Submitter : **Dr. Teresa Moon** **Date: 08/31/2007**

Organization : **Baylor Department of 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
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

As a Baylor College of Medicine Anesthesiology resident 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.

ISSUE Brief

January 2006
Vol. 5, No. 1

Medical Imaging: Cost Challenges and Promising Solutions

NATIONAL COMMITTEE ON **Evidence-Based Benefit Design**

National Business Group on Health

Introduction

Spurred on by its capacity for revealing information about a patient's physical condition without the use of invasive procedures, medical imaging is the fastest growing physician service. Medicare data show annual utilization increases of about nine percent, three times the rate of other physician services.[1] But this highly innovative medical area with its accelerated growth comes with a significant challenge for large employers and payers. According to a study published last year in the *Journal of the American College of Radiology*, an estimated $16 billion is spent each year on unnecessary diagnostic imaging.[2]

One segment of radiology in particular frequently referred to as advanced imaging, is growing at an even sharper rate. Advanced imaging procedures, including magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET) scans and nuclear cardiology studies rose between 13 and 17 percent in 2001, according to the Medicare Advisory Committee (MedPAC).[3] Recent plan data show a sharper increase.[4] National Imaging Associates reports advanced procedures account for about 5 percent of imaging encounters, although they represent more than half of a plan's total radiology spending.[5] And imaging costs are expected to reach $100 billion for 2005, up from $75 billion in 2000, according to a study sponsored by the Blue Cross and Blue Shield Association.[6]

There is no question that radiology advances are aiding in the diagnosis and treatment of illness, and some studies point to less invasive testing and lower total costs as a result.[7] But imaging use varies widely across geographic areas, giving rise to speculation that these increases may be related to other factors such as imaging equipment availability, and do not necessarily correlate with better quality or superior outcomes.[8]

While some combination of preauthorization and member counseling has been tried by many plans in recent years, the latest management techniques use a more aggressive approach in an attempt to improve quality, manage spending and reduce burden for physicians and patients.

For example, Highmark, Inc, Pennsylvania's largest health insurer, introduced a new program in 2004, administered by National Imaging Associates (NIA). The plan imposed a moratorium on contracts for advanced imaging followed by a provider-focused re-credentialing program with new quality standards that limited the number of providers approved to deliver services. Directing patients to fewer centers – but only those that meet quality standards – is expected to improve quality as well as reduce spending.

Some of Highmark's quality standards include the following:

- Services must be offered a minimum of 40 hours per week, at least one evening a week until 8 pm, and at least two Saturdays per month for a minimum of 4 hours a day;
- Centers must be staffed by a Highmark-approved radiologist;
- Centers must offer a minimum of [illegible] including CT, MRI and fluoroscopy; and
- PET scans may only be done in a hospital setting.

The program was also introduced in western Pennsylvania by Highmark Blue Cross Blue Shield. Other Blues plans announced they will revamp their imaging policies along the lines of Highmark's, and Medicare is considering a similar approach.

In another effort, in 2005, UnitedHealth Group began using the American College of Radiology (ACR) Appropriateness Criteria as the standard of care and in physician continuing education. In addition, several other major health plans are soliciting feedback from the ACR on their radiology policies. It is not yet clear how these efforts will affect spending over the long term. Nevertheless, radiology benefit managers report that plans can save between 40% and 70% of spending by carving out the services.

For more information, see text box that follows: "Applying Medical Evidence: American College of Radiology Appropriateness Criteria."

Applying Medical Evidence: American College of Radiology Appropriateness Criteria

The American College of Radiology (ACR) Appropriateness Criteria™ are evidence-based guidelines designed to assist physicians in making the most appropriate imaging decision for a specified clinical condition. The criteria are intended to enhance the quality of patient care while contributing to the wisest use of radiology resources.

The guidelines were developed by expert panels in diagnostic imaging, interventional radiology and radiation oncology. Each panel is chaired by an individual with national recognition for expertise in the area of focus, and includes members who are also leaders in radiology and other medical specialties.

There are currently over 170 topics in the following categories.

Cardiovascular imaging
Gastrointestinal imaging
Musculoskeletal imaging
Neurologic imaging
Thoracic imaging
Urologic imaging
Pediatric imaging
Women's imaging
Women's imaging – breast
Interventional radiology
Radiation oncology – bone metastases
Radiation oncology – brain
Radiation oncology – Hodgkin's
Radiation oncology – lung
Radiation oncology – prostate
Radiation oncology – rectal/anal
Radiation oncology – breast

The ACR recently introduced a personal digital assistant (PDA) application, allowing physicians to use portable handheld devices for accessing the criteria more easily. For more information, visit http://www.acr.org.

MedPAC Recommendations on Imaging Services

In 2005, the Medicare Payment Advisory Commission (MedPAC) made several recommendations to Congress on curbing medical imaging costs while improving value. The recommendations include the following:

- Improve Medicare's coding edits to detect improper claims, and pay more accurately for multiple imaging services;
- Set standards for all providers who bill Medicare for performing and interpreting imaging studies;
- Measure physicians' use of imaging services so that physicians can compare their practice patterns with those of their peers; and
- Strengthen rules that govern physician investment in imaging centers to which they refer patients.

Consumer Impact

Consumers have a lot to gain from better management of medical imaging, such as higher quality services, fewer repeat procedures and greater safety. However, these benefits will come with trade-offs. First, consumers will pay more for outpatient imaging services, particularly advanced imaging, through higher copays or a separate deductible and coinsurance. The effect of greater patient cost-sharing on appropriate use of imaging is not known. In most instances, patients have little influence over the study ordered by a physician.

The other trade-off has to do with convenience. Patients who may have had imaging studies in their doctor's office may now be directed to lower cost providers meeting quality standards. Extra trips and longer waits for appointments may be the results.

Conclusion

Initially, sharply rising costs brought medical imaging to the attention of plan managers. With closer inspection, it was revealed that variable quality and inappropriate use were also problems. Purchasers and plans are trying a number of techniques to slow spending and improve quality. These include evidence-based guidelines, quality standards, prior authorization, member cost-sharing and other utilization management strategies for advanced imaging.

Excessive and inappropriate spending can and should be slowed. However, it is important in the process that the exciting technological advances in imaging and their potential for improving the quality of health care not be curtailed. The research into the uses of imaging, and the assessment of both costs and promises, will continue. Much in this area awaits resolution. But in the meantime, making certain that evidence-based guidelines are followed should improve quality, encourage appropriate use and increase the likelihood of affordability.

