents would be used to maintain the vascular integrity of an initial vessel, there are instances where a patient does need two stents. Since most of these stents cost more than $1,000 each, we ask that CMS provide some guidance to the Medicare contractors regarding how the cost of a second stent, when used, may be separately billable using a HCPCS code.

8. Medicare Physician Payment Rate for 2008

In 2008, physicians and other health care practitioners whose payment rates are tied to the physician fee schedule face a 10% payment rate cut. The SVS urges CMS to work with Congress to avert this cut and ensure that physician payment updates for 2008 and subsequent years accurately reflect increases in medical practice costs.

Payments to physicians today in 2007 are essentially the same as they were six years ago in 2001. Due to the SGR, physicians now face drastic Medicare payment cuts totaling almost 40% over the next eight years. Yet, during this same time period, the Medicare Economic Index (MEI), which measures increases in medical practice costs, is expected to increase by about 20%. Physicians cannot absorb these draconian cuts.

Only physicians and other health professionals face steep cuts under this flawed payment formula. Other providers, such as nursing homes and hospitals have payment updates that reflect the cost of inflation. Further, the 10% cut in payment rates facing physicians is in stark contrast to Medicare Advantage (MA) plans, which are paid on average 112% above the cost of traditional Medicare, with a significant number of MA plans paid from 120% to more than 150% of traditional Medicare. These overpayments are shortening the life of the Medicare trust fund.

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SVS appreciates the opportunity to submit these comments and looks forward to working with CMS to implement these recommendations. Please feel free to contact Pam Phillips, Director of Health Policy and Government Relations at 703-573-7894 or PPhillips@vascularsociety.org, if we can provide further information.

Yours truly,

K. Wayne Johnston, MD
President
Society for Vascular Surgery

Robert M. Zwolak, M.D.
Robert M. Zwolak, M.D.
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Submitter : **Jonathan Kroman** **Date: 08/31/2007**

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Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15498-Attach-1.DOC

15493

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September 14, 2007

Re: File Code CMS – 1385- P

To Whom It May Concern:

We submit these comments on the proposed rules and related comments published on July 12, 2007 at 72 Fed. Reg. 38122 (the "Notice"). Our comments reflect the specific perspective of our client, a public hospital district in the State of Washington with statutory responsibility for providing healthcare to the citizens it serves. While the perspective reflects governmental purposes and policies, including associated legal authority, specific to the State of Washington[1], we believe that the comments are applicable to public entities in other states as well. We refer to them in this comment as "Public Hospitals."

Our client believes that, separately and in combination, a number of the proposed regulations contemplated by the Notice: (1) unnecessarily undermine the ability of Public Hospitals to honor their responsibility to provide the broadest feasible array of cost-effective care in their communities and (2) serve legitimate regulatory objectives which can be met without that undesirable consequence. More specifically, the regulations will result in communities served by
Public Hospitals incurring higher costs, including taxes, associated with a fragmented delivery system burdened by duplicative capital and other expenses rather than integrated systems that maximize the return on community investments in healthcare resources. We urge CMS to consider the special responsibility and character of Public Hospitals as it considers whether and how to act on the proposals and other ideas expressed in the Notice.

PUBLIC HOSPITAL DISTRICTS IN THE STATE OF WASHINGTON AND THE DELIVERY OF COMMUNITY-BASED CARE

Hospital districts in Washington "are municipal corporations, which means that they possess powers unique to governmental entities. For example, they may finance their activities by tax levies, condemn property, hold elections, and join forces with other governmental entities in cooperative ventures. By the same token, special purpose districts are limited by statutory, constitutional, and regulatory provisions in the same manner as other governmental entities. For example, they are prohibited from lending public credit, owning stock, and giving away public property as gifts."
http://www.awphd.org/CommishGuide/section1.asp

[1] A substantial proportion of the hospitals and hospital beds in Washington State are furnished by Public Hospitals.

Washington State has 42 district hospitals, most of which are located in rural areas. Hospital Districts are created expressly to fulfill a need for services to the citizens of the district. Generally, these districts perform functions that are not, for one reason or another, performed by the market or by other governmental agencies, such as the state or a county.

RCW 70.44[2], is the enabling statute which allows for the creation of Public Hospitals in Washington. It "authorize(s) the establishment of public hospital districts to own and operate hospitals and other health care facilities and to provide hospital services and other health care services for the residents of such districts and other persons." RCW 70.44.003. Public Hospitals are municipal corporations. RCW. 70.44. 010. They are established by public vote within a defined geographical area and are governed by elected commissioners. RCW 70.44.040. To support their capital and operating expenses, they have the power to impose taxes and to aquire property by eminent domain, RCW 70.44.060, in addition, they may issue bonds. RCW 70.44.110.

Public Hospitals hold specified and extensive powers to discharge their public purpose. RCW 70.44.060. The enumerated powers provide Public Hospitals with both flexibility and direction. For example, RCW 70.44.060 includes the power:

> To lease existing hospital and other health care facilities and equipment and/or other property used in connection therewith, including ambulances, and to pay such rental therefor as the commissioners shall deem proper; to provide hospital and other health care services for residents of said district by facilities located outside the boundaries of said district, by contract or in any other manner said commissioners may deem expedient or necessary under the existing conditions; and said hospital district shall have the power to contract with other communities, corporations, or individuals for the services provided by said hospital district; and they may further receive in said hospitals and other health care facilities and furnish proper and adequate services to all persons not residents of said district at such reasonable and fair compensation as may be considered proper: PROVIDED, That it must at all times make adequate provision for the needs of the district and residents of said district shall have prior rights to the available hospital and other health care facilities of said district, at rates set by the district commissioners. (emphasis added)

Thus, Public Hospitals have the obligation to provide their citizens with health care services, including but not limited to hospital services, and the authority to do so through leasing and other contractual relationships with others, obviously including other providers.

More generally, the absence of comprehensive, implemented healthcare reform has left Public Hospitals to function in a market environment in which they must rely on local partnerships, integrated delivery systems and increased efficiency in their operations and use of resources to fulfill their mission. R.

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[2] A copy of RCW 70.44 is attached as Appendix A.

Baxter and R. Mechanic[3], *The Status of Local Health Care Safety Nets*, 16 Health Affairs 7, 19 (1997). At the same time, the ability of Public Hospitals to establish relationships with local physicians and other providers to share the cost and consequent use of capital assets and other resources that provide value to the community is largely a matter of their collective ability to negotiate mutually beneficial relationships.

Conversely, regulation that limits the wasteful duplication of resources in key components of the delivery system is not a particularly relevant influence on the strategic direction that providers choose.[4] For example, in Washington, no certificate of need review is necessary to establish facilities to provide any among a wide variety of ancillary and other outpatient services. In Washington, Hospital Districts have no authority to regulate the establishment of duplicative health care facilities. They can, however, exercise control through contracts with other providers.

In this environment and with the tools provided by Washington law, Public Hospitals meet their public responsibility in various ways, critically including collaborative arrangements with local physicians and other providers in their communities. Public Hospitals need great flexibility as they pursue these relationships. Often, public hospitals participate in ventures with physicians in order to further the public interest in a number of important respects. Necessary investment in capital and human resources can be reduced by sharing available capacity among various users, particularly in smaller communities where aggregate volumes are such that duplicative investment increases the total aggregate investment in the community. There is considerable experience in our client's community and, we are confident, in other communities demonstrating that integration and collaboration do indeed result in public benefit in the form of reduced cost and a viable expansion of services available in the community.

PROBLEMATIC PROPOSALS AND PERSPECTIVES REFLECTED IN THE NOTICE

The Notice contains a number of elements that would undermine Public Hospitals' ability to anchor community-based, collaborative efforts to deliver cost-effective care. Initially, we note the following statement in the Notice, which seems to underlie a number of the Notice's specific proposals:

> There appears to be no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals for separately payable services. Many of the services furnished by the joint venture were previously furnished directly by the hospitals, and in most cases, could continue to be furnished directly by hospitals.
>
> ....

[3] Messrs. Baxter and Mechanic prepared the article as members of The Lewin Group, a respected consulting organization.

[4] *See* A. Katz and J. Thompson, *The Role of Public Policy in Health Care Market Change*, 15 Health Affairs 77, 83 (1996)

> It appears that the use of these arrangements may be little more than a method to share hospital revenues with referring physicians in spite of unnecessary costs to the program and to beneficiaries.

72 Fed. Reg. 33186-87 (emphasis added).

Contrary to the foregoing assertion, there are compelling and legitimate reasons for Public Hospitals and local physicians to create collaborative arrangements to deliver care in the community. Participation in collaborative ventures with local physicians reduces the operating burden on Public Hospitals. Often, when physician ventures are undertaken without the involvement of the local Public Hospital, the physicians tend to structure the caseload and scope of service to maximize the economic return; patient services and cases that don't pay well are left to the public hospital to "afford." In such a situation, the Public Hospital often ends up carrying a greater investment burden in an effort to carry out its responsibility of providing locally-delivered services to its constituents. Moreover, in many medium-sized communities, a "competitive" model in which the various providers each invest in the space, equipment and human resources leads to duplicate services, results in a significant amount of unused capacity. The community pays for that additional and functionally unnecessary investment in both capital and operating costs.

In any case, the premise above that if collaborative arrangements with physicians are largely outlawed as contemplated by the Notice, hospitals can and will become the primary and viable providers of services needed in the community is, in our client's judgment, seriously flawed. A more likely scenario is that duplicative facilities will be constructed, more services will be performed in multiple locations, competitors will eventually leave, the local health care market will become more unstable and patient needs will not be met. The consequence is that services will be provided in an environment where direct economic incentives favor excess utilization, while the controls, safeguards and transparency which Public Hospitals can contribute are missing.

Specific proposals described in the Notice obviously limit transactional flexibility and therefore interfere with Public Hospitals' ability to pursue these beneficial relationships. Individually and in combination, the approaches described in the Notice concerning "per-click" and percentage-based pricing in compensation arrangements, "under arrangements" transactions with hospitals, indirect financial relationships (the "stand in the shoes" principle) would interfere with ventures designed to spread resources among provider participants on a sensible economic basis. They would limit the ability of Public Hospitals and community physicians to share cost, risk and economic gain in a way that encourages the common and efficient use of collective resources. Conversely, they favor fixed pricing, "silo" providers and duplication.

In our client's and other smaller and medium-sized communities, a "competitive" model in which the various providers each invest in the space, equipment and human resources needed to duplicate services, results in a significant amount of unused capacity. The community pays for that additional investment in both capital and operating costs.

Needless to say, if enacted, the proposals contained in the Notice would adversely impact current arrangements which comply with existing law. Forcing an unwinding of ventures that currently serve the public interest and have a proven track record of success, in terms of service quality, service access and economics, will inevitably result in an increase in the aggregate cost of healthcare services for those communities, which have worked diligently and cooperatively to stretch the healthcare dollar for the benefit of the patient and the community.[5]

Aside from proposals concerning the Stark Law, the Notice proposes changes to the IDTF certification standards, some of which may be particularly detrimental for a Public Hospital and patients of a hospital district. For example, the Notice proposes adding a requirement that an IDTF not share space, equipment, or staff or sublease its operations to another individual or organization. This proposal is of concern for at least two reasons.

First, the Public Hospital has formed an IDTF as a joint venture with certain physicians. The IDTF provides imaging services in the community. The IDTF has its own staff (some staff-particularly nurses - may moonlight at the hospital). However, the non-physician clinical staff are subject to the oversight of a quality assurance team which includes members of the medical staff practicing in the facility, including IDTF investor-physicians. The proposed rule would specifically prohibit the sharing of supervising physicians, nonphysician personnel, or receptionists; thus eliminating as owners the very physicians who are best suited to participate in the quality assurance process. Ironically, these physicians would be free under the rules to provide the same services as are provided through the IDTF in their own offices, free from the public review and transparency which must be in place with respect to the joint venture. This oversight and transparency is a requirement because of the ownership by the Public Hospital.

Second, Public Hospital patients also receive services in the IDTF's facilities. When this happens the Public Hospital acquires these services under arrangements with the IDTF. In accordance with the existing rules governing under arrangements relationships (and consistent with our client's goals of directly and more expansively controlling the delivery of care to the community), the Public Hospital retains overall responsibility for the care, including the responsibility to coordinate care, supervise and evaluate the services, and ensure the delivery of high quality health treatment. It is unclear whether an under arrangements relationship would violate the prohibited sublease or the prohibited space sharing provisions in the proposed amendments to the rules. We believe that the answer to this question is no; however, any efforts to undo the rules with respect to under arrangements relationships would substantially undermine the tactic used by many Public Hospitals, i.e. to leverage tax dollars by minimizing direct ownership of facilities, relying instead on joint ventures and contractual arrangements to assure the development of needed health care facilities.

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[5] As to the comment in the Notice quoted above, our client believes that, for the most part, it is wrong to expect that the proposed regulatory changes will cause physicians who are now participating in currently lawful collaborative ventures to send their patients to the hospital for the procedures involved. Instead, the physicians will purchase their own separate equipment (likely of lesser quality) and do the procedures on their own. This duplication will increase capacity to more than the level needed in the community, wasting valuable resources, diminishing quality and increasing cost.

PUBLIC HOSPITALS ARE SUBJECT TO LEGAL REQUIREMENTS THAT MITIGATE CONCERNS OVER ABUSIVE PRACTICES

Public Hospitals recognize the importance of addressing over-utilization and inappropriate utilization as the result of inappropriate financial interests. However, unlike other providers, they are subject to a wide variety of requirements and restrictions which serve the public interest, including in ways that reliably ensure that they operate for community benefit and not for the benefit of physicians, including through transparency in the way they conduct themselves.

Public Hospitals' participation in community-based ventures with physicians brings a level of transparency and accountability, as described more specifically below, to the quality, cost and appropriate utilization of health care services. In Washington, Public Hospitals are governed by the Open Public Meetings Act, chapter 42.30 RCW and therefore all meetings of the Hospital District Board must be open to the public. Public Hospitals are also required to make their records open to inspection pursuant to RCW 42.17.250. Further, Hospital District commissioners are prohibited from engaging in activities that result in conflicts of interests. RCW 42.23.030. A district's compliance with state law is routinely reviewed by the State Auditor's Office. Services delivered entirely within a medical practice or otherwise by a private sector provider entail no such beneficial public oversight and disclosure.

Moreover, like many states, Washington law prohibits the use of public credit or gratuitous transfer of public assets for other than incidental private benefit. Article VIII, Section 7 of the Washington State Constitution provides:

> No county, city, town or other municipal corporation shall hereafter give any money, or property, or loan its money, or credit to or in aid of any individual, association, company or corporation, except for the necessary support of the poor and infirm, or become directly or indirectly the owner of any stock in or bonds of any association, company or corporation.

As applied to hospital-physician collaborations, these rules mean that elected district officials must ensure that no payment or other value is made to physicians or other private parties except where appropriate to meet the healthcare needs of the community.

CMS should devote meaningful thought to whether these existing restrictions and mechanisms could be supplemented by more limited requirements which, in combination with the existing safeguards, would adequately address over-utilization and inappropriate utilization as the result of inappropriate financial interests, to which the Notice is directed. These requirements could include, for example, mechanisms by which Public Hospitals must monitor utilization of the services delivered in collaborative arrangements with physicians as well as the establishment and adherence to compliance plans, all with accountability elements that would allow for transparent review by an agency such as our State Auditor. As noted above, the involvement of Public Hospitals in ventures with community physicians would produce a level of openness and accountability that would be greater than if the same services were delivered within the four walls of a medical practice.

In conclusion, while the concerns underlying the Notice are obviously significant, they will interfere with Public Hospitals, as public entities, to meet their obligations to their citizens.
We urge CMS to consider an approach to the problems to which the Notice is addressed- overutilization and inappropriate financial influences on medical judgment - in a manner that recognizes both the safeguards and responsibilities that are unique to Public Hospitals.

Chapter 70.44 RCW

Public hospital districts

Chapter Listing

RCW Sections

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70.44.902	Severability -- 1982 c 84.
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70.44.910	Construction -- 1945 c 264.

70.44.003
Purpose.

The purpose of chapter 70.44 RCW is to authorize the establishment of public hospital districts to own and operate hospitals and other health care facilities and to provide hospital services and other health care services for the residents of such districts and other persons.

[1982 c 84 § 1.]

70.44.007
Definitions.

As used in this chapter, the following words have the meanings indicated:

(1) "Other health care facilities" means nursing home, extended care, long-term care, outpatient and rehabilitative facilities, ambulances, and such other facilities as are appropriate to the health needs of the population served.

(2) "Other health care services" means nursing home, extended care, long-term care, outpatient, rehabilitative, health maintenance, and ambulance services and such other services as are appropriate to the health needs of the population served.

(3) "Public hospital district" or "district" means public health care service district.

[1997 c 332 § 15; 1982 c 84 § 12; 1974 ex.s. c 165 § 5.]

Notes:
Severability -- 1997 c 332: See RCW 70.45.900.

70.44.010
Districts authorized.

Municipal corporations, to be known as public hospital districts, are hereby authorized and may be established within the several counties of the state as hereinafter provided.

[1947 c 225 § 1; 1945 c 264 § 2; Rem. Supp. 1947 § 6090-31. FORMER PART OF SECTION: 1945 c 264 § 1 now codified as RCW 70.44.005.]

70.44.015
Validation of existing districts.

Each and all of the respective areas of land heretofore attempted to be organized into public hospital districts under the provisions of this chapter are validated and declared to be duly existing hospital districts having the respective boundaries set forth in their organization proceedings as shown by the files in the office of the board of county commissioners of the county in question, and by the files of such districts.

[1955 c 135 § 2.]

70.44.016
Validation of districts.

Each and all of the respective areas of land attempted to be organized into public hospital districts prior to June 10, 1982, under the provisions of chapter 70.44 RCW where the canvass of the election on the proposition of creating a public hospital district shows the passage of the proposition are validated and declared to be duly existing public hospital districts having the respective boundaries set forth in their organization proceedings as shown by the files in the office of the legislative authority of the county in question, and by the files of such districts.

[1982 c 84 § 10.]

70.44.020
Resolution — Petition for county-wide district — Conduct of elections.

At any general election or at any special election which may be called for that purpose the county legislative authority of a county may, or on petition of ten percent of the registered voters of the county based on the total vote cast in the last general county election, shall, by resolution, submit to the voters of the county the proposition of creating a public hospital district coextensive with the limits of the county. The petition shall be filed with the county auditor, who shall within fifteen days examine the signatures thereon and certify to the sufficiency thereof, and for that purpose the auditor shall have access to all registration books in the possession of election officers in the county. If the petition is found to be insufficient, it shall be returned to the persons filing it, who may amend or add names thereto for ten days, when it shall be returned to the auditor, who shall have an additional fifteen days to examine it and attach the certificate thereto. No person signing the petition may withdraw his or her

name therefrom after filing. When the petition is certified as sufficient, the auditor shall forthwith transmit it, together with the certificate of sufficiency attached thereto, to the county legislative authority, who shall immediately transmit the proposition to the supervisor of elections or other election officer of the county, and he shall submit the proposition to the voters at the next general election or if such petition so requests, shall call a special election on such proposition in accordance with *RCW 29.13.010 and 29.13.020. The notice of the election shall state the boundaries of the proposed district and the object of the election, and shall in other respects conform to the requirements of law governing the time and manner of holding elections. In submitting the question to the voters, the proposition shall be expressed on the ballot substantially in the following terms:

For public hospital district No. . . . .

Against public hospital district No. . . . .

[1990 c 259 § 38; 1955 c 135 § 1; 1945 c 264 § 3; Rem. Supp. 1945 § 6090-32.]

Notes:

***Reviser's note:** RCW 29.13.010 and 29.13.020 were recodified as RCW 29A.04.320 and 29A.04.330, respectively, pursuant to 2003 c 111 § 2401, effective July 1, 2004. RCW 29A.04.320 was subsequently repealed by 2004 c 271 § 193. Later enactment of RCW 29A.04.320, see RCW 29A.04.321.

70.44.028
Limitation on legal challenges.

Unless commenced within thirty days after the date of the filing of the certificate of the canvass of an election on the proposition of creating a new public hospital district pursuant to chapter 70.44 RCW, no lawsuit whatever may be maintained challenging in any way the legal existence of such district or the validity of the proceedings had for the organization and creation thereof. If the creation of a district is not challenged within the period specified in this section, the district conclusively shall be deemed duly and regularly organized under the laws of this state.

[1982 c 84 § 9.]

70.44.030
Petition for lesser district — Procedure.

Any petition for the formation of a public hospital district may describe a less area than the entire county in which the petition is filed, the boundaries of which shall follow the then existing precinct boundaries and not divide any voting precinct; and in the event that such a petition is filed containing not less than ten percent of the voters of the proposed district who voted at the last general election, certified by the auditor in like manner as for a county-wide district, the board of county commissioners shall fix a date for a hearing on such petition, and shall publish the petition, without the signatures thereto appended, for two weeks prior to the date of the hearing, together with a notice stating the time of the meeting when such petition will be heard. Such publications required by this chapter shall be in a newspaper published in the proposed or established public hospital district, or, if there be no such newspaper, then in a newspaper published in the county in which such district is situated, and of general circulation in such county. The hearing on such petition may be adjourned from time to time, not exceeding four weeks in all. If upon the final hearing the board of county commissioners shall find that any lands have been unjustly or improperly included within the proposed public hospital district the said board shall change and fix the boundary lines in such manner as it shall deem reasonable and just and conducive to the welfare and convenience, and make and enter an order establishing and defining the boundary lines of the proposed public hospital district: PROVIDED, That no lands shall be included within the boundaries so fixed lying outside the boundaries described in the petition, except upon the written request of the owners of such lands. Thereafter the same procedure shall be followed as prescribed in this chapter for the formation of a public hospital district including an entire county, except that the petition and election shall be confined solely to the lesser public hospital district.

[1945 c 264 § 4; Rem. Supp. 1945 § 6090-33.]

70.44.035
Petition for district lying in more than one county — Procedure.

Any petition for the formation of a public hospital district may describe an area lying in more than one county, the boundaries of which shall follow the then existing precinct boundaries and not divide a voting precinct; and if a petition is filed with the county auditor of the respective counties in which a portion of the proposed district is located, containing not less than ten percent of the voters of that area of each county of the proposed district who voted at the last general election, certified by the said respective auditors in like manner as for a county-wide district, the board of county commissioners of each of the counties in which a portion of the proposed district is located shall fix a date for a hearing on the petition, and shall publish the petition, without the signatures thereto appended, for two weeks prior to the hearing, together with a notice stating the time of the meeting when the petition will be heard. The publication required by this chapter shall be in a newspaper published in the portion of each county lying within the proposed district, or if there be no such newspaper published in any such portion of a county, then in one published in the county wherein such portion of said district is situated, and of general circulation in the county. The hearing before the respective county commissioners may be adjourned from time to time not exceeding four weeks in all. If upon the final hearing the respective boards of county commissioners find that any land has been unjustly or improperly included within the

proposed district they may change and fix the boundary lines of the portion of said district located within their respective counties in such manner as they deem reasonable and just and conducive to the welfare and convenience, and enter an order establishing and defining the boundary lines of the proposed district located within their respective counties: PROVIDED, That no lands shall be included within the boundaries so fixed lying outside the boundaries described in the petition, except upon the written request of the owners of the land to be so included. Thereafter the same procedure shall be followed as prescribed for the formation of a district including an entire county, except that the petition and election shall be confined solely to the portions of each county lying within the proposed district.

[1953 c 267 § 1.]

70.44.040
Elections — Commissioners, terms, districts.

(1) The provisions of Title 29A RCW relating to elections shall govern public hospital districts, except as provided in this chapter.

A public hospital district shall be created when the ballot proposition authorizing the creation of the district is approved by a simple majority vote of the voters of the proposed district voting on the proposition and the total vote cast upon the proposition exceeds forty percent of the total number of votes cast in the proposed district at the preceding state general election.

A public hospital district initially may be created with three, five, or seven commissioner districts. At the election at which the proposition is submitted to the voters as to whether a district shall be formed, three, five, or seven commissioners shall be elected from either three, five, or seven commissioner districts, or at-large positions, or both, as determined by resolution of the county commissioners of the county or counties in which the proposed public hospital district is located, all in accordance with RCW 70.44.054. The election of the initial commissioners shall be null and void if the district is not authorized to be created.

No primary shall be held. A special filing period shall be opened as provided in RCW 29A.24.171 and 29A.24.181. The person receiving the greatest number of votes for the commissioner of each commissioner district or at-large position shall be elected as the commissioner of that district. The terms of office of the initial public hospital district commissioners shall be staggered, with the length of the terms assigned so that the person or persons who are elected receiving the greater number of votes being assigned a longer term or terms of office and each term of an initial commissioner running until a successor assumes office who is elected at one of the next three following district general elections the first of which occurs at least one hundred twenty days after the date of the election where voters approved the ballot proposition creating the district, as follows:

(a) If the public hospital district will have three commissioners, the successor to one initial commissioner shall be elected at such first following district general election, the successor to one initial commissioner shall be elected at the second following district general election, and the successor to one initial commissioner shall be elected at the third following district general election;

(b) If the public hospital district will have five commissioners, the successor to one initial commissioner shall be elected at such first following district general election, the successors to two initial commissioners shall be elected at the second following district general election, and the successors to two initial commissioners shall be elected at the third following district general election;

(c) If the public hospital district will have seven commissioners, the successors to two initial commissioners shall be elected at such first following district general election, the successors to two initial commissioners shall be elected at the second following district general election, and the successors to three initial commissioners shall be elected at the third following district general election.

The initial commissioners shall take office immediately when they are elected and qualified. The term of office of each successor shall be six years. Each commissioner shall serve until a successor is elected and qualified and assumes office in accordance with RCW 29A.20.040.

(2) Only a registered voter who resides in a commissioner district may be a candidate for, or hold office as, a commissioner of the commissioner district. Voters of the entire public hospital district may vote at a primary or general election to elect a person as a commissioner of the commissioner district.

If the proposed public hospital district initially will have three commissioner districts and the public hospital district is county-wide, and if the county has three county legislative authority districts, the county legislative authority districts shall be used as public hospital district commissioner districts. In all other instances the county auditor of the county in which all or the largest portion of the proposed public hospital district is located shall draw the initial public hospital district commissioner districts and designate at-large positions, if appropriate, as provided in RCW 70.44.054. Each of the commissioner positions shall be numbered consecutively and associated with the commissioner district or at-large position of the same number.

The commissioners of a public hospital district that is not coterminous with the boundaries of a county that has three county legislative authority districts shall at the times required in chapter 29A.76 RCW and may from time to time redraw commissioner district boundaries in a manner consistent with chapter 29A.76 RCW.

(3) No person may hold office as a commissioner while serving as an employee of the public hospital district.

[2006 c 322 § 1; 1997 c 99 § 1; 1994 c 223 § 78; 1990 c 259 § 39; 1979 ex.s. c 126 § 41; 1957 c 11 § 1; 1955 c 82 § 1; 1953 c 267 § 2; 1947 c 229 § 1; 1945 c 264 § 5; Rem. Supp. 1947 § 6090-34.]

Notes:

Effective date -- 1997 c 99: "This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately [April 21, 1997]." [1997 c 99 § 8.]

Purpose -- 1979 ex.s. c 126: See RCW 29A.20.040(1).

70.44.041
Validity of appointment or election of commissioners — Compliance with 1994 c 223.

No appointment to fill a vacant position on or election to the board of commissioners of any public hospital district made after June 9, 1994, and before April 21, 1997, is deemed to be invalid solely due to the public hospital district's failure to redraw its commissioner district boundaries if necessary to comply with chapter 223, Laws of 1994.

[1997 c 99 § 7.]

Notes:

Effective date -- 1997 c 99: See note following RCW 70.44.040.

70.44.042
Commissioner districts — Resolution to abolish — Proposition to reestablish.

Notwithstanding any provision in RCW 70.44.040 to the contrary, any board of public hospital district commissioners may, by resolution, abolish commissioner districts and permit candidates for any position on the board to reside anywhere in the public hospital district.

At any general or special election which may be called for that purpose, the board of public hospital district commissioners may, or on petition of ten percent of the voters based on the total vote cast in the last district general election in the public hospital district shall, by resolution, submit to the voters of the district the proposition to reestablish commissioner districts.

[1997 c 99 § 2; 1967 c 227 § 2.]

Notes:

Effective date -- 1997 c 99: See note following RCW 70.44.040.

70.44.045
Commissioners — Vacancies.

A vacancy in the office of commissioner shall occur as provided in chapter 42.12 RCW or by nonattendance at meetings of the commission for sixty days, unless excused by the commission. A vacancy shall be filled as provided in chapter 42.12 RCW.

[1994 c 223 § 79; 1982 c 84 § 13; 1955 c 82 § 2.]

70.44.047
Redrawn boundaries — Assignment of commissioners to districts.

If, as the result of redrawing the boundaries of commissioner districts as permitted or required under the provisions of this chapter, *chapter 29.70 RCW, or any other statute, more than the correct number of commissioners who are associated with commissioner districts reside in the same commissioner district, a commissioner or commissioners residing in that redrawn commissioner district equal in number to the number of commissioners in excess of the correct number shall be assigned to the drawn commissioner district or districts in which less than the correct number of commissioners associated with commissioner districts reside. The commissioner or commissioners who are so assigned shall be those with the shortest unexpired term or terms of office, but if the number of such commissioners with the same terms of office exceeds the number that are to be assigned, the board of commissioners shall select by lot from those commissioners which one or ones are assigned. A commissioner who is so assigned shall be deemed to be a resident of the commissioner district to which he or she is assigned for purposes of determining whether a position is vacant.

[1997 c 99 § 6.]

Notes:

***Reviser's note:** Chapter 29.70 RCW was recodified as chapter 29A.76 RCW pursuant to 2003 c 111 § 2401, effective July 1, 2004.

Effective date -- 1997 c 99: See note following RCW 70.44.040.

70.44.050
Commissioners — Compensation and expenses — Insurance — Resolutions by majority vote — Officers — Rules — Seal — Records.

***** CHANGE IN 2007 *** (SEE 1368-S.SL) *****

A district shall provide by resolution for the payment of compensation to each of its commissioners at a rate of seventy dollars for each day or portion thereof devoted to the business of the district, and days upon which he or she attends meetings of the commission of his or her own district, or meetings attended by one or more commissioners of two or more districts called to consider business common to them, except that the total compensation paid to such commissioner during any one year shall not exceed six thousand seven hundred twenty dollars. The commissioners may not be compensated for services performed of a ministerial or professional nature.

Any commissioner may waive all or any portion of his or her compensation payable under this section as to any month or months during his or her term of office, by a written waiver filed with the district as provided in this section. The waiver, to be effective, must be filed any time after the commissioner's election and prior to the date on which the compensation would otherwise be paid. The waiver shall specify the month or period of months for which it is made.

Any district providing group insurance for its employees, covering them, their immediate family, and dependents, may provide insurance for its commissioners with the same coverage. Each commissioner shall be reimbursed for reasonable expenses actually incurred in connection with such business and meetings, including his or her subsistence and lodging and travel while away from his or her place of residence. No resolution shall be adopted without a majority vote of the whole commission. The commission shall organize by election of its own members of a president and secretary, shall by resolution adopt rules governing the transaction of its business and shall adopt an official seal. All proceedings of the commission shall be by motion or resolution recorded in a book or books kept for such purpose, which shall be public records.

[1998 c 121 § 7; 1985 c 330 § 7; 1982 c 84 § 14; 1975 c 42 § 1; 1965 c 157 § 1; 1945 c 264 § 15; Rem. Supp. 1945 § 6090-44.]

70.44.053
Increase in number of commissioners — Proposition to voters.

At any general or special election which may be called for that purpose the board of public hospital district commissioners may, or on petition of ten percent of the voters based on the total vote cast in the last district general election in the public hospital district shall, by resolution, submit to the voters of the district the proposition increasing the number of commissioners to either five or seven members. The petition or resolution shall specify whether it is proposed to increase the number of commissioners to either five or seven members.

[1997 c 99 § 3; 1994 c 223 § 80; 1967 c 77 § 2.]

Notes:

Effective date -- 1997 c 99: See note following RCW 70.44.040.

70.44.054
Increase in number of commissioners — Commissioner districts.

If the voters of the district approve the ballot proposition authorizing the increase in the number of commissioners to either five or seven members, the additional commissioners shall be elected at large from the entire district; provided that, the board of commissioners of the district may by resolution redistrict the public hospital district into five commissioner districts if the district has five commissioners or seven commissioner districts if the district has seven commissioners. The board of commissioners shall draw the boundaries of each commissioner district to include as nearly as possible equal portions of the total population of the public hospital district.

If the board of commissioners increases the number of commissioner districts as provided in this section, one commissioner shall be elected from each commissioner district, and no commissioner may be elected from a commissioner district in which another commissioner resides.

[1997 c 99 § 4.]

Notes:

Effective date -- 1997 c 99: See note following RCW 70.44.040.

70.44.056
Increase in number of commissioners — Appointments — Election — Terms.

In all existing public hospital districts in which an increase in the number of district commissioners is proposed, the additional commissioner positions shall be deemed to be vacant and the board of commissioners of the public hospital district shall appoint qualified persons to fill those vacancies in accordance with RCW 42.12.070.

Each person who is appointed shall serve until a qualified person is elected at the next general election of the district occurring one hundred twenty days or more after the date of the election at which the voters of the district approved the ballot proposition authorizing the increase in the number of commissioners. If needed, special filing periods shall be authorized as provided in *RCW 29.15.170 and 29.15.180 for qualified persons to file for the vacant office. A primary shall be held to nominate candidates if sufficient time exists to hold a primary and more than two candidates file for the vacant office. Otherwise, no primary shall be held and the candidate receiving the greatest number of votes for

each position shall be elected. Except for the initial terms of office, persons elected to each of these additional commissioner positions shall be elected to a six-year term. The newly elected commissioners shall assume office as provided in *RCW 29.04.170.

The initial terms of the new commissioners shall be staggered as follows: (1) When the number of commissioners is increased from three to five, the person elected receiving the greatest number of votes shall be elected to a six-year term of office, and the other person shall be elected to a four-year term; (2) when the number of commissioners is increased from three or five to seven, the terms of the new commissioners shall be staggered over the next three district general elections so that two commissioners will be elected at the first district general election following the election where the additional commissioners are elected, two commissioners will be at the second district general election after the election of the additional commissioners, and three commissioners will be elected at the third district general election following the election of the additional commissioners, with the persons elected receiving the greatest number of votes elected to serve the longest terms.

[1997 c 99 § 5.]

Notes:

***Reviser's note:** RCW 29.15.170, 29.15.180, and 29.04.170 were recodified as RCW 29A.24.170, 29A.24.180, and 29A.20.040, respectively, pursuant to 2003 c 111 § 2401, effective July 1, 2004. RCW 29A.24.170 and 29A.24.180 were subsequently repealed by 2004 c 271 § 193. Later enactment of RCW 29A.24.170 and 29A.24.180, see RCW 29A.24.171 and 29A.24.181.

Effective date -- 1997 c 99: See note following RCW 70.44.040.

70.44.059
Chaplains — Authority to employ.

Public hospital districts may employ chaplains for their hospitals, health care facilities, and hospice programs.

[1993 c 234 § 1.]