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ISSUE**Brief**
January 2006
Vol. 5, No. 1

Medical Imaging: Cost Challenges and Promising Solutions

Institute on Health Care Costs and Solutions

NATIONAL COMMITTEE ON Evidence-Based Benefit Design

Written by:
Veronica V. Goff
Principal, Business Health Network, Falls Church, VA

About The Institute on Health Care Costs and Solutions

The Institute on Health Care Costs and Solutions, an initiative of the National Business Group on Health, was established in November 2001. Its mission is to provide an intense focus on finding effective solutions to the high cost of health care benefits confronting large employers. The National Committee on Evidence-Based Benefit Design was established in October 2004 as an initiative of the Institute.

Additional copies of this Issue Brief are available to members at www.businessgrouphealth.org, or contact Andrew Lundeen at lundeen@businessgrouphealth.org for more information.

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Submitter : **Dr. Ben Sampang** **Date: 08/31/2007**

Organization : **Baylor Department of Anesthesiology**

Category : **Physician**

Issue Areas/Comments

GENERAL

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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.

Submitter : Mr. Eric Zimmerman **Date:** 08/31/2007

Organization : Allergan

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15006-Attach-1.PDF

1506

ALLERGAN

2525 Dupont Drive, P.O. Box 19534, Irvine, CA 92623-9534 • (714) 246-4500

August 31, 2007

VIA ELECTRONIC SUBMISSION

Kerry Weems
Administrator, Centers for Medicare and Medicaid Services-Designate
U.S. Department of Health and Human Services
Attn: CMS-1385-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and other Part B Payment Policies for Calendar Year 2008; Proposed Rule; CMS-1385-P.

Dear Mr. Weems:

On behalf of Allergan Inc. ("Allergan"), we are pleased to submit comments in response to the above-captioned Proposed Rule (the "Proposed Rule") on the Medicare Physician Fee Schedule for 2008, and specifically on the following four matters:

- **ASP ISSUES**
- **CAP ISSUES**
- **CORF ISSUES**
- **DRUG COMPENDIA**

Allergan develops and manufactures BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex. BOTOX® is a biological used to treat patients with blepharospasm (a disorder involving involuntary closure of the eyelids), strabismus (a disorder of muscles that move the eyes), cervical dystonia (abnormal movements of the neck muscles) and severe primary axillary hyperhidrosis (disorder of sweat glands).[1] Botulinum toxin type A is administered by physicians in their offices, in hospital outpatient departments, and in other facility settings. Botulinum toxin

[1] The current package labeling includes the following indications for BOTOX®:
BOTOX® is indicated for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.
BOTOX® is indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.
BOTOX® is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.
The efficacy of BOTOX® treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical over-recession of the antagonist has not been established. BOTOX® is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.
In addition, BOTOX® Cosmetic, which has distinct labeling, packaging and NDC-coding, has been approved by the FDA for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤65 years of age. BOTOX® Cosmetic is never covered by Medicare.

BOTOX
Botulinum Toxin Type A
Purified Neurotoxin Complex

type A is covered as a biological provided incident-to a physician's service under Medicare Part B.[2]

ASP ISSUES

Allergan commends CMS for the cautious and deliberate manner in which it is approaching the question of how to reflect **"Bundled Price Concessions"** in the ASP calculation. (72 *Fed. Reg.* at 38,150). There is a tension between the desirability of a consistent methodology across manufacturers' ASP calculations and the potential complexity that may be introduced by a prescribed approach, and it is important that CMS strive to strike a reasonable balance between these competing interests.

CMS' proposed allocation methodology (i.e., allocation proportionate to the dollar value of the sales of each product sold under the bundled arrangement) does a better job of balancing these competing interests than would the alternative methodology discussed by the Medicare Payment Advisory Commission (i.e., full allocation to the product whose purchase is the contingency for the discount under the bundled arrangement). This methodology is also consistent with the bundling formula specified in the Medicaid AMP final rule. (72 *Fed. Reg.* at 39,142). Nonetheless, CMS should further clarify the allocation methodology to provide expressly that price concessions are to be allocated only to the product sales that qualified the purchaser for the discount.

Many manufacturers operate incentive programs that qualify a physician (or other health care practitioner/purchaser) for discounts on future purchases of a product when the physician purchases a specified quantity of another product. For example, a physician who purchases a specified quantity of Product X (which is covered under Medicare Part B) may qualify the physician for a special purchaser status, which then qualifies the physician for discounts on future purchases of Product Y (which is not covered under Medicare Part B). Under these programs, once the physician becomes eligible for discounts on Product Y based upon meeting a threshold level of purchases on Product X, the discount on future purchases of Product Y remains the same no matter how much more of Product X the physician purchases. In such cases, the discounts provided on Product Y should be allocated across only those units of Product X necessary to trigger the discount, and not on subsequent purchases of Product X.

Illustration:

- Special purchaser status requires the purchase of 100 units of Product X, and qualifies the physician for a 10 percent discount on future purchases of Product Y.
- Unit price of Product X is $100 per unit.
- Total sales of Product X to Dr. Smith are 200 units, $20,000 ($100 x 200 units).
- Unit price of Product Y is $50 per unit.
- Total sales of Product Y to Dr. Smith are 100unit, $5,000 ($50 x 100 units).
- Total discount on Product Y is $500 (10 percent of $5,000).

[2] Soc. Sec. Act §§ 1861(s)(2)(A), (B).

- The total discount furnished ($500) is allocated across 67 percent of Product X, $10,000 (total sales of 100 units of Product X associated with the discount) divided by $15,000 (total sales of Product X associated with the discount plus total sales of Product Y).
- The total discount furnished ($500) is NOT allocated across 80 percent of Product X, $20,000 (total sales of Product X) divided by $25,000 (total sales of Product X and Product Y).

If the discount does not increase commensurate with or contingent upon additional sales of Product X, then there is no discount associated with those subsequent purchases of Product X, and the discounts furnished on Product Y should not be allocated to those additional units of Product X. If incremental sales beyond the eligibility threshold do not increase the discount, then the discount should not be applied to those additional sales.

To make clear that manufacturers are to allocate discounts proportionate to those sales that qualify the physician for the discount, rather than total sales, including those unrelated to the discount, CMS should amend the proposed regulatory language at § 414.804 as follows:

> (iii) For the purposes of paragraph (a)(2)(i) of this section, the total value of all price concessions on all drugs sold under a bundled arrangement must be allocated proportionately ***(excluding sales of products for which no discount is given under the bundled arrangement and which result in no discount on any other product)*** according to the dollar value of the units of each drug sold under the bundled arrangement.

CMS should likewise provide explanatory and clarifying discussion in the preamble to reference the type of incentive programs discussed above, and to make clear that price concessions would not be allocable to sales for which no discount was given.