Notes:

Contingent effective date -- 1993 c 234: "This act shall take effect on January 1, 1994, if the proposed amendment to Article I, section 11 of the state Constitution authorizing the legislature to permit public hospital districts to employ chaplains is validly submitted to and is approved and ratified by the voters at the next general election held. If the proposed amendment is not so approved and ratified, this act is void in its entirety." [1993 c 234 § 2.] House Joint Resolution No. 4200 was approved by the voters on November 2, 1993.

70.44.060
Powers and duties.

All public hospital districts organized under the provisions of this chapter shall have power:

(1) To make a survey of existing hospital and other health care facilities within and without such district.

(2) To construct, condemn and purchase, purchase, acquire, lease, add to, maintain, operate, develop and regulate, sell and convey all lands, property, property rights, equipment, hospital and other health care facilities and systems for the maintenance of hospitals, buildings, structures, and any and all other facilities, and to exercise the right of eminent domain to effectuate the foregoing purposes or for the acquisition and damaging of the same or property of any kind appurtenant thereto, and such right of eminent domain shall be exercised and instituted pursuant to a resolution of the commission and conducted in the same manner and by the same procedure as in or may be provided by law for the exercise of the power of eminent domain by incorporated cities and towns of the state of Washington in the acquisition of property rights: PROVIDED, That no public hospital district shall have the right of eminent domain and the power of condemnation against any health care facility.

(3) To lease existing hospital and other health care facilities and equipment and/or other property used in connection therewith, including ambulances, and to pay such rental therefor as the commissioners shall deem proper; to provide hospital and other health care services for residents of said district by facilities located outside the boundaries of said district, by contract or in any other manner said commissioners may deem expedient or necessary under the existing conditions; and said hospital district shall have the power to contract with other communities, corporations, or individuals for the services provided by said hospital district; and they may further receive in said hospitals and other health care facilities and furnish proper and adequate services to all persons not residents of said district at such reasonable and fair compensation as may be considered proper: PROVIDED, That it must at all times make adequate provision for the needs of the district and residents of said district shall have prior rights to the available hospital and other health care facilities of said district, at rates set by the district commissioners.

(4) For the purpose aforesaid, it shall be lawful for any district so organized to take, condemn and purchase, lease, or acquire, any and all property, and property rights, including state and county lands, for any of the purposes aforesaid, and any and all other facilities necessary or convenient, and in connection with the construction, maintenance, and operation of any such hospitals and other health care facilities, subject, however, to the applicable limitations provided in subsection (2) of this section.

(5) To contract indebtedness or borrow money for corporate purposes on the credit of the corporation or the revenues of the hospitals thereof, and the revenues of any other facilities or services that the

district is or hereafter may be authorized by law to provide, and to issue and sell: (a) Revenue bonds, revenue warrants, or other revenue obligations therefor payable solely out of a special fund or funds into which the district may pledge such amount of the revenues of the hospitals thereof, and the revenues of any other facilities or services that the district is or hereafter may be authorized by law to provide, to pay the same as the commissioners of the district may determine, such revenue bonds, warrants, or other obligations to be issued and sold in the same manner and subject to the same provisions as provided for the issuance of revenue bonds, warrants, or other obligations by cities or towns under the Municipal Revenue Bond Act, chapter 35.41 RCW, as may hereafter be amended; (b) general obligation bonds therefor in the manner and form as provided in RCW 70.44.110 and 70.44.130, as may hereafter be amended; or (c) interest-bearing warrants to be drawn on a fund pending deposit in such fund of money sufficient to redeem such warrants and to be issued and paid in such manner and upon such terms and conditions as the board of commissioners may deem to be in the best interest of the district; and to assign or sell hospital accounts receivable, and accounts receivable for the use of other facilities or services that the district is or hereafter may be authorized by law to provide, for collection with or without recourse. General obligation bonds shall be issued and sold in accordance with chapter 39.46 RCW. Revenue bonds, revenue warrants, or other revenue obligations may be issued and sold in accordance with chapter 39.46 RCW.

(6) To raise revenue by the levy of an annual tax on all taxable property within such public hospital district not to exceed fifty cents per thousand dollars of assessed value, and an additional annual tax on all taxable property within such public hospital district not to exceed twenty-five cents per thousand dollars of assessed value, or such further amount as has been or shall be authorized by a vote of the people. Although public hospital districts are authorized to impose two separate regular property tax levies, the levies shall be considered to be a single levy for purposes of the limitation provided for in chapter 84.55 RCW. Public hospital districts are authorized to levy such a general tax in excess of their regular property taxes when authorized so to do at a special election conducted in accordance with and subject to all of the requirements of the Constitution and the laws of the state of Washington now in force or hereafter enacted governing the limitation of tax levies. The said board of district commissioners is authorized and empowered to call a special election for the purpose of submitting to the qualified voters of the hospital district a proposition or propositions to levy taxes in excess of its regular property taxes. The superintendent shall prepare a proposed budget of the contemplated financial transactions for the ensuing year and file the same in the records of the commission on or before the first day of November. Notice of the filing of said proposed budget and the date and place of hearing on the same shall be published for at least two consecutive weeks, at least one time each week, in a newspaper printed and of general circulation in said county. On or before the fifteenth day of November the commission shall hold a public hearing on said proposed budget at which any taxpayer may appear and be heard against the whole or any part of the proposed budget. Upon the conclusion of said hearing, the commission shall, by resolution, adopt the budget as finally determined and fix the final amount of expenditures for the ensuing year. Taxes levied by the commission shall be certified to and collected by the proper county officer of the county in which such public hospital district is located in the same manner as is or may be provided by law for the certification and collection of port district taxes. The commission is authorized, prior to the receipt of taxes raised by levy, to borrow money or issue warrants of the district in anticipation of the revenue to be derived by such district from the levy of taxes for the purpose of such district, and such warrants shall be redeemed from the first money available from such

taxes when collected, and such warrants shall not exceed the anticipated revenues of one year, and shall bear interest at a rate or rates as authorized by the commission.

(7) To enter into any contract with the United States government or any state, municipality, or other hospital district, or any department of those governing bodies, for carrying out any of the powers authorized by this chapter.

(8) To sue and be sued in any court of competent jurisdiction: PROVIDED, That all suits against the public hospital district shall be brought in the county in which the public hospital district is located.

(9) To pay actual necessary travel expenses and living expenses incurred while in travel status for (a) qualified physicians or other health care practitioners who are candidates for medical staff positions, and (b) other qualified persons who are candidates for superintendent or other managerial and technical positions, which expenses may include expenses incurred by family members accompanying the candidate, when the district finds that hospitals or other health care facilities owned and operated by it are not adequately staffed and determines that personal interviews with said candidates to be held in the district are necessary or desirable for the adequate staffing of said facilities.

(10) To employ superintendents, attorneys, and other technical or professional assistants and all other employees; to make all contracts useful or necessary to carry out the provisions of this chapter, including, but not limited to, (a) contracts with private or public institutions for employee retirement programs, and (b) contracts with current or prospective employees, physicians, or other health care practitioners providing for the payment or reimbursement by the public hospital district of health care training or education expenses, including but not limited to debt obligations, incurred by current or prospective employees, physicians, or other health care practitioners in return for their agreement to provide services beneficial to the public hospital district; to print and publish information or literature; and to do all other things necessary to carry out the provisions of this chapter.

[2003 c 125 § 1; 2001 c 76 § 1; 1997 c 3 § 206 (Referendum Bill No. 47, approved November 4, 1997); 1990 c 234 § 2; 1984 c 186 § 59; 1983 c 167 § 172; 1982 c 84 § 15; 1979 ex.s. c 155 § 1; 1979 ex.s. c 143 § 4; 1977 ex.s. c 211 § 1; 1974 ex.s. c 165 § 2; 1973 1st ex.s. c 195 § 83; 1971 ex.s. c 218 § 2; 1970 ex.s. c 56 § 85; 1969 ex.s. c 65 § 1; 1967 c 164 § 7; 1965 c 157 § 2; 1949 c 197 § 18; 1945 c 264 § 6; Rem. Supp. 1949 § 6090-35.]

Notes:

Intent -- 1997 c 3 §§ 201-207: See note following RCW 84.55.010.

Application -- Severability -- Part headings not law -- Referral to electorate -- 1997 c 3: See notes following RCW 84.40.030.

Purpose -- 1984 c 186: See note following RCW 39.46.110.

Liberal construction -- Severability -- 1983 c 167: See RCW 39.46.010 and note following.

Severability -- 1979 ex.s. c 155: "If any provision of this amendatory act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected." [1979 ex.s. c 155 § 3.]

Severability -- 1979 ex.s. c 143: See note following RCW 70.44.200.

Severability -- Effective dates and termination dates -- Construction -- 1973 1st ex.s. c 195: See notes following RCW 84.52.043.

Purpose -- 1970 ex.s. c 56: See note following RCW 39.52.020.

Purpose -- Severability -- 1967 c 164: See notes following RCW 4.96.010.

Eminent domain
by cities: Chapter 8.12 RCW.
generally: State Constitution Art. 1 § 16.

Limitation on levies: State Constitution Art. 7 § 2; RCW 84.52.050.

Port districts, collection of taxes: RCW 53.36.020.

Tortious conduct of political subdivisions, municipal corporations and quasi-municipal corporations, liability for damages: Chapter 4.96 RCW.

70.44.062
Commissioners' meetings, proceedings, and deliberations concerning health care providers' clinical or staff privileges to be confidential — Final action in public session.

(1) All meetings, proceedings, and deliberations of the board of commissioners, its staff or agents, concerning the granting, denial, revocation, restriction, or other consideration of the status of the clinical or staff privileges of a physician or other health care provider as that term is defined in RCW 7.70.020, if such other providers at the discretion of the district's commissioners are considered for such privileges, shall be confidential and may be conducted in executive session: PROVIDED, That the final action of the board as to the denial, revocation, or restriction of clinical or staff privileges of a physician or other health care provider as defined in RCW 7.70.020 shall be done in public session.

(2) All meetings, proceedings, and deliberations of a quality improvement committee established under RCW 4.24.250, 43.70.510, or 70.41.200 and all meetings, proceedings, and deliberations of the board of commissioners, its staff or agents, to review the report or the activities of a quality improvement committee established under RCW 4.24.250, 43.70.510, or 70.41.200 may, at the discretion of the quality improvement committee or the board of commissioners, be confidential and may be conducted in executive session. Any review conducted by the board of commissioners or quality improvement committee, or their staffs or agents, shall be subject to the same protections, limitations, and exemptions that apply to quality improvement committee activities under RCW 4.24.240, 4.24.250, 43.70.510, and 70.41.200. However, any final action of the board of commissioners on the report of the quality improvement committee shall be done in public session.

[2005 c 169 § 1; 1985 c 166 § 1.]

70.44.065
Levy for emergency medical care and services.

See RCW 84.52.069.

70.44.067
Community revitalization financing — Public improvements.

In addition to other authority that a public hospital district possesses, a public hospital district may provide any public improvement as defined under RCW 39.89.020, but this additional authority is limited to participating in the financing of the public improvements as provided under RCW 39.89.050.

This section does not limit the authority of a public hospital district to otherwise participate in the public improvements if that authority exists elsewhere.

[2001 c 212 § 22.]

Notes:

Severability -- 2001 c 212: See RCW 39.89.902.

70.44.070
Superintendent — Appointment — Removal — Compensation.

(1) The public hospital district commission shall appoint a superintendent, who shall be appointed for an indefinite time and be removable at the will of the commission. Appointments and removals shall be by resolution, introduced at a regular meeting and adopted at a subsequent regular meeting by a majority vote. The superintendent shall receive such compensation as the commission shall fix by resolution.

(2) Where a public hospital district operates more than one hospital, the commission may in its discretion appoint up to one superintendent per hospital and assign among the superintendents the powers and duties set forth in RCW 70.44.080 and 70.44.090 as deemed appropriate by the commission.

[1987 c 58 § 1; 1982 c 84 § 16; 1945 c 264 § 7; Rem. Supp. 1945 § 6090-36.]

70.44.080
Superintendent — Powers.

(1) The superintendent shall be the chief administrative officer of the public district hospital and shall have control of administrative functions of the district. The superintendent shall be responsible to the commission for the efficient administration of all affairs of the district. In case of the absence or temporary disability of the superintendent a competent person shall be appointed by the commission. The superintendent shall be entitled to attend all meetings of the commission and its committees and to take part in the discussion of any matters pertaining to the district, but shall have no vote.

(2) Where the commission has appointed more than one superintendent as provided in RCW 70.44.070, the commission shall assign among the superintendents the powers set forth in this section as deemed appropriate by the commission.

[1987 c 58 § 2; 1982 c 84 § 17; 1945 c 264 § 9; Rem. Supp. 1945 § 6090-38.]

70.44.090
Superintendent — Duties.

(1) The public hospital district superintendent shall have the power, and duty:

(a) To carry out the orders of the commission, and to see that all the laws of the state pertaining to matters within the functions of the district are duly enforced.

(b) To keep the commission fully advised as to the financial condition and needs of the district. To prepare, each year, an estimate for the ensuing fiscal year of the probable expenses of the district, and to recommend to the commission what development work should be undertaken, and what extensions and

additions, if any, should be made, during the ensuing fiscal year, with an estimate of the costs of such development work, extensions and additions. To certify to the commission all the bills, allowances and payrolls, including claims due contractors of public works. To recommend to the commission a range of salaries to be paid to district employees.

(2) Where the commission has appointed more than one superintendent as provided in RCW 70.44.070, the commission shall assign among the superintendents the duties set forth in this section as deemed appropriate by the commission.

[1987 c 58 § 3; 1982 c 84 § 18; 1945 c 264 § 11; Rem. Supp. 1945 § 6090-40.]

70.44.110
Plan to construct or improve — General obligation bonds.

Whenever the commission deems it advisable that the district acquire or construct a public hospital, or other health care facilities, or make additions or betterments thereto, or extensions thereof, it shall provide therefor by resolution, which shall specify and adopt the plan proposed, declare the estimated cost thereof, and specify the amount of indebtedness to be incurred therefor. General indebtedness may be incurred by the issuance of general obligation bonds or short-term obligations in anticipation of such bonds. General obligation bonds shall mature in not to exceed thirty years. The incurring of such indebtedness shall be subject to the applicable limitations and requirements provided in section 1, chapter 143, Laws of 1917, as last amended by section 4, chapter 107, Laws of 1967, and RCW 39.36.020, as now or hereafter amended. Such general obligation bonds shall be issued and sold in accordance with chapter 39.46 RCW.

[1984 c 186 § 60; 1974 ex.s. c 165 § 3; 1969 ex.s. c 65 § 2; 1955 c 56 § 1; 1945 c 264 § 12; Rem. Supp. 1945 § 6090-41.]

Notes:

Purpose -- 1984 c 186: See note following RCW 39.46.110.

70.44.130
Bonds — Payment — Security for deposits.

The principal and interest of such general bonds shall be paid by levying each year a tax upon the taxable property within the district sufficient, together with other revenues of the district available for such purpose, to pay said interest and principal of said bonds, which tax shall be due and collectible as

any other tax. All bonds and warrants issued under the authority of this chapter shall be legal securities, which may be used by any bank or trust company for deposit with the state treasurer, or any county or city treasurer, as security for deposits, in lieu of a surety bond, under any law relating to deposits of public moneys.

[1984 c 186 § 61; 1971 ex.s. c 218 § 3; 1945 c 264 § 14; Rem. Supp. 1945 § 6090-43.]

Notes:

Purpose -- 1984 c 186: See note following RCW 39.46.110.

70.44.140
Contracts for material and work — Call for bids — Alternative procedures — Exemptions.

(1) All materials purchased and work ordered, the estimated cost of which is in excess of fifty thousand dollars, shall be by contract. Before awarding any such contract, the commission shall publish a notice at least thirteen days before the last date upon which bids will be received, inviting sealed proposals for such work. The plans and specifications must at the time of the publication of such notice be on file at the office of the public hospital district, subject to public inspection: PROVIDED, HOWEVER, That the commission may at the same time, and as part of the same notice, invite tenders for the work or materials upon plans and specifications to be submitted by bidders. The notice shall state generally the work to be done, and shall call for proposals for doing the same, to be sealed and filed with the commission on or before the day and hour named therein. Each bid shall be accompanied by bid proposal security in the form of a certified check, cashier's check, postal money order, or surety bond made payable to the order of the commission, for a sum not less than five percent of the amount of the bid, and no bid shall be considered unless accompanied by such bid proposal security. At the time and place named, such bids shall be publicly opened and read, and the commission shall proceed to canvass the bids, and may let such contract to the lowest responsible bidder upon plans and specifications on file, or to the best bidder submitting his or her own plans and specifications: PROVIDED, HOWEVER, That no contract shall be let in excess of the estimated cost of the materials or work, or if, in the opinion of the commission, all bids are unsatisfactory, they may reject all of them and readvertise, and in such case all bid proposal security shall be returned to the bidders. If the contract is let, then all bid proposal security shall be returned to the bidders, except that of the successful bidder, which is retained until a contract shall be entered into for the purchase of such materials for doing such work, and a bond to perform such work furnished, with sureties satisfactory to the commission, in an amount to be fixed by the commission, not less than twenty-five percent of contract price in any case, between the bidder and commission, in accordance with the bid. If such bidder fails to enter into the contract in accordance with the bid and furnish such bond within ten days from the date at which the bidder is notified that he or she is the successful bidder, the bid proposal security and the amount thereof shall be forfeited to the public hospital district. A low bidder who claims error and fails to enter into a contract is prohibited from bidding on the same project if a second or subsequent call for bids is made for the project.

(2) As an alternative to the requirements of subsection (1) of this section, a public hospital district may let contracts using the small works roster process under RCW 39.04.155.

(3) Any purchases with an estimated cost of up to fifteen thousand dollars may be made using the process provided in RCW 39.04.190.