CAP ISSUES

We appreciate the deliberate manner in which CMS is considering questions concerning **"Prefilled Syringes."** (72 *Fed. Reg.* at 38,159). Whether and how to permit CAP vendors to repackage drugs raises numerous issues, not the least of which are patient efficacy and safety concerns, which should be thoroughly considered before proposing changes to Medicare regulations. As such, we applaud CMS for first soliciting comments on these questions before proposing regulatory changes.

We likewise appreciate CMS's interest in minimizing waste and promoting efficiency wherever possible, and agree that it might be appropriate in some limited circumstances to permit CAP vendors to repackage CAP drugs where such repackaging would benefit Medicare beneficiaries, the program, and the physicians who participate in it. However, we urge CMS to proceed with great caution. Changes of this nature are fraught with potential patient efficacy and safety concerns. This is not a simple case of weighing interests. Although in some calculations significant waste and efficiency concerns may outweigh minor efficacy or safety concerns, this is a setting where CMS should proceed only where economic benefits would result without *any* additional safety or efficacy risk to the patient.

Many biologicals are fragile, complex substances that must be specially handled to maintain their biologic structure and character in order to retain their efficacy as well as safety. BOTOX®, for example, is shipped directly to physicians in a vacuum-dried powder form, which must be reconstituted using sterile, non-preserved saline prior to intramuscular injection. Because the product and diluent do not contain preservative, once opened and reconstituted, the activated product must be refrigerated at specified temperatures (2° to 8° C) and used within four hours. Reconstituted BOTOX® that is exposed to temperatures outside the specified range, or that is allowed to sit for more than four hours may denature and lose its effectiveness.

Liberalized regulations that would allow CAP vendors to furnish physicians with reconstituted BOTOX® raise numerous concerns about quality control. Product shipped from CAP vendors to physicians may change hands numerous times, and oftentimes is entrusted to commercial courier services. Although federal and state governments oversee CAP vendors – at least those that are licensed pharmacies – and specially trained CAP vendors potentially may maintain necessary environmental controls in their own facilities, the couriers that they would rely on to transport reconstituted product to physicians are not adequately controlled, and could not be similarly entrusted. Federal and state governments do not possess adequate controls over these middlemen to ensure that they would properly handle product and deliver it in an uncompromised form. Having entrusted the reconstituting process to the CAP vendor, the physician who receives the product would have no way of knowing whether the product was properly processed and handled, and whether it remains safe and effective for the patient.

BOTOX® is certainly not unique in this regard. Many biologicals require refrigeration; some require freezing, or even subfreezing; some need to be protected from light; some products, including BOTOX®, should not be shaken once reconstituted.

For these reasons, Allergan encourages CMS to consider carefully any changes that would allow CAP vendors to offer compounded *drugs*. In no case, however, should CAP vendors be permitted to compound or open in any manner *biologicals*. Allergan recommends that CMS continue to require that CAP vendors ship biologicals only in "unopened vials or other original containers as supplied by the manufacturer."

CORF ISSUES

Allergan objects to CMS's proposal no longer to permit separate payment to Comprehensive Outpatient Rehabilitation Facilities ("CORFs") for **"Drugs and Biologicals"** administered to CORF patients as part of a treatment plan. (72 *Fed. Reg.* at 38,175). While we are sensitive to CMS's concern about the risks of duplicative payment that could arise by permitting both CORFs and physicians to bill separately for drugs and biologicals administered to CORF patients, this concern is outweighed by the risk that neither the CORF nor the physician could be reimbursed for the cost of the items purchased.

If CMS prohibits CORFs from submitting claims for drugs and biologicals, CORFs that purchase a drug or biological that is administered to a patient would be unable to be compensated for that expense. In such instances, the physician also could not be compensated, because the drug or biological would not satisfy CMS's own "incident to" rules, and therefore would not be covered.

The Benefit Policy Manual provides, "To be covered, supplies, including drugs and biologicals, must represent an expense to the physician or legal entity billing for the services or supplies." Medicare Benefit Policy Manual, Ch. 15, § 60.1. If the physician does not incur an expense associated with the purchase of the drug or biological, he or she could not be paid for those items. If the CORF also could not be paid, then nobody would be compensated for the provision of those items, and Medicare would realize a windfall benefit.

CMS might be justified in establishing such limitations if indeed there were documented instances of abuse or unintended duplicative payment. However, the agency cites no such instances, and seems to be merely concerned about a hypothetical situation.

In light of these concerns, until CMS can demonstrate genuine reimbursement problems associated with permitting separate payment to CORFs and physicians for drugs and biologicals, the agency should maintain 42 C.F.R. §410.100(k) and continue to permit separate payment to CORFs and physicians for drugs and biologicals.

DRUG COMPENDIA

Allergan applauds CMS for proposing a process to ensure that an adequate number of compendia are available to assist Medicare contractors in determinations of medically-accepted off-label uses of drugs and biologicals in anti-cancer chemotherapeutic regimens. (72 *Fed. Reg.* at 38,177). Although Allergan neither makes nor markets anti-cancer chemotherapeutic drugs or biologicals, we nonetheless have a deep interest in this situation and proposal.

Although § 1861(t)(2)(B)(ii)(I) of the Social Security Act lists drug compendia solely for the purpose of determining the medically-accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimens, as a practical matter Medicare contractors generally refer to these same compendia when making off-label determinations for *all* Part B drugs.[3] As such, a deficiency of appropriate compendia could hamper the availability of all drugs and biologicals.

To ensure that Medicare contractors have access to an appropriate array of compendia from which to make timely and accurate coverage determinations, CMS should devise a process that ensures quality, yet that is flexible and efficient to allow new compendia options to be available as quickly as is reasonable. Although the timetable CMS proposes for consideration of new compendia attempts to strike a balance between the importance of public notice and comment and careful consideration by CMS on the one hand, and the need for swift decisionmaking and implementation on the other, the proposed timetable appears unnecessarily long. However, given the consequences of having too few compendia available, CMS should abbreviate the

[3] *See*, Noridian Local Coverage Determination for Drugs Used Incident to a Physician's Service and Their Covered Diagnoses (L24296) effective 12/01/2006 which provides that NAS will cover those drugs for off-label diagnoses that are listed by one of two compendia: United States Pharmacopeia Dispensing Information (USP DI, published by Thomson Micromedex) or the American Hospital Formulary Service Drug Information (AHFS Drug Information published by the American Society of Health-System Pharmacists).

timelines in the following steps.

- CMS could abbreviate the 45-day period between publication of the notice and the soonest that it will begin accepting requests. Given that CMS intends to annually notify the public of the opportunity to request compendia additions/deletions, stakeholders will anticipate the solicitation, and could adequately prepare and submit requests within 30-days.

- Given the interest of making new compendia available, we would likewise suggest that CMS abbreviate its own consideration period from 120 days to no more than 90 days.

- CMS has not specified how soon after publishing its decision such decision would become effective. Again, in light of the need for more compendia options, we encourage CMS to make its determinations to add compendia effective immediately, but not longer than 30 days following a determination; determinations to delete a compendium should be effective no sooner than 30 days after publication.

We also agree that the characteristics developed by Medicare Evidence Development and Coverage Advisory Committee (MedCAC) are a suitable starting point from which to evaluate new compendia options. Nonetheless, we encourage CMS to define further and refine several of these characteristics, and to implement a criteria set in a manner that enables qualified compendia to be efficiently added. Specifically, we make the following recommendations with respect to the compendia review criteria:

- CMS should bifurcate the criteria into essential and desirable classes, and then require compendia to satisfy only those criteria that are essential, plus perhaps a select number of those characteristics that are desirable. While it is illuminating to evaluate compendia on many different levels, it is not necessary to require that compendia satisfy all established criteria. Criteria can and should be weighted differently. We believe that accuracy, timeliness of updates, and transparency are among the most essential characteristics of a compendium, and should be weighted most heavily when evaluating new listings.

- MedCAC listed as desirable the following characteristic: Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies. We agree that this is a desirable characteristic. However, it is not an essential characteristic of a compendium, and CMS should not make it a requirement.

- It also is not essential that a compendia be indexed. So long as the compendia is available in an electronic format, and searchable electronically, all relevant information about a drug can be found and accessed through an electronic search.

- CMS should further clarify any criteria related to conflicts to recognize that conflicts can arise between publishers and payors, as well as manufacturers.

We encourage CMS to finalize a review process in the final Physician Fee Schedule update for calendar year 2008 as soon as possible to ensure that mechanisms are in place to evaluate and

add new criteria as quickly as possible. In the meantime, we also urge CMS to immediately recognize *DrugPoints*® as the successor publication to the USP-DI.

When Congress amended § 1861(t)(2)(B)(ii)(I) of the Social Security Act in 2005 by inserting "(or its successor publications)" after "United States Pharmacopoeia-Drug Information" it was fully aware that Thomson would be replacing the USP-DI in mid-2007 with a successor publication. Moreover, Congress was clearly seeking to ensure that this successor publication would be available to Medicare contractors to support coverage determinations. Had Congress sought to leave the decision of whether to recognize *DrugPoints*® as a successor to the USP-DI to CMS, it could have remained silent on the matter. By amending the statute in this manner, Congress clearly intended to resolve any doubt as to whether the replacement publication would step into the shoes of the USP-DI. There is no other possible explanation for why Congress took this action. To regard *DrugPoints*® as anything but the successor to the USP-DI, and to do other than make it immediately available for use to support coverage determinations would be contrary to congressional intent.

Moreover, if *DrugPoints*® is not recognized as an official compendium for Medicare, there will be only one compendium left, at least during the period while CMS evaluates applications for new compendia. Reliance on only one compendium may leave patients without coverage of emerging uses of new drugs.

* * * *

We appreciate having the opportunity to comment on the Proposed Rule and hope CMS will consider these recommendations in developing the final rule. If you have any questions about our comments, please contact Jim Hayes, Director, Reimbursement Strategy and Healthcare Policy, Neuroscience Division at 714-246-6401 or by e-mail at hayes_jim@allergan.com. Thank you.

Sincerely yours,

/s/ Jim Hayes

Director, Reimbursement Strategy and Healthcare Policy
Neuroscience Division
Allergan Inc.

Submitter : Ms. Jill Rathbun **Date:** 08/31/2007

Organization : Pelvic Health Coalition

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Greetings - Please "See Attachment" for the comment letter from the Pelvic Health Coalition which discusses practice expense, the budget neutrality work adjustor, and Medicare 2008 Payment Rates.

CMS-1385-P-15007-Attach-1.DOC

1500

PHC

1301 K Street, N. W. Suite 1100, East Tower, Washington, DC 20005
Barbara Levy, M.D., Co-Chair, Vincent Lucente, M.D., Co-Chair

Executive Board: Robert Harris, M.D., Steve Segal, M.D.,
G. Willy Davila, MD, Edward Stanford, M.D.,

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:

The Pelvic Health Coalition ("PHC") welcomes the opportunity to submit comments in response to the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2008 and other Changes to Payment under Part B.

The PHC is dedicated to raising awareness, particularly among elected Federal healthcare policy makers, of the critical importance of pelvic health and to promote education about pelvic health issues. By dispelling myths and misunderstandings, the PHC is committed to improving the quality of life for women with pelvic health disorders.

Since it inception, the PHC has been committed to raising awareness of pelvic health issues by promoting and expanding patient, public, and professional education; promoting advocacy efforts; and strengthening the voice of the pelvic health community. The PHC is a broad-based coalition representing leading obstetric, urology, and gynecology healthcare professionals as well as the major industry leaders involved with developing innovative technologies used to treat pelvic health disorders. The PHC provides a forum where all critical stakeholders share viewpoints and reach consensus on major healthcare policy and reimbursement matters impacting pelvic health issues.

Our comments and recommendations regarding the Proposed 2008 Medicare Physician Fee Schedule are outlined and discussed below.

I. "Resource-based Practice Expense (PE) RVUs"

A. Equipment Use Rate

PHC 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 is used approximately one – two days a week, depending on the service mix of a specific office.

In general for surgical specialties, we spend usually 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.

Then we 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.

PHC 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. PHC 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. PHC 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.

B. Changes to PE Inputs in Ob/Gyn Codes

PHC 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, PHC 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

PHC 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 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.

III. Medicare Physician Payment Rate for 2008

I.

In 2008, physicians and other health care practitioners whose payment rates are tied to the physician fee schedule face a 10% payment rate cut. PHC 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.

***

As always, we look forward to working with CMS to address these important issues. If PHC can provide CMS with additional information, please do not hesitate to contact Jill Rathbun, at 703-486-4200 or Gail Daubert at 202-414-9241.

Sincerely,

Barbara Levy, MD
Barbara Levy, M.D.
Co-Chair

Vince Lucente, MD
Vincent Lucente, M.D.
Co-Chair

cc: PHC members via email only

Submitter : Dr. Marcos Hazday **Date:** 08/31/2007

Organization : Mid-Florida Cardiology Specialists

Category : Physician

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

see attached comment

CMS-1385-P-15008-Attach-1.DOC

5008

MID-FLORIDA CARDIOLOGY SPECIALISTS

Board Certified
Adult Cardiovascular Diseases and Internal Medicine
407-351-5384

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: VMS-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 at Mid Florida Cardiology Specialist, 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 coverage for implantable cardioverter defibrillators (ICDs) as a preventative 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 typical receive no significant reduction in cardiac arrest-related deaths, allowing us to identify patient who are likely to benefit from an ICD.