(4) The commission may waive the competitive bidding requirements of this section pursuant to RCW 39.04.280 if an exemption contained within that section applies to the purchase or public work.

[2002 c 106 § 1; 2000 c 138 § 213; 1999 c 99 § 1; 1998 c 278 § 9; 1996 c 18 § 15; 1993 c 198 § 22; 1965 c 83 § 1; 1945 c 264 § 17; Rem. Supp. 1945 § 6090-46.]

Notes:

Purpose -- Part headings not law -- 2000 c 138: See notes following RCW 39.04.155.

Contractor's bond: Chapter 39.08 RCW.

Lien on public works, retained percentage of contractor's earnings: Chapter 60.28 RCW.

70.44.171
Treasurer — Duties — Funds — Depositaries — Surety bonds, cost.

The treasurer of the county in which a public hospital district is located shall be treasurer of the district, except that the commission by resolution may designate some other person having experience in financial or fiscal matters as treasurer of the district. If the treasurer is not the county treasurer, the commission shall require a bond, with a surety company authorized to do business in the state of Washington, in an amount and under the terms and conditions which the commission by resolution from time to time finds will protect the district against loss. The premium on any such bond shall be paid by the district.

All district funds shall be paid to the treasurer and shall be disbursed by him only on warrants issued by an auditor appointed by the commission, upon orders or vouchers approved by it. The treasurer shall establish a public hospital district fund, into which shall be paid all district funds, and he shall maintain such special funds as may be created by the commission, into which he shall place all money as the commission may, by resolution, direct.

If the treasurer of the district is the treasurer of the county all district funds shall be deposited with the county depositaries under the same restrictions, contracts, and security as provided for county depositaries. If the treasurer of the district is some other person, all funds shall be deposited in such bank or banks authorized to do business in this state as the commission by resolution shall designate, and with surety bond to the district or securities in lieu thereof of the kind, no less in amount, as provided in

*RCW 36.48.020 for deposit of county funds. Such surety bond or securities in lieu thereof shall be filed or deposited with the treasurer of the district, and approved by resolution of the commission.

All interest collected on district funds shall belong to the district and be deposited to its credit in the proper district funds.

A district may provide and require a reasonable bond of any other person handling moneys or securities of the district. The district may pay the premium on such bond.

[1967 c 227 § 1.]

Notes:

***Reviser's note:** RCW 36.48.020 was repealed by 1984 c 177 § 21.

70.44.185
Change of district boundary lines to allow farm units to be wholly within one hospital district — Notice.

Notwithstanding any other provision of law, including RCW 70.44.040, whenever the boundary line between contiguous hospital districts bisects an irrigation block unit placing part of the unit in one hospital district and the balance thereof in another such district, the county auditor, upon his approval of a request therefor after public hearing thereon, shall change the hospital district boundary lines so that the entire farm unit of the person so requesting shall be wholly in one of such hospital districts and give notice thereof to those hospital district and county officials as he shall deem appropriate therefor.

[1971 ex.s. c 218 § 4.]

70.44.190
Consolidation of districts.

Two or more contiguous hospital districts, whether the territory therein lies in one or more counties, may consolidate by following the procedure outlined in chapter 35.10 RCW with reference to consolidation of cities and towns.

[1953 c 267 § 3.]

70.44.200
Annexation of territory.

(1) A public hospital district may annex territory outside the existing boundaries of such district and contiguous thereto, whether the territory lies in one or more counties, in accordance with this section.

(2) A petition for annexation of territory contiguous to a public hospital district may be filed with the commission of the district to which annexation is proposed. The petition must be signed by the owners, as prescribed by RCW 35A.01.040(9) (a) through (e), of not less than sixty percent of the area of land within the territory proposed to be annexed. Such petition shall describe the boundaries of the territory proposed to be annexed and shall be accompanied by a map which outlines the boundaries of such territory.

(3) Whenever such a petition for annexation is filed with the commission of a public hospital district, the commission may entertain the same, fix a date for public hearing thereon, and cause notice of the hearing to be published once a week for at least two consecutive weeks in a newspaper of general circulation within the territory proposed to be annexed. The notice shall also be posted in three public places within the territory proposed to be annexed, shall contain a description of the boundaries of such territory, and shall specify the time and place of hearing and invite interested persons to appear and voice approval or disapproval of the annexation.

(4) Following the hearing, if the commission of the district determines to accomplish the annexation, it shall do so by resolution. The resolution may annex all or any portion of the proposed territory but may not include in the annexation any property not described in the petition. Upon passage of the annexation resolution, the territory annexed shall become part of the district and a certified copy of such resolution shall be filed with the legislative authority of the county or counties in which the annexed property is located.

(5) If the petition for annexation and the annexation resolution so provide, as the commission may require, and such petition has been signed by the owners of all the land within the boundaries of the territory being annexed, the annexed property shall assume and be assessed and taxed to pay for all or any portion of the outstanding indebtedness of the district to which it is annexed at the same rates as other property within such district. Unless so provided in the petition and resolution, property within the boundaries of the territory annexed shall not be assessed or taxed to pay for all or any portion of the indebtedness of the district to which it is annexed that was contracted prior to or which existed at the date of annexation. In no event shall any such annexed property be released from any assessments or taxes previously levied against it or from its existing liability for the payment of outstanding bonds or warrants issued prior to such annexation.

(6) The annexation procedure provided for in this section shall be an alternative method of annexation applicable only if at the time the annexation petition is filed either there are no registered voters residing in the territory proposed to be annexed or the petition is also signed by all of the registered voters residing in the territory proposed to be annexed.

[1993 c 489 § 1; 1979 ex.s. c 143 § 1; 1953 c 267 § 4.]

Notes:

Severability -- 1979 ex.s. c 143: "If any provision of this amendatory act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected." [1979 ex.s. c 143 § 3.]

70.44.210
Alternate method of annexation — Contents of resolution calling for election.

As an alternate method of annexation to public hospital districts, any territory adjacent to a public hospital district may be annexed thereto by vote of the qualified electors residing in the territory to be annexed, in the manner provided in RCW 70.44.210 through 70.44.230. An election to annex such territory may be called pursuant to a resolution calling for such an election adopted by the district commissioners.

Any resolution calling for such an election shall describe the boundaries of the territory to be annexed, state that the annexation of such territory to the public hospital district will be conducive to the welfare and benefit of the persons or property within the district and within the territory proposed to be annexed, and fix the date, time and place for a public hearing thereon which date shall be not more than sixty nor less than forty days following the adoption of such resolution.

[1967 c 227 § 6.]

70.44.220
Alternate method of annexation — Publication and contents of notice of hearing — Hearing — Resolution — Special election.

Notice of such hearing shall be published once a week for at least two consecutive weeks in one or more newspapers of general circulation within the territory proposed to be annexed. The notice shall contain a description of the boundaries of the territory proposed to be annexed and shall state the time and place of the hearing thereon and the fact that any changes in the boundaries of such territory will be considered at such time and place. At such hearing or any continuation thereof, any interested person may appear and be heard on all matters relating to the proposed annexation. The district commissioners may make such changes in the boundaries of the territory proposed to be annexed as it shall deem reasonable and proper, but may not delete any portion of the proposed area which will create an island of included or excluded lands. If the district commissioners shall determine that any additional territory should be included in the

territory to be annexed, a second hearing shall be held and notice given in the same manner as for the original hearing. The district commissioners may adjourn the hearing on the proposed annexation from time to time not exceeding thirty days in all. At the next regular meeting following the conclusion of such hearing, the district commissioners shall, if it finds that the annexation of such territory will be conducive to the welfare and benefit of the persons and property therein and the welfare and benefit of the persons and property within the public hospital district, adopt a resolution fixing the boundaries of the territory to be annexed and causing to be called a special election on such annexation to be held not more than one hundred twenty days nor less than sixty days following the adoption of such resolution.

[1967 c 227 § 7.]

70.44.230
Alternate method of annexation — Conduct and canvass of election — Notice — Ballot.

An election on the annexation of territory to a public hospital district shall be conducted and canvassed in the same manner as provided for the conduct of an election on the formation of a public hospital district except that notice of such election shall be published in one or more newspapers of general circulation in the territory proposed to be annexed and the ballot proposition shall be in substantially the following form:

ANNEXATION TO (herein insert name of public hospital district)

"Shall the territory described in a resolution of the public hospital district commissioners of (here insert name of public hospital district) adopted on . . ., ..., 19. . ., be annexed to such district?

YES . . . . . ☐
NO . . . . . ☐

If a majority of those voting on such proposition vote in favor thereof, the territory shall thereupon be annexed to the public hospital district.

[1967 c 227 § 8.]

70.44.235
Withdrawal or reannexation of areas. (Effective until January 1, 2007.)

(1) As provided in this section, a public hospital district may withdraw areas from its boundaries, or reannex areas into the public hospital district that previously had been withdrawn from the public hospital district under this section.

(2) The withdrawal of an area shall be authorized upon: (a) Adoption of a resolution by the hospital district commissioners requesting the withdrawal and finding that, in the opinion of the commissioners, inclusion of this area within the public hospital district will result in a reduction of the district's tax levy rate under the provisions of RCW 84.52.010; and (b) adoption of a resolution by the city or town council approving the withdrawal, if the area is located within the city or town, or adoption of a resolution by the county legislative authority of the county within which the area is located approving the withdrawal, if the area is located outside of a city or town. A withdrawal shall be effective at the end of the day on the thirty-first day of December in the year in which the resolutions are adopted, but for purposes of establishing boundaries for property tax purposes, the boundaries shall be established immediately upon the adoption of the second resolution.

The withdrawal of an area from the boundaries of a public hospital district shall not exempt any property therein from taxation for the purpose of paying the costs of redeeming any indebtedness of the public hospital district existing at the time of the withdrawal.

(3) An area that has been withdrawn from the boundaries of a public hospital district under this section may be reannexed into the public hospital district upon: (a) Adoption of a resolution by the hospital district commissioners proposing the reannexation; and (b) adoption of a resolution by the city or town council approving the reannexation, if the area is located within the city or town, or adoption of a resolution by the county legislative authority of the county within which the area is located approving the reannexation, if the area is located outside of a city or town. The reannexation shall be effective at the end of the day on the thirty-first day of December in the year in which the adoption of the second resolution occurs, but for purposes of establishing boundaries for property tax purposes, the boundaries shall be established immediately upon the adoption of the second resolution. Referendum action on the proposed reannexation may be taken by the voters of the area proposed to be reannexed if a petition calling for a referendum is filed with the city or town council, or county legislative authority, within a thirty-day period after the adoption of the second resolution, which petition has been signed by registered voters of the area proposed to be reannexed equal in number to ten percent of the total number of the registered voters residing in that area.

If a valid petition signed by the requisite number of registered voters has been so filed, the effect of the resolutions shall be held in abeyance and a ballot proposition to authorize the reannexation shall be submitted to the voters of the area at the next special election date specified in *RCW 29.13.020 that occurs forty-five or more days after the petitions have been validated. Approval of the ballot proposition authorizing the reannexation by a simple majority vote shall authorize the reannexation.

[1987 c 138 § 4.]

Notes:

***Reviser's note:** As enacted by 1987 c 138 § 4, this section contained an apparently erroneous reference to RCW 29.13.030, a section repealed in 1965. Pursuant to RCW 1.08.015, this reference has been changed to RCW 29.13.020, a later enactment of the section repealed. RCW 29.13.020 was subsequently recodified as RCW 29A.04.330 pursuant to 2003 c 111 § 2401, effective July 1, 2004.

RCW 70.44
Withdrawal or reannexation of areas. (Effective January 1, 2007.)

(1) As provided in this section, a public hospital district may withdraw areas from its boundaries, or reannex areas into the public hospital district that previously had been withdrawn from the public hospital district under this section.

(2) The withdrawal of an area shall be authorized upon: (a) Adoption of a resolution by the hospital district commissioners requesting the withdrawal and finding that, in the opinion of the commissioners, inclusion of this area within the public hospital district will result in a reduction of the district's tax levy rate under the provisions of RCW 84.52.010; and (b) adoption of a resolution by the city or town council approving the withdrawal, if the area is located within the city or town, or adoption of a resolution by the county legislative authority of the county within which the area is located approving the withdrawal, if the area is located outside of a city or town. A withdrawal shall be effective at the end of the day on the thirty-first day of December in the year in which the resolutions are adopted, but for purposes of establishing boundaries for property tax purposes, the boundaries shall be established immediately upon the adoption of the second resolution.

The withdrawal of an area from the boundaries of a public hospital district shall not exempt any property therein from taxation for the purpose of paying the costs of redeeming any indebtedness of the public hospital district existing at the time of the withdrawal.

(3) An area that has been withdrawn from the boundaries of a public hospital district under this section may be reannexed into the public hospital district upon: (a) Adoption of a resolution by the hospital district commissioners proposing the reannexation; and (b) adoption of a resolution by the city or town council approving the reannexation, if the area is located within the city or town, or adoption of a resolution by the county legislative authority of the county within which the area is located approving the reannexation, if the area is located outside of a city or town. The reannexation shall be effective at the end of the day on the thirty-first day of December in the year in which the adoption of the second resolution occurs, but for purposes of establishing boundaries for property tax purposes, the boundaries shall be established immediately upon the adoption of the second resolution. Referendum action on the proposed reannexation may be taken by the voters of the area proposed to be reannexed if a petition calling for a referendum is filed with the city or town council, or county legislative authority, within a

thirty-day period after the adoption of the second resolution, which petition has been signed by registered voters of the area proposed to be reannexed equal in number to ten percent of the total number of the registered voters residing in that area.

If a valid petition signed by the requisite number of registered voters has been so filed, the effect of the resolutions shall be held in abeyance and a ballot proposition to authorize the reannexation shall be submitted to the voters of the area at the next special election date according to RCW 29A.04.330. Approval of the ballot proposition authorizing the reannexation by a simple majority vote shall authorize the reannexation.

[2006 c 344 § 39; 1987 c 138 § 4.]

Notes:

Effective date -- 2006 c 344 §§ 1-16 and 18-40: See note following RCW 29A.04.311.

70.44.240
Contracting or joining with other districts, hospitals, corporations, or individuals to provide services or facilities.

Any public hospital district may contract or join with any other public hospital district, publicly owned hospital, nonprofit hospital, legal entity, or individual to acquire, own, operate, manage, or provide any hospital or other health care facilities or hospital services or other health care services to be used by individuals, districts, hospitals, or others, including providing health maintenance services. If a public hospital district chooses to contract or join with another party or parties pursuant to the provisions of this chapter, it may do so through establishing a nonprofit corporation, partnership, limited liability company, or other legal entity of its choosing in which the public hospital district and the other party or parties participate. The governing body of such legal entity shall include representatives of the public hospital district, which representatives may include members of the public hospital district's board of commissioners. A public hospital district contracting or joining with another party pursuant to the provisions of this chapter may appropriate funds and may sell, lease, or otherwise provide property, personnel, and services to the legal entity established to carry out the contract or joint activity.

[2004 c 261 § 7; 1997 c 332 § 16; 1982 c 84 § 19; 1974 ex.s. c 165 § 4; 1967 c 227 § 3.]

Notes:

Severability -- 1997 c 332: See RCW 70.45.900.

70.44.260
Contracts for purchase of real or personal property.

Any public hospital district may execute an executory conditional sales contract with any other municipal corporation, the state, or any of its political subdivisions, the government of the United States, or any private party for the purchase of any real or personal property, or property rights, in connection with the exercise of any powers or duties which such districts now or hereafter are authorized to exercise, if the entire amount of the purchase price specified in such contract does not result in a total indebtedness in excess of the limitation imposed by RCW 39.36.020, as now or hereafter amended, to be incurred without the assent of the voters of the district: PROVIDED, That if such a proposed contract would result in a total indebtedness in excess of three-fourths of one percent of the value of taxable property in such public hospital district, a proposition in regard to whether or not such a contract may be executed shall be submitted to the voters for approval or rejection in the same manner that bond issues for capital purposes are submitted to the voters. The term "value of taxable property" shall have the meaning set forth in RCW 39.36.015.

[1975-'76 2nd ex.s. c 78 § 1.]

70.44.300
Sale of surplus real property.

(1) The board of commissioners of any public hospital district may sell and convey at public or private sale real property of the district if the board determines by resolution that the property is no longer required for public hospital district purposes or determines by resolution that the sale of the property will further the purposes of the public hospital district.

(2) Any sale of district real property authorized pursuant to this section shall be preceded, not more than one year prior to the date of sale, by market value appraisals by three licensed real estate brokers or professionally designated real estate appraisers as defined in RCW 74.46.020 or three independent experts in valuing health care property, selected by the board of commissioners, and no sale shall take place if the sale price would be less than ninety percent of the average of such appraisals.

(3) When the board of commissioners of any public hospital district proposes a sale of district real property pursuant to this section and the value of the property exceeds one hundred thousand dollars, the board shall publish a notice of its intention to sell the property. The notice shall be published at least once each week during two consecutive weeks in a legal newspaper of general circulation within the public hospital district. The notice shall describe the property to be sold and designate the place where and the day and hour when a hearing will be held. The board shall hold a public hearing upon the proposal to dispose of the public hospital district property at the place and the day and hour fixed in the notice and consider evidence offered for and against the propriety and advisability of the proposed sale.

(4) If in the judgment of the board of commissioners of any district the sale of any district real property not needed for public hospital district purposes would be facilitated and greater value realized through use of the services of licensed real estate brokers, a contract for such services may be negotiated and concluded. The fee or commissions charged for any broker service shall not exceed seven percent of the resulting sale price for a single parcel. No licensed real estate broker or professionally designated real estate appraisers as defined in RCW 74.46.020 or independent expert in valuing health care property selected by the board to appraise the market value of a parcel of property to be sold may be a party to any contract with the public hospital district to sell such property for a period of three years after the appraisal.