MTWA testing is a non-invasive procedure that takes about (60) 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,

Marcos S. Hazday, M.D.

Submitter : Dr. Scott Piland **Date:** 08/31/2007

Organization : The University of Southern Mississippi

Category : Academic

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Scott G. Piland, I am a PhD Athletic Training educator who has been a certified athletic trainer for 10 years. I currently teach and conduct human factors research at the University of Southern Mississippi

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 G. Piland PhD, ATC

Assistant Professor
School of Human Performance and Recreation
The University of Southern Mississippi
Hattiesburg, MS

Submitter : Dr. Joseph DeCarlo

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-15010-Attach-1.DOC

15010

UROLOGY TYLER, PA, 700 OLYMPIC PLAZA # 700, TYLER, TEXAS 75701

Center 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: Urology Tyler, PA, Comments to Proposed Revisions to the 2008 Physician Fee Schedule

Dear Sir or Madam:

This letter is submitted in response to the request of the Centers for Medicare and Medicaid Services ("CMS") for comments regarding proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2008 ("Proposed Revisions"). Specifically, the comments of this commentator address those Proposed Revisions as they relate to the existing Medicare anti-markup rules and reassignment rules that apply to diagnostic tests, as well as the potential changes to the Stark Statute in office ancillary services exception.

I. Technical Comments to the Proposed Revisions

A simple reading of the Proposed Revisions to 42 CFR § 414.50 would seem to imply that the anti-markup provisions would apply to the technical component ("TC") of a diagnostic test billed by a physician if only one condition exists, i.e., the TC is performed by an "outside supplier." An "outside supplier" is defined as "someone other than a full time employee of the billing physician or medical group." This does not make sense if the physician or practice group is otherwise performing the TC of the test, as opposed to purchasing the test. In circumstances where (i) the physician actually owns the diagnostic equipment, (ii) the test is performed on premises owned or leased by the physician on a full time basis, and (iii) the test is supervised by a member of the physician's group practice or "physician in the group" as defined by the Stark Statute, the physician is clearly performing the TC and not purchasing the TC, and the Proposed Revision to Section 414.50 should not limit the billing for the TC. From our informal discussions with personnel at CMS over the past two months, it is our understanding that CMS did not intend to apply the anti-markup provisions in the above circumstances, and that a clarifying revision would be made.

The Proposed Revision to 42 CFR § 424.80 seeks to apply a similar anti-markup restriction to the professional component ("PC") of a diagnostic test billed by a physician pursuant to a contractual reassignment from a provider who is not a full time employee of the billing group. Rules requiring full time services of either technical or professional personnel as a precondition of full Medicare reimbursement unfairly penalize persons who desire to work less

than full time. For a variety of reasons, physicians and technical staff may be forced to, or may choose to, work less than 35 hours a week. In rural or other outlying areas part-time services are the only available services. By prohibiting providers from recovering costs or profiting from these providers, CMS is discriminating against part-time workers and will make existing services no longer available in areas where services are already limited.

The anti-markup provisions are intended to prohibit profiting on tests not performed by the billing physician practice. They are not intended to penalize a program participant who provides services on a less than full time basis. CMS should permit providers to recover the actual costs of overhead allocable to persons that provide Medicare reimbursed diagnostic services. This will permit groups to provide those services without losing money, and will lower the cost of these services to the Medicare program to the extent actual costs are lower than the Medicare reimbursement for services provided. If Medicare requires these services be provided at a loss, they will be referred out, lowering quality of care, and resulting in no cost savings to the Medicare program. Another likely result of such a provision is that physician practices will no longer globally bill for both the TC and PC. Separate billing of the TC by the physician practices and the PC by the interpreting physicians will just increase the administrative burdens and costs for both the physician practices and the Medicare program. Volume will remain unchanged. Urological pathology volume is based upon objectively demonstrated medical necessity, and is not affected by profit margin or who is billing for services.

II. General Comments in Support of Centralized Pathology Laboratories

In the Commentary to the Proposed Revisions, CMS seeks comments to potential suggested revisions to the Stark Statute in office ancillary services exception. In its Commentary, CMS once again attacks physician practice centralized pathology laboratories, and solicits public comment on potential Proposed Revisions that would eliminate these labs. We addressed the CMS unjustified condemnation of office based path labs in our comments to the 2007 Medicare physician fee schedule revisions, and are reaffirming those comments once again below.

A. Unsupported Rationale for the Elimination of Centralized Pathology Laboratories

In the Commentary to the Proposed Revisions, CMS has concluded that remotely located centralized pathology laboratories ("Path Labs") pose significant fraud and abuse risks. Nothing within the Proposed Revisions provides any hint of why CMS has reached this conclusion, nor is there any indication that CMS has undertaken any sort of balanced analysis, looking carefully at the potential benefits – both in terms of improved quality of care and financial economy to the program - of these arrangements. We are confident that properly structured Path Labs (i) can be actively integrated into a physician practice, (ii) pose little to no risk of over-utilization, and (iii) provide substantial advancements to quality of patient care. This commentator urges CMS to carefully analyze these arrangements from a risk-benefit analysis prior to undertaking broad-sweeping revisions purportedly specifically designed to eliminate their existence.

The need for a balanced analysis is also apparent in light of the stated concern, apparently voiced by commentators in response to Phase II Interim Final Regulations ("IFC"), that Path Labs would encourage over-utilization. CMS expressly took note of commentary and stated that, with regard to its centralized building requirement, it was "persuaded by commentators who responded to the Phase II IFC that our present definition may encourage the unnecessary ordering of ancillary services." (August 22, 2006 Federal Register, page 49056)

Just as it is the case with all types of treatment modalities, there are bad Path Labs that may encourage over-utilization and provide no corresponding program and patient benefits, and there are good Path Labs that protect against over-utilization and significantly improve the quality of patient care. The CBLPath path lab model addressed in Advisory Opinion 04-17 was obviously submitted by the commercial lab industry with a vested economic interest in portraying all physician-owned labs as violating the tenants prescribed by the April 2003 Advisory Opinion on Passive Physician Joint Ventures. As addressed later herein, physician Path Labs can be integrated into a physician's active medical practice and structured to protect against over-utilization concerns. The commercial lab industry cannot provide the benefits outlined herein that are unique to physician Path Labs, and they stand to lose huge profits if physician Path Labs continue to operate.

CMS should also take note that the radiologist lobby used similar over-utilization arguments with Congress over the last two years to push through statutory restrictions on the reassignment rules. Those attempts failed – and for good reason. It was promoted by those whose economic interests would be furthered by such restrictions. The promotion of specific economic interests, disguised in a rationale of alleged over-utilization, ignores what should be the fundamental purpose of the regulations: improved quality outcomes in an economically efficient manner. If the number of patients treated and specimens processed do not materially vary due to where the specimens are processed, it simply boils down to who gets the reimbursement. Regardless of the venue of where the specimens are processed, the treating physician must always document the medical necessity for the testing. Elevated PSA counts, DRE results and prior medical history are not subjective criteria than can be manipulated by physicians motivated by financial gain.

Further, when Congress drafted the Stark in office ancillary services exception, it clearly indicated that all DHS services other than those it specifically excluded (e.g., durable medical equipment and parenteral and enteral nutrients) should benefit from the protection of the exception. Office based path lab services were not excluded by Congress from the protection of the exception, which raises serious questions whether CMS can issue new regulations that would conflict with clear Congressional intent.

The remainder of this commentary focuses on specific benefits of Path Labs as well as appropriate ways in which over-utilization risks could be addressed, without sacrificing those benefits.

B. Benefits of Path Lab Arrangements

It is virtually impossible to overstate the importance of early detection and accurate professional interpretation to successful treatment of prostate cancer. Path Labs provide significant, unique benefits in the promotion of early detection. The specific benefits of these types of arrangements include the following:

(1) **Quality Assurance and Outcomes Tracking:** A properly structured Path Lab allows the treating physician to maintain control of the entire process, beginning with specimen collection and processing, continuing through interpretation, and ending with appropriate follow-up with the patient. This ability to supervise and direct the entire process makes information and outcomes tracking much simpler, efficient, and reliable.

In addition, as a direct result of the Path Lab existing under the supervision and control of the treating physicians, it has been the experience of this commentator that the flow of relevant information regarding the patient's condition between the pathologist and the treating physician has increased dramatically. Questions regarding the specimen collection process and clarification of pathology findings are easily accomplished. Prior to the Path Lab arrangement, this type of vital exchange was difficult at best and often impossible.

Certainly, one might argue that the ideal situation might be one in which the Path Lab was located in the same building as the office of the treating physician. However, the primary effect of a "same building" restriction would be to limit physician controlled Path Labs to large practices in metropolitan areas that could afford to equip and fully utilize a full-time Path Lab. The end result of such a restriction would invariably result in increasing disparate treatment among Medicare patients, with the potential to disproportionately adversely affect care provided to patients in rural or small communities.

(2) **Expertise.** The use of Path Labs in pod type arrangements allows specialization by pathologists that would otherwise only been seen in the largest medical centers or reference laboratories. Prior to the establishment of its Path lab, this commentator had no choice but to use a reference lab for interpretations. While these pathologists are certainly competent, the level of expertise of pathologists who limit their practice to urology, as seen in pathologists who staff Path Labs, allows those pathologists to obtain the highest level of expertise by virtue of this specialized experience. In fact, this model follows the government's own methodology, employed at the Armed Forces Institute of Pathology, where the technical staff and pathologists are specialized in a specific area of interest, with urology being one of those areas.

(3) **Availability of Communication and Consultation.** In addition to the foregoing, the Path Lab offers a fairly unique opportunity of pathologists who work together in Path Lab arrangements and who specialize in urology related pathology, to consult with each other in-house on a regular basis. This allows for on-site, immediate consultation in addition to the availability of the treating physician to clarify and consult with the pathologists.

C. Controlling the Risk of Over-utilization

It is the position of this commentator that regulations could be adopted that place specific requirements on Path Labs that will address over-utilization concerns, while preserving the benefits of these types of arrangements. Such regulations could also ensure that the Path Labs are actively integrated into the urologists professional practices, as opposed to being suspect passive joint ventures. Ultimately, broadly defined wholesale prohibitions do not serve the interests of patient care or the government's interest in economically efficient care. The overbroad nature of the Proposed Revisions will likely create roadblocks to improved patient care and outcomes, resulting in delayed treatment and ultimately increased treatment costs. Moreover, they have the potential to do nothing other than to promote the economic interests of one health care group (the commercial lab industry) over another (physician practices).

It is this commentators position that the best way to ensure that Path Labs are maximizing their potential for improving care and outcomes, while discouraging over-utilization, is by ensuring that these arrangements are not passive investments of the treating physicians. Physicians who own off-site Path Labs should be actively involved in their direction and supervision, and responsible for the services provided by the Path Lab. With that goal in mind, this commentator believes the following recommendations, specific to this type of arrangement, would balance those two important interests:

(1) Treating physician groups who own Path Labs should be required to appoint a member of their group as an active physician liaison for the lab, with audit and utilization oversight responsibilities. The physician liaison's duties should include periodic on-site visitation to the Path Lab.

(2) Ownership in the Path Lab should include an investment and ownership in all the necessary equipment to operate the Path Lab, the equipment should be permanently located in space reserved exclusively for the ownership group, and reserved exclusively for use by the group.

(3) Space requirements should be sufficient to provide exclusively reserved space that is adequate to prepare and perform the interpretations. This commentator is not opposed to specific space requirements, as long as they are rationally related to the amount of space required to safely and competently perform the service. For purposes of State integrated regulatory oversight and the convenience of practice groups to oversee operations, it is also logical that the Path Labs should be located in the same State as the practice group.

(4) Periodic consultation and quality assurance should be required, including periodic meetings between the practice group physician liaison and the contracted pathologist to review results and take appropriate action for improvement of defined deficiencies.

(5) Protocols should be established to ensure refinement of the specific criteria for pathology testing and methods for tracking and addressing outliers.

(6) To ensure active practice integration, an independent contractor "physician in the group practice" (the Pathologist) should only be able to provide professional or technical services on behalf of the group practice, and for which the group practice bills or collects, if the services are provided on the premises of the group practice as historically defined in the Stark Statute. This would discourage the contractual reassignment of services by Pathologists whose only relationship with the billing practice group exists on paper. Further, in 2004 CMS clarified that diagnostic tests provided by leased employees, such as lab technicians, are not "purchased tests" for purposes of the rule. That argument is strengthened when the leased lab technician is supervised by a Pathologist who has a direct independent contractor relationship with the practice.

(7) This commentator agrees that if a group practice intends to bill for the technical component of a path lab services, it ought to also perform the professional component of that same service. The Stark Statute clearly allows that professional component to be performed by the group practice through a Pathologist acting as a physician in the group practice.

(8) Consistent with current CLIA regulations that were promulgated to ensure quality lab standards, a single pathologist should be limited to being the medical director of five or fewer path labs.

(9) Regulatory oversight is required in the form of refined credentialing criteria which incorporate the above recommendations. In fact, the auditing recommendations set forth above should be applied to all pathology laboratories, regardless of ownership or location.