[1997 c 332 § 17; 1984 c 103 § 4; 1982 c 84 § 2.]

Notes:

Severability -- 1997 c 332: See RCW 70.45.900.

70.44.310
Lease of surplus real property.

The board of commissioners of any public hospital district may lease or rent out real property of the district which the board has determined by resolution presently is not required for public hospital district purposes in such manner and upon such terms and conditions as the board in its discretion finds to be in the best interest of the district.

[1982 c 84 § 3.]

70.44.315
Evaluation criteria and requirements for acquisition of district hospitals.

(1) When evaluating a potential acquisition, the commissioners shall determine their compliance with the following requirements:

(a) That the acquisition is authorized under chapter 70.44 RCW and other laws governing public hospital districts;

(b) That the procedures used in the decision-making process allowed district officials to thoroughly fulfill their due diligence responsibilities as municipal officers, including those covered under chapter 42.23 RCW governing conflicts of interest and chapter 42.20 RCW prohibiting malfeasance of public officials;

(c) That the acquisition will not result in the revocation of hospital privileges;

(d) That sufficient safeguards are included to maintain appropriate capacity for health science research and health care provider education;

(e) That the acquisition is allowed under Article VIII, section 7 of the state Constitution, which prohibits gifts of public funds or lending of credit and Article XI, section 14, prohibiting private use of public funds;

(f) That the public hospital district will retain control over district functions as required under chapter 70.44 RCW and other laws governing hospital districts;

(g) That the activities related to the acquisition process complied with chapters 42.56 and 42.32 RCW, governing disclosure of public records, and chapter 42.30 RCW, governing public meetings;

(h) That the acquisition complies with the requirements of RCW 70.44.300 relating to fair market value; and

(i) Other state laws affecting the proposed acquisition.

(2) The commissioners shall also determine whether the public hospital district should retain a right of first refusal to repurchase the assets by the public hospital district if the hospital is subsequently sold to, acquired by, or merged with another entity.

(3)(a) Prior to approving the acquisition of a district hospital, the board of commissioners of the hospital district shall obtain a written opinion from a qualified independent expert or the Washington state department of health as to whether or not the acquisition meets the standards set forth in RCW 70.45.080.

(b) Upon request, the hospital district and the person seeking to acquire its hospital shall provide the department or independent expert with any needed information and documents. The department shall charge the hospital district for any costs the department incurs in preparing an opinion under this section. The hospital district may recover from the acquiring person any costs it incurs in obtaining the opinion from either the department or the independent expert. The opinion shall be delivered to the board of commissioners no later than ninety days after it is requested.

(c) Within ten working days after it receives the opinion, the board of commissioners shall publish notice of the opinion in at least one newspaper of general circulation within the hospital district, stating how a person may obtain a copy, and giving the time and location of the hearing required under (d) of this subsection. It shall make a copy of the report and the opinion available to anyone upon request.

(d) Within thirty days after it received the opinion, the board of commissioners shall hold a public hearing regarding the proposed acquisition. The board of commissioners may vote to approve the acquisition no sooner than thirty days following the public hearing.

(4)(a) For purposes of this section, "acquisition" means an acquisition by a person of any interest in a hospital owned by a public hospital district, whether by purchase, merger, lease, or otherwise, that results in a change of ownership or control of twenty percent or more of the assets of a hospital currently licensed and operating under RCW 70.41.090. Acquisition does not include an acquisition where the other party or parties to the acquisition are nonprofit corporations having a substantially similar charitable health care purpose, organizations exempt from federal income tax under section 501(c)(3) of the internal revenue code, or governmental entities. Acquisition does not include an acquisition where the other party is an organization that is a limited liability corporation, a partnership, or any other legal entity and the members, partners, or otherwise designated controlling parties of the organization are all nonprofit corporations having a charitable health care purpose, organizations exempt from federal income tax under section 501(c)(3) of the internal revenue code, or governmental entities. Acquisition does not include activities between two or more governmental organizations, including organizations acting pursuant to chapter 39.34 RCW, regardless of the type of organizational structure used by the governmental entities.

(b) For purposes of this subsection (4), "person" means an individual, a trust or estate, a partnership, a corporation including associations, a limited liability company, a joint stock company, or an insurance company.

[2005 c 274 § 334; 1997 c 332 § 18.]

Notes:

Part headings not law -- Effective date -- 2005 c 274: See RCW 42.56.901 and 42.56.902.

Severability -- 1997 c 332: See RCW 70.45.900.

70.44.320
Disposal of surplus personal property.

The board of commissioners of any public hospital district may sell or otherwise dispose of surplus personal property of the district which the board has determined by resolution is no longer required for public hospital district purposes in such manner and upon such terms and conditions as the board in its discretion finds to be in the best interest of the district.

[1982 c 84 § 4.]

70.44.350
Dividing a district.

An existing public hospital district upon resolution of its board of commissioners may be divided into two new public hospital districts, in the manner provided in RCW 70.44.350 through 70.44.380, subject to the approval of the plan therefor by the superior court in the county where such district is located and by a majority of the voters voting on the proposition for such approval at a special election to be held in each of the proposed new districts. The board of commissioners of an existing district shall by resolution or resolutions find that such division is in the public interest; adopt and approve a plan of division; authorize the filing of a petition in the superior court in the county in which the district is located to obtain court approval of the plan of division; request the calling of a special election to be held, following such court approval, for the purpose of submitting to the voters in each of the proposed new districts the proposition of whether the plan of division should be approved and carried out; and direct all officers and employees of the existing district to take whatever actions are reasonable and necessary in order to carry out the division, subject to the approval of the plan therefor by the court and the voters.

[1982 c 84 § 5.]

70.44.360
Dividing a district — Plan.

The plan of division authorized by RCW 70.44.350 shall include: Proposed names for the new districts; a description of the boundaries of the new districts, which boundaries shall follow insofar as reasonably possible the then-existing precinct boundaries and include all of the territory encompassed by the existing district; a division of all the assets of the existing district between the resulting new districts, including funds, rights, and property, both real and personal; the assumption of all the outstanding obligations of the existing district by the resulting new districts, including general obligation and revenue bonds, contracts, and any other liabilities or indebtedness; the establishing and constituting of new boards of three commissioners for each of the new districts, including fixing the boundaries of commissioner districts within such new districts following insofar as reasonably possible the then-existing precinct boundaries; and such other matters as the board of commissioners of the existing district may deem appropriate. Unless the plan of division provides otherwise, all the area and property of the existing district shall remain subject to the outstanding obligations of that district, and the boards of commissioners of the new districts shall make such levies or charges for services as may be necessary to pay such outstanding obligations in accordance with their terms from the sources originally pledged or otherwise liable for that purpose.

[1982 c 84 § 6.]

70.44.370
Dividing a district — Petition to court, hearing, order.

After adoption of a resolution approving the plan of division by the board of commissioners of an existing district pursuant to RCW 70.44.350 through 70.44.380, the district shall petition the superior court in the county where such district is located requesting court approval of the plan. The court shall conduct a hearing on the plan of division, after reasonable and proper notice of such hearing (including notice to bondholders) is given in the manner fixed and directed by such court. At the conclusion of the hearing, the court may enter its order approving the division of the existing district and of its assets and outstanding obligations in the manner provided by the plan after finding such division to be fair and equitable and in the public interest.

[1982 c 84 § 7.]

70.44.380
Dividing a district — Election — Creation of new districts — Challenges.

Following the entry of the court order pursuant to RCW 70.44.370, the county officer authorized to call and conduct elections in the county in which the existing district is located shall call a special election as provided by the resolution of the board of commissioners of such district for the purpose of submitting to the voters in each of the proposed new districts the proposition of whether the plan of division should be approved and carried out. Notice of the election describing the boundaries of the proposed new districts and stating the objects of the election shall be given and the election conducted in accordance with the general election laws. The proposition expressed on the ballots at such election shall be substantially as follows:

> "Shall the plan of division of public hospital district No. . . . ., approved by the Superior Court on . . . . . (insert date), be approved and carried out?
>
> Yes ☐ No ☐

At such election three commissioners for each of the proposed new districts nominated by petition pursuant to RCW 54.12.010 shall be elected to hold office pursuant to RCW 70.44.040. If at such

election a majority of the voters voting on the proposition in each of the proposed new districts shall vote in favor of the plan of division, the county canvassing board shall so declare in its canvass of the returns of such election and upon the filing of the certificate of such canvass: The division of the existing district shall be effective; such original district shall cease to exist; the creation of the two new public hospital districts shall be complete; all assets of the original district shall vest in and become the property of the new districts, respectively, pursuant to the plan of division; all the outstanding obligations of the original district shall be assumed by the new districts, respectively, pursuant to such plan; the commissioners of the original district shall cease to hold office; and the affairs of the new districts shall be governed by the newly elected commissioners of such respective new districts. Unless commenced within thirty days after the date of the filing of the certificate of the canvass of such election, no lawsuit whatever may be maintained challenging in any way the legal existence of the resulting new districts, the validity of the proceedings had for the organization and creation thereof, or the lawfulness of the plan of division. Upon the petition of either or both new districts, the superior court in the county where they are located may take whatever actions are reasonable and necessary to complete or confirm the carrying out of such plan.

[1982 c 84 § 8.]

70.44.400
Withdrawal of territory from public hospital district.

Territory within a public hospital district may be withdrawn therefrom in the same manner provided by law for withdrawal of territory from water-sewer districts, as provided by chapter 57.28 RCW. For purposes of conforming with such procedure, the public hospital district shall be deemed to be the water-sewer district and the public hospital board of commissioners shall be deemed to be the water-sewer district board of commissioners.

[1999 c 153 § 65; 1984 c 100 § 1.]

Notes:

Part headings not law -- 1999 c 153: See note following RCW 57.04.050.

70.44.450
Rural public hospital districts — Cooperative agreements and contracts.

In addition to other powers granted to public hospital districts by chapter 39.34 RCW, rural public hospital districts may enter into cooperative agreements and contracts with other rural public hospital

districts in order to provide for the health care needs of the people served by the hospital districts. These agreements and contracts are specifically authorized to include:

(1) Allocation of health care services among the different facilities owned and operated by the districts;

(2) Combined purchases and allocations of medical equipment and technologies;

(3) Joint agreements and contracts for health care service delivery and payment with public and private entities; and

(4) Other cooperative arrangements consistent with the intent of chapter 161, Laws of 1992. The provisions of chapter 39.34 RCW shall apply to the development and implementation of the cooperative contracts and agreements.

[1992 c 161 § 3.]

Notes:

Intent -- 1992 c 161: "The legislature finds that maintaining the viability of health care service delivery in rural areas of Washington is a primary goal of state health policy. The legislature also finds that most hospitals located in rural Washington are operated by public hospital districts authorized under chapter 70.44 RCW and declares that it is not cost-effective, practical, or desirable to provide quality health and hospital care services in rural areas on a competitive basis because of limited patient volume and geographic isolation. It is the intent of this act to foster the development of cooperative and collaborative arrangements among rural public hospital districts by specifically authorizing cooperative agreements and contracts for these entities under the interlocal cooperation act." [1992 c 161 § 1.]

70.44.460
Rural public hospital district defined.

Unless the context clearly requires otherwise, the definition in this section applies throughout RCW 70.44.450.

"Rural public hospital district" means a public hospital district authorized under chapter 70.44 RCW whose geographic boundaries do not include a city with a population greater than thirty thousand.

[1992 c 161 § 2.]

Notes:

Intent -- 1992 c 161: See note following RCW 70.44.450.

70.44.470
Chapter not applicable to certain transfers of property.

This chapter does not apply to transfers of property under *sections 1 and 2 of this act.

[2006 c 35 § 9.]

Notes:

***Reviser's note:** The reference to "sections 1 and 2 of this act" appears to be erroneous. Reference to "sections 2 and 3 of this act" codified as RCW 43.99C.070 and 43.83D.120 was apparently intended.

Findings -- 2006 c 35: See note following RCW 43.99C.070.

70.44.900
Severability — Construction — 1945 c 264.

Adjudication of invalidity of any section, clause or part of a section of this act [1945 c 264] shall not impair or otherwise affect the validity of the act as a whole or any other part thereof. The rule of strict construction shall have no application to this act, but the same shall be liberally construed, in order to carry out the purposes and objects for which this act is intended. When this act comes in conflict with any provisions, limitation or restriction in any other law, this act shall govern and control.

[1945 c 264 § 21; no RRS.]

70.44.901
Severability — Construction — 1974 ex.s. c 165.

If any section, clause, or other provision of this 1974 amendatory act, or its application to any person or circumstance, is held invalid, the remainder of such 1974 amendatory act, or the application of such section, clause, or provision to other persons or circumstances, shall not be affected. The rule of strict construction shall have no application to this 1974 amendatory act, but the same shall be liberally construed, in order to carry out the purposes and objects for which this 1974 amendatory act is intended.

When this 1974 amendatory act comes in conflict with any provision, limitation, or restriction in any other law, this 1974 amendatory act shall govern and control.

[1974 ex.s. c 165 § 6.]

70.44.902
Severability — 1982 c 84.

If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

[1982 c 84 § 21.]

70.44.903
Savings — 1982 c 84.

All debts, contracts, and obligations made or incurred prior to June 10, 1982, by or in favor of any public hospital district, and all bonds, warrants, or other obligations issued by such district, and all other actions and proceedings relating thereto done or taken by such public hospital districts or by their respective officers within their authority are hereby declared to be legal and valid and of full force and effect from the date thereof.

[1982 c 84 § 11.]

70.44.910
Construction — 1945 c 264.

This act [1945 c 264 § 22] shall not be deemed or construed to repeal or affect any existing act, or any part thereof, relating to the construction, operation and maintenance of public hospitals, but shall be supplemental thereto and concurrent therewith.

[1945 c 264 § 22; no RRS.]

Submitter : ROBIN NAVA **Date:** 08/31/2007

Organization : ST. VINCENT HEALTH CARE

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Dr. Frederick Curtis** **Date: 08/31/2007**

Organization : **Dr. Frederick Curtis**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Frederick L. Curtis, MD

Submitter : **Dr. marina swee** **Date: 08/31/2007**

Organization : **Dr. marina swee**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

c Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,
Marina Swee, D.O.

Submitter : Dr. NAGESWARARAO CHALASANI **Date:** 08/31/2007

Organization : VALLEY ANESTHESIA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

RE CMS-1385-P
ANESTHESIA CODING

Dear Ms.Norwalk:
I am writing to you in support of proposed increase for anesthesia services under 2008 Medicare physician fee schedule.In our practice we are facing increasing expenses every year,while reimbursements are decreasing.As more and more insurance companies are basing their payments on medicare fee schedule,the undervaluation of anesthesia work is having a very high impact on anesthesia practices.
I fully support the RUC recommendation to increase anesthesia conversion factor.This will be a step in the right direction in correcting the flawed work valuation that existed for a long time.
I request you to fully implement this recommondation.

sincerely,
Nagesh Chalasani

Submitter : **Dr. anthony carantzas** **Date: 08/31/2007**

Organization : **Dr. anthony carantzas**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I feel that physician owned PT and MRI should be allowed. I feel that it is beneficial to patients. Many times patients return for follow up with me and state that there PT has told them there is nothing else they can do for them and discharge them from there services without contacting me. When the therapist are present in your office and you have an open line of communication with them it facilitates interaction as a team and a provides a better approach to patient care. Perhaps the treatment plan needs to be altered or redirected and this can be more easily done when you know who is treating your patient and you trust their professional opinion because you work with them. I also here many times that patients prefer to have all of there treatment done in one facility. they usually come to our office because it is convenient for their appts. they wish to have the same convenience for there therapy. also minimizes need for further paperwork and insurance approval if everything is done under one roof. of course patient who wish to go elsewhere are able to...it merely provides them with another choice.

i guess from my perspective a question to ask is why is the georgia PT organization pushing to get rid of physician owned pt centers... is it really a patient care issue or is it a financial issue. we havc a much higher ratio of therapists to patients than most of the other pt facilities and our patients constantly praise the therapy that they get at our facilities. often times when patients are forced to go elsewhere they come back and state that they feel they are wasting there money going to therapy because they are put in a corner with a list of exercises to do without any supervision. unfortunately if they are not getting therapy done at my office i can do little about that especially if their insurance compay mandates that they attend a specific place. i strongly feel that self referral to physician owned facilities improves the quality of care and treatment patients get we are held accountalbe for that treatement. if services in our office are bad it directly reflects on us...therefore there is this inherent checks and balance system to make sure it is better than average.

thank you for your time in this important matter

Submitter : Mr. Patrick Laverty **Date:** 08/31/2007

Organization : Modern Nuclear, Inc.

Category : Health Care Industry

Issue Areas/Comments

IDTF Issues

IDTF Issues

410.33(g)(15)As an Independent Mobile provider being unable to share space (parking) would dis-allow our service to be utilized by smaller medical facilities and could put mobile services out of business. Not to mention the inconvience or the denying of service to the patients, when such services are otherwise not reseaonably accessible.

Performing procedures on patients at a facility where the facility does not have the technology requires the use of (sharing) the facilities parking and waiting room. Staff time is needed in order to provide medical records to demonstrate appropriateness of use for the test performed by the mobile IDTF. Parking fees or electricity fees may be requircd from the mobile IDTF by the building ownership especially when the facility practice does not own the building they occupy,(which is usually the case).

Using these suggested guidline changes for mobile IDTF's would only encouragc small facilities to purchase equipment which they do not have the patient volumc for, hcnce promoting abuse of such cquipment in ordcr to cover the purchase price payments of such equipment and will drive our Mcdicare cost even highcr than they arc. We must ask how many one or two person Cardiology practices own their own Echo or Nuclear Medicine equipment now as apposed to 10 or cven 5 years ago? How do they afford such equipment?