It is this my belief, and the belief of the other seven physicians of Urology Tyler, that more stringent credentialing regulations under the general criteria set forth above would not only serve to promote quality of care and economic efficiency in Path Labs, but would more than adequately address passive investment and over-utilization concerns.

Respectfully submitted,

J. Leonard DeCarlo, MD
Treasurer
Urology Tyler, PA

Submitter : **Dr. John Porter** **Date: 08/31/2007**

Organization : **Baylor Department of 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
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

As a Baylor College of Medicine Anesthesiology resident 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. Ronald Jones** **Date: 08/31/2007**

Organization : **R.W. Jones, D.O., P.A.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-1385-P-15012-Attach-1.DOC

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,

Dr. Ron Jones
200 Arch St.
Royse City, Tx 75189
972-636-9577

Submitter : Dr. Carolyn Langford **Date:** 08/31/2007

Organization : SWFUA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15013-Attach-1.DOC

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, MD 21244– 8018.

Dear Mr. Kuhn:

I am a urologist who practices in group setting. Medicare beneficiaries represent approximately 75% of our patient population and our Practice treat the full range of urology services to Senior Citizens. I am writing to comment on the proposed changes to the physician fee schedule rules that were published on July 12, 2007 that concern the Stark self-referral rule and the reassignment and purchased diagnostic test rules.

The changes proposed in these rules will have a serious impact on the way our group of urologists practice medicine and will not lead to the best medical practices. With respect to the in-office ancillary services exception, the definition should not be limited in any way. It is important for patient care, that urologists have the ability to provide pathology services in their own offices. It is equally important to allow urologists to work with radiation oncologists in a variety of ways to provide radiation therapy to our patients.

The proposed changes to the reassignment and purchased diagnostic test rules will make it difficult, if not impossible for me to provide pathology services in a timely and reliable manner.

The sweeping changes to the Stark regulations and the reassignment and purchased diagnostic test rules go far beyond what is necessary to protect the Medicare program from fraud and abuse. The rules should be revised to only prohibit those specific arrangements that are not beneficial to patient care.

Thank you for your consideration,

Carolyn F. Langford, D.O.

Submitter : Mr. Santiago Munoz **Date:** 08/31/2007

Organization : University of California

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment:

CMS-1385-P-15014-Attach-1.PDF

CMS-1385-P-15014-Attach-2.PDF

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August 31, 2008

Mr. Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphery Building
200 Independence Ave. SW
Washington, DC. 20201

SUBJECT: ***CMS-1385-P*** Medicare Physician Fee Schedule 2008

Dear Administrator Kuhn:

Thank you for the opportunity to comment on the proposed revisions to the Medicare physician fee schedule for calendar year 2008. These comments are provided on behalf of the University of California (UC) Health System and its nearly five thousand faculty physicians. While the proposed rule includes various items designed to protect and improve health care access for Medicare beneficiaries, we are extremely concerned with the conversion factor (CF) payment update of -9.9% scheduled to occur under the Sustainable Growth Rate (SGR). We urge the Centers for Medicaid and Medicare Services (CMS) to amend the rule and help mitigate the deleterious impact of this physician payment cut.

Since the Medicare program's inception, UC's faculty physicians have been committed to caring for a large share of the Medicare population. Currently, nearly a quarter of all clinical activity by UC physicians is dedicated to Medicare beneficiaries. The commitment of our physicians, nurses, and staff to medically vulnerable patients – including Medicare beneficiaries – is the foundation of the UC Health System. UC physicians ensure that Medicare beneficiaries have access to a range of high quality healthcare services; this includes primary and preventive care as well as highly advanced care in quaternary settings, such as burn and cancer centers. UC faculty also educates and trains medical students, residents, and other health professionals who will become the next generation of caregivers for the Medicare population. Finally, UC faculty physicians conduct clinical research that informs the country's healthcare providers on effective and efficient healthcare strategies for all Americans.

For all of these reasons, the UC Health System wholeheartedly endorses CMS's efforts to improve access for Medicare beneficiaries, including expanding Medicare's preventive services. Unfortunately, the negative physician payment update is not consistent with the

effort to protect access for Medicare beneficiaries. The SGR payment formula unfairly cuts physician payments if growth in Medicare patients' use of services exceeds the growth in the gross domestic product (GDP). This link is inappropriate because the medical needs of patients do not decline during economic downturns.

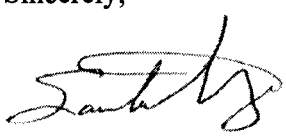
While we understand that structural changes to the flawed SGR payment formula will require Congressional action, we believe that CMS has the authority to amend the 2008 payment rule and address issues created by the SGR payment formula. In particular, CMS can ensure drugs are removed from the growth target that trigger the negative update. We understand drugs were included in the growth target in order to reduce over-utilization. However, much of the expenses associated with drugs are related to oncology treatments, where the physician has little utilization discretion. As such, we respectfully request that CMS remove drugs from the SGR system in the CY 2008 Physician Fee Schedule Rule.

Absent CMS and Congressional action on the flawed SGR mechanism, Medicare payment rates for physicians will be cut by 9.9 percent beginning January 1, 2008. For UC faculty physicians, the direct effect of these pending payment reductions is substantial; the cuts will total over $15 million in 2008. Since many other professional agreements are tied to Medicare rates, indirect losses are estimated at an additional $7 million for a total 2008 financial impact of approximately $22 million. Moreover, while Medicare payment rates plummet, practice costs continue to increase at a significant rate.

Declining Medicare payments greatly affect UC physicians as they provide medical education and care for extremely high-cost Medicare beneficiaries. Medicare beneficiaries rely on academic physicians and health systems like the University of California to provide high quality, innovative, and accessible healthcare. Absent leadership from CMS and Congress, the University's ability to continue to meet the diverse clinical needs of a growing Medicare population will be severely compromised.

Thank you for the opportunity to comment on the Medicare Physician Fee Schedule for CY 2008. If there are questions or if I can provide any additional information or input, please contact me at 510-987-9062 or santiago.munoz@ucop.edu.

Sincerely,



Santiago Muñoz
Associate Vice President
Clinical Services Development

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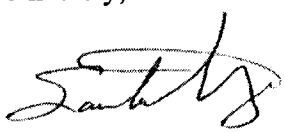

Santiago Muñoz
Associate Vice President
Clinical Services Development

Submitter : Mr. Jason Kizzee **Date:** 08/31/2007

Organization : U.S. Naval Academy Preparatory School

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Jason Kizzee and I am a certified athletic trainer at the United States Naval Academy Preparatory school in Newport, Rhode Island. I provide care, prevention, rehabilitation, and documentation of injuries for all active duty military personnel at the school. I have a master of science degree in health and human performance and bachelor of science in physical education with an option in athletic training. I passed the National Athletic Trainers' Association Board of Certification Exam 8 years ago and have been providing care to physically active persons ever since. I work close with general physicians, orthopedists, physical therapists, physical therapy technicians, and other specialists to provide a team approach to medicine. We all play a very important and vital role to the healthcare industry and our patients.