In order to reduce cost and abuse of Medicare and other insurance by physicians, guidelines should encourage the use of mobile IDTFs and not promote physicians to purchase their own equipment. The sales force from the manufacturers are continually pushing physicians to purchase cquipment they have which their practice size does not support, however guidelines allow it and the equipment manufactuerer sell more equipment and insurance billings are increased. Once most physicians own a piece of equipment, history demonstrates the use of such equipment on a same number patient practice tests ordered rise significantly, hence cost increase to the insurance carrier.

Providing scanning services by mobile IDTF reduce cost and should be encouraged and not restricted IDTFs to the point of elimination.

Submitter : **Mrs. DANIELLE MUNYAN** **Date: 08/31/2007**

Organization : **Mrs. DANIELLE MUNYAN**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Mr. Deric Hert** **Date: 08/31/2007**

Organization : **Oregon Imaging Centers**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

The Physician Work RVU-CPT 77080 (DXA)
The Direct Practice Expense RVU for 77080 (DXA)
Indirect Practice Expense for DXA and VFA
Deficit Reduction Act
Dear Mr. Weems:
I appreciate the opportunity to offer general comments on the proposed rule regarding changes to the Medicare physician fee schedule CMS-1385-P.
As a provider of DXA and/or VFA services, I request CMS to reevaluate the following:
a. The Physician Work RVU for 77080 (DXA) should be increased from 0.2 to 0.5, consistent with the most comprehensive survey data available;
b. The Direct Practice Expense RVU for 77080 (DXA) should reflect the following adjustments:
? the equipment type for DXA should be changed from pencil beam to fan beam with a corresponding increase in equipment cost from $41,000 to $85,000;
? the utilization rate for preventive health services involving equipment designed to diagnose and treat a single disease or a preventive health service should be calculated in a different manner than other utilization rates so as to reflect the actual utilization of that service. In the case of DXA and VFA, the 50% utilization rate should be changed to reflect the utilization rate for DXA to 12%.
c. The inputs used to derive Indirect Practice Expense for DXA and VFA should be made available to the general public, and
d. DXA (77080) should not be considered an imaging service within the meaning of the section 5012 (b) of the Deficit Reduction Act of 2005 because the diagnosis and treatment of osteoporosis is based on a score and not an image.

Submitter : **Dr. Richard Hambley, MD** **Date: 08/31/2007**

Organization : **Dr. Richard Hambley, MD**

Category : **Individual**

Issue Areas/Comments

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

August 31, 2007

The Honorable Herbert Kuhn
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Fax 202 690-6262

RE: CMS 1385-P: 2008 Medicare Fee Schedule
Coding Multiple Procedure Payment Reduction for Mohs Surgery

Dear Herbert Kuhn:

I am a Mohs surgeon in a small town in California. I am deeply concerned about the proposal to make Mohs surgery subject to the Multiple Procedure Reduction Rule.

Mohs micrographic surgery of CPT codes 17311 and 17313 has been proposed to become subject to the Multiple Procedure Reduction Rule (MPRR). I would like to convince you that it is wrong to make Mohs surgery subject to the MPRR. This is because the amount of work to do two Mohs surgeries on the same day or to do Mohs surgery followed by a reconstruction that costs more than the Mohs surgery does not significantly decrease the work of either. Unlike most surgeries, a lot of the payment for Mohs 17311 and 17313 is for work that is done on the tissue after it is removed from the patient and this is not lessened by doing other surgery on the patient. After tissue is excised from the patient I cleanse it, apply ink to the epidermis edge, diagram a map of the tissue and patient, divide the tissue into manageable size pieces, color code the margins, and align the pieces in order. Then each separate piece of tissue is frozen, mounted onto a metal disk, then sectioned in a cryostat. The shavings are mounted on slides, the slides a put through ten steps of staining, the slides are dried and cover slips mounted. I then examine all of every section under the microscope and diagram areas of residual cancer. These steps are time consuming and are the same if I am doing one or two Mohs surgeries or if I later do a reconstruction. It does not make since to cut the reimbursement for Mohs surgeries when other surgery is also done because so much of the work is not reduced.

I am concerned that the proposed cut in payment for multiple Mohs surgeries or Mohs surgeries requiring a reconstruction will make the surgery pay less than it costs me to provide the service. I am not sure how I could deal with the inadequate reimbursement but it would be terrible.

Mohs surgery should continue to be exempt from the Multiple Procedure Reduction Rule because that is fair. Please keep 17311 and 17313 exempt from the MPRR. Please feel free to call me if you have any questions.

Thank you,

Richard Hambley, MD
977B Pacific Street
Monterey, CA 93940
831 648-8000

Submitter : **Dr. Rose Campise-Luther** **Date: 08/31/2007**

Organization : **University of Illinois at Chicago**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Rose Campise-Luther, MD
Department of Anesthesiology
University of Illinois at Chicago

Submitter : **Dr. Matthew Fisher** **Date: 08/31/2007**

Organization : **UTMB Anesthesiology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

As a current resident in Anesthesiology at the University of Texas Medical Branch in Galveston, Texas, I am gaining the training necessary to provide optimal care and appreciate your consideration of this serious matter.

Submitter : Mr. Scott Peck **Date:** 08/31/2007

Organization : Olympic High School

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Scott Peck and I am a Certified Athletic trainer for Olympic High School.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Scott Peck MS, ATC

Submitter : Dr. edward kent **Date:** 08/31/2007

Organization : american society of interventional pain physicians

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. JEREMY JAMES **Date:** 08/31/2007

Organization : Mr. JEREMY JAMES

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Ms. Kate Watkins** **Date: 08/31/2007**

Organization : **Ms. Kate Watkins**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am a Certified Athletic Trainer in hopes of working for a hospital's outpatient rehabilitation clinic with a high school outreach program, or emergency department in the future. Ruling in favor of such revisions as outlined in this docket would not only make it nearly impossible for me to realize my occupational ideals, but it would essentially put those Certified Athletic Trainers already working in those areas at risk of losing their jobs.

Thank you.

Submitter : **Date: 08/31/2007**

Organization :

Category : Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 28, 2007

RE: PHYSICIAN SELF-REFERRAL PROVISIONS

Dear Sir or Madam,

I am writing to express my concerns regarding certain proposals in the recently released 2008 Proposed Physician Fee Schedule. As a physician practicing in Greer, SC as well as Columbus, NC, I fear that several of the proposed changes to the physician self-referral rules will needlessly and unjustifiably harm Medicare patients and providers. Although I understand and support the efforts by CMS to prevent abusive practices, I believe the current proposals will extend beyond this worthy goal to hamper valuable and legitimate joint venture arrangements. I believe that CMS could address its concerns in a much less intrusive manner.

As a urologist, I have seen firsthand the beneficial effects that joint ventures have had for the healthcare system. I have been involved with providing my patients lithotripsy and other cutting edge therapies for urological disease that would not have been widely available to my patients, including Medicare beneficiaries, unless physician joint ventures had provided the services. By accepting the risk of providing these costly services when hospitals refused to do so, urology joint ventures have greatly expanded patient access to worthwhile and effective treatments. Yet the proposals in your 2008 Physician Professional Fee Schedule attack the substance of the very joint ventures that by all accounts have saved Medicare millions of dollars and increased beneficiary access to effective treatments.

I will discuss below the various anti-physician ownership proposals that I believe will have a negative effect on the healthcare system, if adopted, in the order in which they were presented in the proposed rule.

1. Burden of Proof
CMS proposes that a provider should bear the burden of proving that referrals were not made in violation of Stark in any appeal of a denial of payment on this basis. This appears to me to require providers to prove a negative (that a prohibited arrangement leading to a referral did not exist), which would be difficult if not impossible to accomplish. Complicating matters is that most Stark exceptions require payments to be made at fair market value and in a manner that does not reflect the volume or value of referrals or other business between the parties. Valuation experts often disagree on that as fair market value and I am unable to think of an efficient and effective method of proving that a payment does not reflect the volume or value of referrals.

This proposal will mean that CMS or its contractors will sit as judge and jury over complex matters in which experts themselves may have varying opinions- with the burden of proof on the provider. This seems to me to be an abuse of power. If a better example of abuse of power can be shown, I would like to see it. Not only do I take care of the health problems of my Medicare beneficiary patients at a price set arbitrarily by CMS, I now face the burden of a hidden tax in which I must prove my actions were legal, rather than the governmental agency which writes the law proving that my actions were illegal.

2. Per Click Payments
As I understand, it was the intent of Congress, as recognized by CMS in its Phase I rulemaking, to permit time-based or unit-of-service-based payments for space and equipment leases. The proposal to prohibit these arrangements, therefore, directly contradicts Congressional intent. CMS should not prohibit an arrangement that Congress expressly intended to permit.

Moreover, CMS indicates that it is concerned with per click lease arrangements involving designated health services (DHS). Yet the proposed rule suggests that the prohibition will be applied to all lease arrangements in which physicians have ownership in the service, not only those involving DHS. Although I am unconvinced that per click arrangements are, by definition, abusive, at the very least the ban should not apply to

Submitter : KATHY LETENDRE **Date:** 08/31/2007

Organization : KATHY LETENDRE

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter : **Miss. Melissa Cruice** **Date: 08/31/2007**

Organization : **Haverford College**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am Melissa Cruice, ATC, CSCS. I am the assistant athletic trainer at Haverford College in Haverford, Pennsylvania. I hold a Bachelor of Science in Athletic Training from the University of Delaware and will complete my Master of Science in Exercise Science, with a concentration in Rehabilitation Science, in December, from California University of Pennsylvania. I have been a certified athletic trainer for 8 years. Although I currently work in the collegiate setting, I. have also worked in outpatient rehabilitation clinics.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality heath care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in the hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Melissa Ann Cruice, ATC, CSCS

Submitter : Mrs. Maryrose Gulapa **Date:** 08/31/2007

Organization : Bayonne Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I urge you to exlude phsyical therapy services from in-office ancillary services from the exceptions to the federal physiclian self-referral laws (Stark Law). Referral of physicians for theirs pts. to undergo physical therapy services from a facility wherein they have financial gains shows conflict of interest. The said physician would benefit from the said referral and it may not be widespread or applicable all the time , but such arrangement harbors overuse or abuse of system (self-referral for more financial benefits, orders for or continuation of uneeded services just because they are "under" the supervision of their "in-house" doctor).Why not eliminate any possibility of fraud and abuse in the first place? Some patients (who has had therapy before) even feel they don't have a choice of which facility to go to when their doctors tell them to undergo skilled PT from their own partly-owned facility. I hope you will review the exceptions to the stark law and close any loopholes to prevent faud and abusc and protect physical therapy services.

Submitter : **Ms. Patricia Taylor** **Date: 08/31/2007**

Organization : **Metro Hand Rehabilitation**

Category : **Physical Therapist**

Issue Areas/Comments

Background

Background

Dear Sirs,

I was unsure of where to enter my comment because the issue heading were confusing so I am entering it into the background heading. I am writing in regards to the proposed decrease in Medicare reimbursement to therapists.

I was shocked to see that a 9.9% decrease was proposed. When I reviewed my monthly operating statement for July, I noticed that when all expenses including write-offs, therapist and office staff salaries, rent, and medical supplies were paid it costs me $87.61 per patient visit to operate my clinic. The expected Medicare reimbursement for one of our typical visits would be moist heat(not paid), ultrasound (10.59), paraffin (5.93), and two units of therapeutic exercise (2 @ 24.53) for a total of $65.58. We are already operating at a deficit for this group of patients and you want to cut it an additional 9.9%!!!!!

I operate a group of outpatient non hospital based clinics that specializes in hand therapy. Our typical therapist salary is $35-40 an hour. Therapists salaries continue to increase as the shortage increases and you are going to force us into a situation where we will not be able to continue seeing Medicare patients at a deficit! We already operate with profit margins of only 10-15%. We have to be financially responsible at some point and begin to say 'no".

Please do not do this. I was actually expecting an increase in reimbursement and was shocked to see that you felt our services were worth even less than what you currently pay! Especially since your regulations require increased time in documentation and your non allowance of support personnel to assist with treatment causes more one on one time between therapists and patients which also increases direct costs of providing care.

Do not dump us into the same category as physicians and their services. We have much tighter profit margins and I feel we need separate consideration for our reimbursement.

Please do not do this! I would be happy to discuss this further if you would like to speak to me at (405) 359-7575

Thank you for your time

Patricia A. Taylor, PT, CHT

Submitter : Mr. kirk steinam **Date:** 08/31/2007

Organization : Manhatan beach animal hospital

Category : Other Health Care Professional

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

I support increase in anesthesiologist reimbursement to a reasonable level in face of cost of running a practice, malpractice insurance and cost of living. Medicare patients, and all of us when we grow old, will depend on fast action and critical care by anesthesiologist during critical time in our illness. We cannot make this specialty so undesirable that few qualified medical students will be interested in this field.

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

PHYSICIAN SELF REFERRAL PROVISIONS SEE ATTACHMENT

15520

EPARTMENT OF HEALTH AND HUMAN SERVICES
ENTERS FOR MEDICARE AND MEDICAID SERIVICES
FFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

lea.. note: We did not receive the attachment that was cited in his comment. We are not able to receive attachments that have been repared in excel or zip files. Also, the commenter must click the ellow "Attach File" button to forward the attachment.

lease direct your questions or comments to 1 800 743-3951..

Submitter : **Jaime Lowe** **Date: 08/31/2007**

Organization : **Tuality Hospital**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer and certified strength and conditioning specialist formerly employed by Tuality Hospital in Hillsboro, Oregon. My duties in that position included rehabilitation of athletes and the physically active in the outpatient setting as well as sports medicine coverage for a local high school. I held that position for 8 years before recently relocating to Hawaii after obtaining a similar position in the high school setting.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jaime M. Lowe, ATC, CSCS

Submitter : **Date: 08/31/2007**

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

The Physician Work RVU-CPT 77080 (DXA)
The Direct Practice Expense RVU for 77080 (DXA)
Indirect Practice Expense for DXA and VFA
Deficit Reduction Act

Dear Mr. Weems:

I appreciate the opportunity to offer general comments on the proposed rule regarding changes to the Medicare physician fee schedule CMS-1385-P.
As a provider of DXA and/or VFA services, I request CMS to reevaluate the following:
a. The Physician Work RVU for 77080 (DXA) should be increased from 0.2 to 0.5, consistent with the most comprehensive survey data available;
b. The Direct Practice Expense RVU for 77080 (DXA) should reflect the following adjustments:
? the equipment type for DXA should be changed from pencil beam to fan beam with a corresponding increase in equipment cost from $41,000 to $85,000;
? the utilization rate for preventive health services involving equipment designed to diagnose and treat a single disease or a preventive health service should be calculated in a different manner than other utilization rates so as to reflect the actual utilization of that service. In the case of DXA and VFA, the 50% utilization rate should be changed to reflect the utilization rate for DXA to 12%.
c. The inputs used to derive Indirect Practice Expense for DXA and VFA should be made available to the general public, and
d. DXA (77080) should not be considered an imaging service within the meaning of the section 5012 (b) of the Deficit Reduction Act of 2005 because the diagnosis and treatment of osteoporosis is based on a score and not an image.

Submitter : Mr. Gary Schindler **Date:** 08/31/2007

Organization : Spine and Sport Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15523-Attach-1.DOC

15523

Gary D. Schindler PT, ATC, CSCS
Spine & Sport Physical Therapy
586 Shepard Street
Rhinelander, WI 54501

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Medicare Program;
Proposed Revisions to Payment Policies under the Physician Fee Schedule,
and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Kerry,

I wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. I would like to highlight the abusive nature of physician-owned physical therapy services and support PT services removal from permitted services under the in-office ancillary exception.

I am a Physical Therapist (PT) practicing in a relatively rural area of Northern Wisconsin in a Physical Therapist owned practice for over 5 years. We are Neuromusculoskeletal experts in outpatient orthopedics, and add value to the quality of life for many individuals in our three clinic sites. One of the biggest threats to our business in Wisconsin continues to be a local physician group that would choose to open a PT practice they would own. We already have more than enough competition in our small service area including a "Non-profit" health system .

In many areas of the country physical therapy clinics are barely surviving the impact of physician groups (including orthopedists) opening PT practices and referring directly to themselves. In our local area a hospital system tries to dominate the local market and control physician referrals; but our relationships with the local physicians, grass roots marketing efforts, local community involvement and our quality of care allows us to survive. If our independent orthopedists (who currently display excellent ethical, legal, and community minded behavior) decided to employ their own PT's or rehabilitation services, as has happened in so many other areas, I do not know if we could survive.

Please remove the temptation of physicians in unethical referral for profit by removing Physical Therapy as a Designated Health Service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws. I know this is supported by the majority of physicians who practice ethically, and would not cross that line.

In addition, as you probably know, physician direct supervision is not needed to administer physical therapy services. However, I recently learned that an increasing number of physician-owned physical therapy clinics are using the reassignment of benefits laws to collect payment in order to circumvent "incident-to" requirements.

Please put an end to the above ethical temptations by clearly stating that referral for profit is illegal, and be sure to maintain Physical Therapy Services are to be provided for consumers by Physical Therapists and

Physical Therapist Assistants only, to protect the safety of the public, and to be sure that they are truly receiving Physical Therapy!

Please feel free to contact me for any additional information, and thank-you for taking action in this critical area of potential fraud and abuse.

Sincerely,

Gary D. Schindler PT, ATC, CSCS
(Physical Therapist WI Lic. #9766-024, Certified Athletic Trainer # 069902725)

Submitter : **Dr. Ronald Osborn** **Date: 08/31/2007**

Organization : **Dr. Ronald Osborn**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When thc RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Ronald D. Osborn, D.O.
Anesthesiologist

Submitter : **Mr. James Brown** **Date: 08/31/2007**

Organization : **J. Clifford Brown DC**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: TECHNICAL CORRECTIONS

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medieare for an X-ray taken by a non-treating provider and used by a Doetor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, ete.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

J. Clifford Brown DC

Submitter : Mr. Ethan Nayback **Date:** 08/31/2007

Organization : Hillsdale Community Health Center

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I'm Ethan Nayback, ATC, a recent graduate of an accredited athletic training program. I believe, as an athletic trainer, I am equally qualified at my job as a PTA employee, if not more-so in some aspects of the rehabilitation process. This policy could greatly effect my job and livelihood as an athletic trainer. There should be a field study executed to test the skills of a PTA and an ATC to test the skill level of each in regards to their own educational basics. I believe this type of study would greatly show that athletic trainers are equally compatible, if not above the level of entry level PTA's.

Submitter : **Mr. Doug Hepburn** **Date: 08/31/2007**

Organization : **Pioneer Sports Medicine and Physical Therapy**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Doug Hepburn and I am a Certified Athletic Trianer. I have recieved a bachelors degree and a masters. I have been working in the physical therapy and high school setting for 8 years. I have worked with all medical professions with much success. I have trained and educated many athletic trainers and physical therapists.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Doug Hepburn MS, ATC

Submitter : **Date: 08/31/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please support the proposed changes to Stark III concerning physician referred PT/OT clinics. Most patients are not aware that they have a choice for these services after their doctor has "recommended" his or her facility. Not all clinics are equal in price or practice, and this is definitely a conflict of interest. It is too easy to scam both the patient and insurance companies.

Submitter : **Jeff Smith** **Date: 08/31/2007**

Organization : **Abilene Sports Medicine**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

This is Jeff Smith from Abilene, TX. I am a Texas Licensed and nationally certified athletic trainer (LAT, ATC). I received both my BBS and MEd from Hardin-Simmons University here in Abilene. I am currently employed as an athletic trainer for Abilene Sports Medicine & Orthopedics.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jeff Smith, ATC, LAT

Submitter : Dr. Forrest Hamon **Date:** 08/31/2007

Organization : Metro Anesthesia

Category : Physician

Issue Areas/Comments

Background

Background

I am an anesthesiologist practicing in Arizona, where a significant number of medicare beneficiaries live. The work value proposal for anesthesia services is badly needed. Medicare reimburses less than 40% of commercial insurance rates. Our seniors should not be less desireable patients than those with commercial insurance. Hospitals and practices in higher than average medicare populations continue to have difficulty obtaining coverage for anesthesia services since physicians can go elsewhere and receive higher reimbursement for the same work. I urge the adoption of the anesthesia work value increase

Submitter : **Dr. Beth Ann Traylor** **Date: 08/31/2007**

Organization : **Anesthesia Consultants of Indianapolis**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from arcas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To cnsure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Beth Ann Traylor M.D.

Submitter : **Mr. Keith Berman** **Date: 08/31/2007**

Organization : **Health Research Associates**

Category : **Individual**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Dear CMS:

PLEASE REPLACE TEMP. COMMENT #209338 (CMS-1385-P-T209238-Attach-1.doc) and TEMP. COMMENT #209332 (CMS-1385-P-T209332-Attach-1.doc) WITH THE ATTACHED COMMENT LETTER. The earlier versions contained text and format errors.

I apologize for this inconvenience.

Keith Berman

CMS-1385-P-15532-Attach-1.DOC

Health Research Associates

HRA

2500 E. Foothill Blvd., Suite 408
Pasadena, CA 91107-7125 USA
(626) 564-0456 fax: (626) 564-1010
e-mail: kberman@sbcglobal.net

August 30, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: **CMS-1385-P**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: RESOURCE-BASED PE RVUs – Photopheresis and Therapeutic Plasma Exchange

Extracorporeal photopheresis (CPT 36522) and therapeutic plasma exchange (TPE; CPT 36514) can be safely provided in a physician-directed clinic, and are each covered by Medicare for a number of serious hematological, neurological and/or autoimmune disorders in this setting.[1,2]

Like many other procedures that began in the hospital setting and have moved to the physician office or clinic, benefits of doing so with photopheresis and TPE include an improved patient treatment experience, reduced nosocomial infection risk in these usually immunocompromised patients, and potentially significant overall cost savings to the Medicare Trust Fund.

Unfortunately, physicians interested in bringing these two historically hospital-based apheresis procedures into the office-based setting are being completely stymied by severe under-valuations of their proposed "fully implemented" practice expense RVUs (PE RVUs). The proposed valuations will yield payment rates that fall far short of actual direct and indirect costs of providing these unusually supply-intensive procedures.

The basis for this undervaluation is driven by CMS' application of a roughly 40% "direct PE budget neutrality adjustment" ("direct adjustment"),[3] which CMS applies equally to clinical labor, supplies and equipment expenses. The impact of this "direct adjuster" then ripples through the entire calculation of PE RVUs: the "adjusted direct RVUs," reduced by about 40%, are fed into the indirect RVU calculation: *Indirect Pct * (Adj. Direct*

---

[1] Medicare Coverage Manual Sect. 110.14 (Coverage Issues Manual §35.60).
[2] *Fed Reg.* July 12, 2007; 72(133):38273.
[3] This direct adjuster appears likely to range between the 0.584 value published in the July 12 *Federal Register* and the 0.6186 value used in a sample PE RVU calculation for TPE which was provided to me by CMS.

RVU/Direct Pct.) + Work RVU, which in turn is further sharply reduced by an "indirect adjustment."

Applying SMS and supplemental survey data across all physicians, a hypothetical procedure involving 5 physician work RVUs and $100 in direct practice expense is accompanied by roughly $200 in indirect practice expense, for a total of $300.[4] At the end of the sequence of adjustments that CMS uses to bring down payments to match available budget dollars, that presumptive $300 in non-physician practice expenses has been pared to an average payment rate of roughly $130.

One might ask how physician providers, for whom Medicare patients often constitute a large share if not the bulk of their caseload, can afford to accept and treat Medicare patients without losing huge amounts of money and quickly going out of business. That they *are* accepting Medicare patients and not going out of business all but dictates that there is a large and widespread overstatement of direct cost inputs for many or most of the 7,000-odd procedures and services, despite having passed through the AMA "refinement" process by its RUC and PEAC bodies.

Because the allocation of RVUs is a "zero-sum" game where more RVUs assigned for some procedures means less for others, there is unfortunately a powerful incentive for physician survey respondents and medical specialty societies to exaggerate cost inputs.

In the case of photopheresis and TPE, I will document that the direct cost inputs for these two services are *not* exaggerated and that proposed fully transitioned PE RVUs fall well short of actual costs. I will then address how these and likely certain other highly supply-intensive procedures are systematically undervalued using the proposed PE RVU development methodology, and finally I will suggest an methodological "fix" that will enable providers to cover their actual costs and provide this pair of important services.

For each procedure, below are:

1. Aggregated direct clinical labor, supply and equipment costs;
2. Total direct PE RVUs and "adjusted" total direct PE RVUs
3. Calculated indirect PE RVUs applying direct cost-adjusted PE RVUs;
4. Total direct costs restated in RVUs, applying the originally scheduled 2007 conversion factor (CF) of $35.9848 per RVU..

Some values presented below in Table 1 may not exactly agree with your calculated values, but I believe they are fair approximations for purposes of understanding the nature and rough magnitude of our underpayment issue.

---

[4] *Fed Reg.* July 12, 2007; 72(133):38132. Table 2 (all physicians).

Table 1. Unadjusted and adjusted direct and indirect PEs

Therapeutic Plasma Exchange (CPT 36514):

	Direct Costs (CPEP)	Direct PE RVUs	Total Direct RVUs Total Direct Adj. RVUs[5]
Clinical labor	$76.86	2.136	***9.13*** ↓ **5.65**
Supplies	$210.08	5.838	
Equipment	$41.67	1.158	
Total direct costs:	**$328.61**	***9.13***	+ Total Indirect Adj. RVUs[6] **4.76**

Proposed fully implemented non-facility PE RVUs: **10.41**

Photopheresis (CPT 36522):

	Direct Costs (CPEP)	Direct PE RVUs	Total Direct RVUs Total Direct RVUs (Adj.)[5]
Clinical labor	$92	2.56	***32.98*** ↓ **20.40**
Supplies[7]	$1,045	29.03	
Equipment[8]	$50	1.39	
Total direct costs:	**$1,187**	***32.98***	+ Total Indirect Adj. RVUs[9] **16.64**

Proposed fully implemented non-facility PE RVUs: **37.04**

The mathematics of arriving at total PE RVUs that "fully implement" the CMS "bottom-up" methodology are no different for any of the other 7,000-odd procedures and services in the Physician Fee Schedule. However, one very important distinction sets these two

[5] Applying a "direct adjustment" factor of 0.60 to total direct RVUs; CMS applied 0.584 in 7/12/07 *Fed. Reg.*
[6] Applying an indirect adjustment factor of 0.362 to total indirect RVUs, followed by a 0.973 PCI adjustment
[7] Based on CPEP supply , updated with current average prices for photopheresis procedure kit ($976.39) and methoxsalen ($59.48) which have been submitted separately in a comment letter from the American Academy of Dermatology. NOTE: procedure kit price reflects discounts based on very high volume orders by large hospital users.
[8] Estimated from CPEP equipment , with addition of light source, photopheresis, whose average price is approximately $8.64 per procedure (source: Therakos Inc.).
[9] Applying an indirect adjustment factor of 0.362 to total indirect RVUs, followed by a 0.973 PCI adjustment

services (and likely a small number of others) apart: disposable supplies account for most -- 64% and 88% -- of the direct practice expense for TPE and photopheresis, respectively.

CPEP database – direct supply costs

TPE procedure. The CPEP supply inputs accurately reflect both the types and quantities of supplies that are actually used for this procedure. Notably, the major disposable item, the tubing set used in tandem with the apheresis machine, accounts for about 83% of total supply costs, while the remaining 17% comprises mostly inexpensive items commonly used in IV injection and blood collection procedures.

The $173.33 price identified for the tubing set, entered into the CPEP file in 2004, reasonably approximates the average selling price (ASP) by the product's leading supplier, which serves approximately 85-90% of the U.S. market.[10] However, this ASP reflects the heavy influence of very large-volume purchase activity – in the thousands of units – by the small minority of its largest customers, whose pricing is well below $173. Approximately 80% of customers – individual hospitals and clinics – pay between $190 and $215 (the current list price) per tubing set, reflecting in part their higher transaction and customer service-related costs. Generally the smaller the customer, the higher the unit price; according to the leading manufacturer, the ASP for most physician-directed clinics will fall close to the list price.[10]

The price for the tubing set in the CPEP database is therefore roughly $20 to $40 below the actual cost that applies for relatively low-volume physician-directed offices. The total of $210.08 that CMS presumes to reflect actual supply costs therefore may underestimate actual costs by roughly 10% to 15%, more importantly, it certainly is not an overestimate.

Photopheresis procedure. While most supply items in the CPEP database are accurate, a few important corrections need to be made. I have collaborated with the American Academy of Dermatology on these issues, and you should receive comments from the Academy requesting specific item and pricing corrections. In particular, the price identified for the photopheresis procedure kit ($858) is about $118 lower than the year-to-date ASP supplied by the manufacturer ($976.39).

Like the circumstance with the TPE tubing set, the price of this item is tiered according to customer ordering volume. At one end of the pricing spectrum are very large hospital-based cancer centers, which pay marginally less than $976 per kit. At the other end are smaller programs, including the office-based photopheresis provider, which ordinarily purchase between 4 to 36 kits ($1,100 per kit) or 37 to 104 kits ($1,013.25 per kit). At an order quantity of more than 104 kits, the price drops to about $900 per kit. Rarely if ever

[10] Personal communication: Dawson Smith, Director of Sales, Therapeutics Division, North America, Gambro BCT, Inc.

would an office-based provider purchase the nearly $100,000 worth of inventory required to capture the lower $900 per kit price.

Thus, the current CPEP price for the kit, which accounts for fully 93% of total procedural supply costs, is more accurately between $155 and $245 lower than the actual price now paid by the small office-based customer.

Again, the supply component of direct costs for photopheresis are moderately understated, and certainly not overstated.

CPEP database – direct clinical labor costs

For both TPE and photopheresis, direct labor costs are a significant element of total costs, but are dwarfed by supply costs. It happens that these procedures are unusual, however, for the fact that a highly trained nurse specialist must work one-on-one through the set-up, intra-procedural phase and post-procedural phase. I understand that CMS officers have personally observed this procedure and are aware that there are no meaningful opportunities for staff "multi-tasking" during this complex procedure, which requires many steps and close monitoring of the patient's vital signs and overall health status.

Underpayment for TPE and photopheresis: a formula-driven problem

As noted earlier and presented in Table 1, supply costs account for about 64% and 83% of total direct costs in TPE and photopheresis procedures, respectively. According to data supplied by CMS at a February 15, 2006 Town Hall meeting[11] to address PE methodology options, supplies accounted for just 18% of total practice expense-related payments under the PFS.

In contrast, two other survey processes found that supplies account for 28% or 32.3% of total direct costs (Table 2):

Table 2. Cost distribution of direct PEs by SMS and SMS/supplemental surveys

Source	Clinical labor	Supplies	Equipment
SMS surveys[11]	57%	**28%**	16%
Fed Reg 7/12/07; 38132; Table 2	53.7% ($15.68/hr)	**32.3%** ($9.44/hr)	14.0% ($4.08/hr)

[11] Summary of CMS Town Hall Meeting on Practice Expense (PE) Methodology, Feb. 15, 2006. Prepared by the American Society of Nuclear Cardiology. File attached to this comment letter and available online at: http://www.asnc.org/imageuploads/HPM%206%20-%20Summary%20of%20CMS%20February%2015%20Town%20Hall%20meeting%20on%20PE.pdf

While random surveys of physicians imply that supplies account for roughly 30% of direct practice expenses, the contribution of supplies driven by CPEP inputs via the RUC/PEAC process is (or recently was) just 18% of the total.

This suggests that supplies are underrepresented as a proportion of overall direct practice expenses. I propose that the review and audit of procedural supply inputs is far more objective and readily auditable than is the case for either clinical labor or equipment. Both clinical labor time and equipment amortization demand very close and extensive investigation, of a nature that I believe was at best only partly accomplished by the RUC/PEAC direct PE "refinement" process.

The most obvious means of clinical labor overstatement is assignment of more activity minutes by clinical staff persons than actually are devoted to the procedure or service. Equipment cost overstatement can be occur, for example, through overstatement of the cost of capital equipment items and/or useful life of those items. In the instance of the two procedures in consideration here, equipment-related costs account for a small contribution (13% and 4% for TPE and photopheresis, respectively).

Consequently, the dramatic formulaic reductions by CMS in direct PE across labor, supplies and equipment is – and must be – ameliorated for many or most services by significant overstatements of labor and equipment amortization costs.

In the case of TPE and photopheresis, where direct supply costs constitute most of direct cost burden, the "direct adjustment" factor of approximately 40% reduces very real costs that are actually paid before the procedure can even be initiated.

Consider the direct PEs for these two procedures and the proposed payment rate based on the currently published "fully implemented" PE RVUs:

Procedure	Direct procedural costs	Proposed PE RVUs	Proposed payment ($36/RVU)	Implied indirect RVUs and payment
TPE	$328.61	**10.41**	$374.76	**1.28** ($46.15)
Photophereresis	$1,187	**37.04**	$1,333	**4.05** ($146)

The effective indirect cost contribution of the proposed fully implemented PE RVUs is therefore 1.28/10.41 = 12.3% for TPE and 4.05/37.04 = 10.9% for photopheresis.

These contributions to indirect practice overhead are clearly far below what is financially feasible for office-based providers.

Recommendation

I recommend that CMS make a single modification to its direct PE RVU adjustment formula, to address procedures for which supply costs represent more than 40% to 50% of total direct costs.

Specifically, I recommend that, for procedures for which supply costs represent more than 40% to 50% of total direct costs, that all supply costs be passed through and the direct adjustment factor be applied as usual to direct labor and equipment costs sourced from the CPEP database.

I recognize that, to remain compliant with your budget neutrality imperative, this will necessitate a small adjustment in the direct adjustment factor to assure that total RVUs remain unchanged.

Amid all the jockeying by various interest groups to capture Medicare practice expense dollars, and CMS' sincere efforts to fairly allocate those dollars, are a relatively small number of procedures, provided by a small cadre of trained specialists, that do not have the good fortune to have a vocal or well-financed organization to aggressively advocate for them. For two of these procedures – photopheresis and TPE – the losers stand to be seriously ill patients with such diagnoses as cutaneous T-cell lymphoma, chronic graft-versus-host disease, myasthenia gravis and chronic relapsing polyneuropathy.

While I ask you to resolve the unfair and financially untenable impact of the "direct adjustment" on these two supply-intensive services, I would also like to commend the work of the CMS staff, who face the unenviable task of balancing the interests of U.S. taxpayers, providers and the Medicare beneficiaries they ultimately serve.

In a recent phone discussion recently about our particular concern, a CMS officer reassured me that "we want to get this right."

On behalf of office-based providers and Medicare beneficiaries who require photopheresis and therapeutic plasma exchange, I am confident that you will get this right.

Sincerely,

Keith E. Berman, MPH, MBA

cc: Rick Ensor, CMS
Terry Kay, CMS
Carolyn Mullen, CMS
Don Thompson, CMS
Pam West, CMS

Submitter : Dr. Alexander Omura **Date:** 08/31/2007

Organization : Dr. Alexander Omura

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-1385-P Anesthesia Coding (Part of 5-year Review)

Dear Ms. Norwalk:

I am writing to support the proposed increase the Anesthesia reimbursement for the 2008 Fee Schedule. In most practices, Medicare is the most common payer, and the current payment of just $16.19 per unit is so undervalued that in areas with a high percentage of Seniors, it it difficult or impossible to recruit new anesthesiologists. This has and will limit the availability of medical services to our nation's Seniors.

Several months ago my dishwasher broke, and the repairman who came during regular hours charged a substantially higher hourly rate than I am reimbursed by Medicare. The proposed increase in Medicare reimbursement is a major step towards correcting the undervaluation of Anesthesia work compared to other medical services.

Thank you,
Alexander Omura, MD
Missoula, MT

Submitter : **Dr. Beth Ann Traylor** **Date: 08/31/2007**

Organization : **Anesthesia Consultants of Indianapolis**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Beth Ann Traylor M.D.

Submitter : **Mr. Robert Runge** **Date: 08/31/2007**

Organization : **Mr. Robert Runge**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I strongly urge CMS to remove physical therapy as a designated health service permissible under the in-office ancillary exception of the federal physician self-referral laws. Thank you for considering my comments.

CMS-1385-P-15535-Attach-1.DOC

15535

Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Physician Self-Referral Issues

Dear Ms. Weems:

I am a physical therapist writing to express my concerns regarding physician self referral. I own a small physical therapy practice and have seen an increase physician self referral. These self referral relationships have a significant potential for abuse. There are physician owned clinics in our area that have an unusually high number of physical therapists employed considering the size of the physician practice. Some clinics use reassignment of benefit agreements to circumvent current "incident-to service" requirements. I believe that Medicare beneficiaries are best served by physical therapists that have no financial relationship with the referring providers. Current "in-office ancillary services" exception creates opportunities for expansion of physician owned arrangements and which can lead to physical therapy services that are being provided by unqualified staff.

There are also corporate providers that provide incentives (bonuses) or disincentives (loss of bonuses) which are tied to a percentage of patients that are referred to "in house" services. I have had some patients complain that they are pressured excessively by their physicians to stay with the "in house" physical therapy service. Some of those patients will insist on choosing their own physical therapy provider while others will give in and go to the "in house" corporate PT department. Some of those referred under such arrangements are Medicare Beneficiaries. I believe that CMS has an obligation to protect the rights of Medicare Beneficiaries to choose providers that they feel offer quality care rather than being directed to receive care where it is most financially beneficial to the referring physician.

I strongly urge CMS to remove physical therapy as a designated health service permissible under the in-office ancillary exception of the federal physician self-referral laws. Thank you for considering my comments.

Sincerely,

Robert Runge PT OCS CSCS
420 N. Koeller St.
Oshkosh, Wisconsin 54902

Submitter : Lennea Zink **Date:** 08/31/2007

Organization : Foothills Orthopedic and Sport Therapy

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

There is an increasing amount of physicans who own practices that are providing physical therapy services. I feel this increases the potential for fraud and abuse when physicians are able to refer medicare beneficiaries to places in which they have a financial interest. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to over-utilize those services for financial reasons. By eliminating physical therapy as a DHS furnished under the in-office ancillary services exception, CMS would reduce the amount of potential abuse and over-utilization of physical therapy services under the medicare program, and enhance the quality of patient care. In the past few years I have seen several patients who have been to local physician owned practices and then come our practice due to location or dissatisfication of previous care who have informed me that they were strongly encouraged to have physical therapy at the physician's office and were not given additional choices for therapy. Due to current medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. In addition, due to the repetitive nature of physical therapy services it is no more convenient for patients to recieve services in the physicians office than at an independent physical therapy practice. Physician direct supervision is not needed to administer physical therapy services. Thank you very much for your consideration of my comments. Sincerely, Lennea Zink, MSPT

15537

Submitter :

Date: 08/31/2007

Organization :

Category : Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please see attached Word document

CMS-1385-P-15537-Attach-1.DOC

Re: Physical Therapy as in-office ancillary service:

It is important that CMS recognizes that there are critical differences among the types of physician practices that employ physical therapists in order to provide in-office physical therapy.

In my geographic area there are several such practices--those operated by family physicians as part of their family practices, a hospital-sponsored office-based occupational/industrial medicine practice, orthopedic surgery practices, and a physical medicine spine rehabilitation practice.

Most of these practices can make a good case for providing in-house physical therapy (PT) services:
For the orthopedic practices, the issue of programmed post-op PT by therapists familiar with the techniques and desires of the specific operating surgeon provides consistency and quality control, the chance to respond immediately to complications, and assures a better functional outcome. In-house PT guarantees these outcomes best.
For the occupational med/industrial med practice, business and industry frequently contract or prearrange that such services such as PT can be provided at a per-head cost that is hard to assure unless the provided service itself is controlled. By keeping such services in-house, it can be priced and sold, and the level of care is consistent. Also, the industrial/occupational arena has unique aspects regarding providing services as an extension of the employer--this is best effected under a single practice's "banner". There are also worker's compensation issues that can get quite out-of-hand if one practice is "played" against another by competing interests..
In the case of the physical medicine spine rehab practice, under one roof are physician, physical therapists, and physical therapy assistants whose sole collective purpose is to evaluate, diagnose and non-invasively treat patients with non-operative or post-operative spine conditions. The seamless and comprehensive care that can be provided in such a setting benefits the patient and assures that this most basic level of spine treatment (compared to injections and surgeries) has been competently and consistently provided to all patients before they might move "up the ladder" to more invasive and costly procedures.

The American Physical Therapy Association discourages any form of employment of physical therapists by a physician-owned entity (Physician Owned Physical Therapy Services--"POPTS"). Of those practicies described above, it is only in the family practice model that "physical therapy" is provided as a purely ancillary (dictionary definition: "subsidiary, subordinate, auxiliary) service. The family practice could just as easily offer ultrasound or bone density screening, as long as it employs the proper personnel and contracts for the appropriate equipment. But in the case of the occupational/industrial med practice, the PT offering is central to the mission, which is to provide a "one-stop shop" for the employer-customers. Similarly, in the orthopedic practices, the desire to assure consistency and quality of results of their surgical interventions justifies that the

patients are seen-through until the end. Finally, in the physical medicine spine rehab practice, physical therapy IS what is practiced as an integral component of the physician-physical therapy practice—it is part of why the practice even exists, i.e., PT is not an "ancillary" service when the practice exists to provide the service. The "purity" of this model illustrates an area that APTA does not address in its arguments against POPTS. I would contend that APTA should define what kind of practices provides PT as an ancillary service, versus the practices that exist to provide PT as part of their central mission. "Conspicuous by its absence" is any argument by APTA that contends that quality and consistency of care suffers in a single-purpose environment as several that were outlined above. As such, I would contend that the ownership of the physical therapy service is the real issue...

The single-purpose environment of a practice makes good medical sense for the reasons stated above. If physical therapists were the owners, there would be no issue. While APTA does not call POPTS "unethical", they do describe it as a matter of "poor public policy" that results in possible abuse of the "quality' and "price" of PT, and puts independent physical therapists at a disadvantage in the free-marketplace. It is notable that APTA provides neither support nor representation to its members that work in a POPTS practice. It is also notable that APTA refuses to allow any employment advertising by POPTS in their national or state-affiliated publications. Even if a physical therapy practice is half-owned or even 99%-owned by the physical therapist, no representation or advertising privileges are accorded.

CMS should continue the present program of reimbursement for physical therapy services. APTA does not speak for all its physical therapist membership—especially its members that work in a POPTS setting. APTA is fighting against in-office physical therapy services across the board for economic issues that are cloaked as a quality of care issue. There may be an argument against PT as a purely ancillary service in some practice settings, but CMS must not simplify the issues (as APTA would wish) and should not become party to a matter that is more political than anything else.

Submitter : Dr. Scott Picker **Date:** 08/31/2007

Organization : Conejo Los Robles Anesthesia Medical Group

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Scott D. Picker, M.D.
double-reefed@charter.net

Submitter : Mr. Scott DeCiantis **Date:** 08/31/2007

Organization : USC Aiken

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am an Instructor in the Exercise and Sports Science Department at USC Aiken. I educate students interested in many fields within Exercise Science, including Athletic Training. One of my experiences that I always share with the students is my former work in the clinical setting, where I, as a Certified Athletic Trainer, treated patients referred by physicians for Sports Medicine rehabilitation. I worked in the outpatient rehabilitation clinic of a hospital, where I treated my own patient load alongside other rehabilitation professionals, such as physical therapists and occupational therapists. This was an excellent work setting for me, and I believe that I provided a high level of cost-effective care to the patients who were referred by physicians to be treated under my care.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Scott A. DeCiantis, MS, ATC
Instructor in Exercise and Sports Science
University of South Carolina Aiken
471 University Parkway
Aiken, SC 29801
Office: 132 B&E
Phone: (803) 641-3207
Fax: (803) 641-3723
Email: scottd@usca.edu
www.usca.edu

Submitter : **Donna Farrell** **Date: 08/31/2007**

Organization : **Physiotherapy Associates**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Donna Farrell and I am a certified athletic trainer employed in a physical therapy clinic. Through this position I provide outreach AT services to a high school.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Donna M. Farrell ATC

Submitter : **Mrs. Sarah Chapman** **Date: 08/31/2007**

Organization : **Alabama Orthopedic Clinic**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To whom it may concern:

I would like to thank you for allowing me to comment regarding self referral provision. Im a Physical Thearapist Assistant and have been employed previously by an independent clinc and now by a physician owned clinic. After working in both clinics I would like to express how much more constant care is when a therapist has a direct relationship with a referring physcian. When a thearapist is able to walk next door while the patient is in the clinic, to discuss a specific treatment ,protocol ,suggest DME, or give an update on progress. versus calling leaving a message and hoping for a return call in a few hours, the patient directly benefits. As it will be that day of treatment will be implemented. Doctor visits and thearpy visits can also be made in the same day. When a new doctor or therapist is added to a team a relationship starts that day, Not months later with a rumor of a new person in town.

Ultimately when our patients or a person are debilitated in some way the convinence of being able to come to one place and recieve the services they need makes every person a happier person period.

Submitter : Mr. Michael Clanton **Date:** 08/31/2007

Organization : ProTherapy

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Michael Clanton. I am an athletic trainer working for a rehabilitation clinic named Pro Therapy in Gainesville, GA. My primary duties at Pro Therapy are as the head trainer for the entire athletic Department at Brenau University, a NAIA women's college, however I also work with the athletes of the local area high school programs during the week. I also see patients needing rehabilitation for their injuries whether injured on the job as worker s comp or weekend warriors billable through their private health insurances in the mornings in my clinic.

I have completed the requirements for both the Master's degree in Sports Management and the NATA Certification Exam as well as a bachelor degree in Zoology/Pre-Med. I am licensed both as an athletic trainer and an emergency Medical technician in the state of Georgia. I am also a certified strength and conditioning specialist.

Prior to my taking the position at ProTherapy, I worked as the trainer for the University of Georgia's basketball team from 1990 to 2005. During my tenure as an athletic trainer, I have worked with many individuals who have signed professional contracts in football, baseball and basketball, including Derek Lilliquist, Cris Carpenter, and Steve Carter in baseball, Scott Adams, Bill Goldberg, Ben Smith, Tim Worley, Rodney Hampton and many others in Pro Football, Alec Kessler, Litterial Green in professional basketball. Also, I have worked with several Olympic athletes.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services, and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Michael D Clanton M.Ed., ATC, CSCS, NREMT-I
Pro Therapy Rehab\ Brenau University Athletics
655 Jesse Jewell Parkway Suite C
Gainesville, GA 30501
770-539-9001 work
770-539-9217 fax
706-338-2716 cell

Submitter : **Dr. Kirby Tirk** **Date: 08/31/2007**

Organization : **American Society of Anesthesiologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I strongly urgc you to approve the increase in the Medicare conversion factor..Because of the undervaluation of Anesthesia services in my area (SE Pennsylvania), we are having difficulty recruiting qualified physicians to bolster our aging workforce..

Yours truly,

Kirby Tirk ,MD

Submitter : **Dr. Unser Khan** **Date: 08/31/2007**

Organization : **Dr. Unser Khan**

Category : **Physician**

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Unser Khan
7728 Yosemite Lane
Parkland, FL 33067

Submitter : **Brenda Bucol** **Date: 08/31/2007**

Organization : **Brenda Bucol**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter

Submitter : Mr. Patrick Laverty **Date:** 08/31/2007

Organization : Modern Nuclear, Inc.

Category : Health Care Industry

Issue Areas/Comments

IDTF Issues

IDTF Issues

This comment is in regards to the established criteria for interpreting physicians for IDTFs. Specifically Nuclear Medicine studies. An exception should be made to include Cardiologist that are certified for the interpretation of nuclear cardiology studies for an IDTF. When the Department of Health Services, Radiologic Health Branch, recognise and allow the interpreation of nuclear cardiology studies by cardiologist Medicare should also be allow interpetation of nuclear cardiology studies for an IDTF. They have demonstrated competency in this area. As a mobile provider primarily in the nuclear cardiac field it would be a benefit for us, and the patients we service alike having the ability to use such physicians expertise in the interpretation of nuclear medicine cardiac studies.

Submitter : Mr. Kevin Crossman **Date:** 08/31/2007

Organization : Agility Health

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To whom it may concern,

I would like to voice my opinion against physician self-referral for Physical Therapy Services.
I have been practicing for over 20 years and have served as a staff physical therapist, have been the Director of Rehabilitation Services for 3 hospitals and presently serve as Director of Outpatient Operations for West Michigan for AgilityHealth. I managed an outpatient physical therapy office for 12+ years in a large town in Michigan.
I have seen multiple instances in which physician self referral has not served the patient's best interest.
The most glaring instance was a patient I was treating for low back pain that had been referred to me by their family physician. I had worked very hard to develop a strong professional relationship with this physician and saw frequent referrals. I had treated this patient prior to this episode for other issues, and had treated relatives of this patient.
The patient was not progressing in treatment and I contacted the family physician requesting referral to a spine surgeon as I suspected a herniated disc.
The spine surgeon saw the patient and referred her to a physical therapist employed by the physician. When the patient requested to return to see me, she was told no. The reason given was "he never sends me reports". I had, in fact, not seen patients from this physician before.
I made a promise to the patient to communicate at the physicans wishes, offered to meet him or phone to discuss the case, and personally hand delivered reports to the physican. The physician then followed up with the patient, informing her he had not received any reports from me and insisting she see the PT in his office.
It is my opinion that this referral was made for the financial gain of the physician and not for the patient's needs.
I ask only to be given a fair chance in a fair market. In the argument that care is better able to be managed in the physicians office, I suggest that the physician rent space to the physical therapist at fair market value. I am certain that many physical therapists, myself included, would be interested in the opportunity.
Thank you for your time.

Submitter : **Dr. Allen Gown** **Date: 08/31/2007**

Organization : **PhenoPath Laboratories**

Category : **Laboratory Industry**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I wish to comment on one of the proposed rules that appeared in vol. 72 of the Federal Register, No. 133, Pages 38179 to 38187, July 12, 2007, in section 1. (Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)

CMS has proposed that the following condition be required when a physician or medical group bills for the professional component (PC) of a diagnostic test:

The physician or medical group billing for the interpretation must have performed the TC (technical component) of the test.

I wish to applaud CMS for this proposal, as it addresses an important underlying issue in the pod laboratories controversy that has attracted attention and have engendered this CMS proposal. I believe it is an inherently dangerous arrangement to separate technical and professional components of anatomic pathology laboratory tests. And as noted, in these arrangements, there are strong pressures for overutilization through ordering excessive and medically unnecessary tests.

Thank you for your attention to this matter. I would be happy to answer any specific questions you might have regarding this.

Sincerely,

Allen M. Gown, M.D.
Medical Director and Chief Pathologist

Submitter : **Dr. Edward Baptista** **Date: 08/31/2007**

Organization : **Cardiovascular Association, PLLC**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

See Attached Comment

CMS-1385-P-15549-Attach-1.DOC

15549

August 31, 2007

Amy Bassano
Director, Division of Practitioner Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, C4-01-26
Baltimore, MD 21244

Re: CMS-1285-P: CY 2008 Physician Fee Schedule Proposed Rule
Practice Expense -- Equipment Usage Percentage

Dear Ms. Bassano:

Thank you for considering this comment on the 2008 Physician Fee Schedule Proposed Rule. I am a cardiologist with Cardiovascular Association, PLLC in Houston, Texas, and I am writing to discuss payment for Microvolt T-wave Alternans (MTWA) diagnostic test. MTWA is an important tool to determine a patient's risk of sudden cardiac death. I am concerned that Medicare payment for physicians for MTWA is based on an incorrect utilization assumption that results in a significantly lower payment. CMS should consider the actual utilization of MTWA when calculating the practice expense for MTWA.

In patients at high risk for sudden cardiac death, Medicare has expanded coverage of implantable cardioverter defibrillators (ICDs) as a preventive measure. MTWA is extremely valuable in identifying which patients will benefit most from an ICD. Published data indicates that patients with negative MTWA tests will typically receive no significant reduction in cardiac arrest-related deaths, allowing us to identify patients who are more likely to benefit from an ICD.

MTWA testing is a non-invasive procedure that takes about 45 minutes. Unfortunately, the Medicare Practice Expense formula significantly decreases physician payment for MTWA. Reimbursement for MTWA is calculated using an "equipment usage assumption" of 50 percent. The assumption that the MTWA equipment is used 50 percent of the time is inaccurate and results in an inappropriately low payment. In my practice, MTWA is typically used only for the specific high-risk patients who will benefit greatly from its analysis. On average, we use MTWA several times per week, but significantly less than 50 percent of the time.

In order for Medicare to pay appropriately for this valuable technology, and to ensure that physicians continue to use it for their patients when appropriate, CMS should use the actual usage rate when available. I would be happy to provide documentation to demonstrate our actual utilization rate. Please do not hesitate to contact me for this information or if I can answer any other questions about MTWA.

Sincerely,

Edward G. Baptista, M.D., F.A.C.C.

Cardiovascular Association, P.L.L.C.
6410 Fannin, Suite 1425
Houston, TX 77030