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 Kizzee MS, ATC

Submitter : Dr. Thomas Stauss **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15016-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

ADVANCED PAIN MANAGEMENT

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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.

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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,

Thomas Stauss, MD
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

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

Organization :

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15017-Attach-1.DOC

1501

ALLIANCE
FOR
REHABILITATION QUALITY
AND
ACCESS

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-1398-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 CMS-1385-P

PHYSICIAN SELF-REFERRAL ISSUES

Dear Administrator-Designate Weems:

The undersigned organizations provide physical therapy, occupational therapy, and speech-language pathology services to hundreds of thousands of Medicare beneficiaries. Together they have formed the Alliance for Outpatient Rehabilitation Quality and Access ("the Alliance") to ensure that Medicare patients have full access to quality rehabilitation services. The Alliance is pleased to have the opportunity to comment on the physician self-referral issues delineated in the Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 which were published in the Federal Register on July 12, 2007.

The Alliance's comments focus on the "In-Office Ancillary Services Exception" to the physician self-referral prohibition. For the reasons set out in detail below, the Alliance strongly recommends that the Centers for Medicare and Medicaid Services ("CMS") issue a regulation or establish a binding policy that eliminates physical therapy as a designated health service which is permissible under the in-office ancillary services exception to the federal prohibition on physician self-referrals. If CMS decides not to adopt this approach, the agency should, at a minimum, significantly tighten the definition of "in-office" services to reverse the considerable relaxation in the contiguous space rules

which has occurred over time. CMS should then aggressively enforce the refined definition.

In the mid-1980s, Congress became alarmed at a series of reports which demonstrated that physician ownership of certain types of health care facilities precipitated substantially greater utilization of those facilities by the doctors who owned them. For example, Congress was aware of studies showing that physician-owned physical therapy centers, diagnostic imaging centers, and clinical laboratories provided more health care services per patient and that the services furnished by them were of lower quality than the care furnished by non-physician owned facilities. In response to the serious adverse consequences flowing from physician referrals to health care facilities in which they have a financial stake, Congress added the "Stark I" provision to section 1877 of the Social Security Act. (Section 6204 of the Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239). Stark I applied only to physician referrals to clinical laboratories but in 1993, Congress enacted the "Stark II" provision which expanded the group of services to which the self-referral prohibition applied—physical therapy services were included in the expanded list. (Section 13562 of the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66).

Stark I and II provide that if a physician or a member of the physician's immediately family has a financial relationship with a health care entity, the physician is prohibited from referring a Medicare beneficiary to that entity for designated health care services (physical therapy is such a service) unless a specified exception applies. Section 1877 (b)(2) of the Social Security Act provides an exception for certain services (other than durable medical equipment and parenteral and enteral nutrients) that are provided "ancillary" to medical services provided by a physician or a group practice that meets certain conditions. Regulations governing the "in-office ancillary services exception" are set out in 42 C.F.R. section 411.355(b).

CMS' rules provide that the in-office ancillary services exception to the Stark self-referral ban is available when:

- The services are furnished personally by the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual who is supervised by the referring physician or by another physician in the group practice;
- The services are furnished in the same building in which the referring physician provides physician services unrelated to the furnishing of the designated health service or, in the case of a group practice, in another building where there is a centralized provision of the group's designated health care services; and
- The services must be billed by the physician performing or supervising the service, the group practice under a billing number assigned to the group practice, an entity that is wholly owned by the performing or supervising physician under the entity's own billing number or a number assigned to the

group practice, or an independent third party billing company acting as agent for the physician or group practice.

In its July 12, 2007 proposed rule, CMS noted that it had received comments in response to the Stark Phase I and Phase II rulemakings "that the in-office ancillary services exception is susceptible to abuse." In particular, CMS observed that "In response to Phase II, we received hundreds of letters from physical therapists and occupational therapists stating that the in-office ancillary exception encourages physicians to create physical and occupational therapy practices."

While declining "to issue a specific proposal for amending the in-office ancillary services exception", CMS solicited "comments as to whether changes are necessary and, if so, what changes should be made." CMS sought comments on: "Whether 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); (2) whether and, if so, how we should make changes to our definitions of same building and centralized building; (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists; and (4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse."

Predicated on the considerable collective experience and expertise of its members, the Alliance is convinced that the protection of patients, the Medicare program, and physical therapy providers demands that physical therapy services be removed from the list of designated health services that are eligible for the in-office ancillary exception to the physician self-referral prohibition under federal law. There is ample precedent for this approach because, as noted above, the in office ancillary services exception is not available for durable medical equipment or parenteral and enteral nutrients. In the alternative, realistic and enforceable limitations should be imposed to ensure that the exception embraces only those services that are truly "in-office"

There Is a Compelling Body of Evidence That Physician-Owned Physical Therapy Services Are Harmful To Patients, Medicare, and Physical Therapists

Although many states have removed or modified the requirement that a patient receive a referral from a physician before being allowed to obtain services from a physical therapist, Medicare has not done so. As a result, Medicare invests physicians with the exclusive power to direct referrals to certain physical therapy providers—and away from others. Ideally, when a physician's patient requires physical therapy, the physician would refer the patient to a qualified independent entity that furnishes the physical therapy service—e.g. an independently practicing physical therapist, a physical therapist clinic, a rehabilitation agency, or a hospital outpatient department. Ideally, the

referral would be made to the physical therapist who is best qualified to meet the patient's specific medical needs. Unfortunately, financial pressures on physicians enable them to utilize their referral power to direct their referrals to entities in which they have a financial interest in an effort to produce additional revenue sources.

From a competitive perspective, Medicare's referral requirement is harmful to the health care market. The Alliance is aware of instances in which physicians (or physician groups) have presented an "either/or" option to physical therapists in the relevant service market—viz. the physical therapist either agrees to join the physician practice as an employee or captive contractor or the physical therapist will receive no more referrals from the physician. The physician's control over the referral makes it extremely difficult, if not impossible, for physical therapists who own and operate their own practices to compete for patients whose access to physical therapy is controlled by the doctor. In a very real sense, therefore, the referral requirement lessens competition in the market and constrains the number of physical therapists from whom patients can select to obtain services.

Of even greater importance, however, are the deleterious effects which physician owned-physical therapy services may have on patients, payors, and physical therapists. It cannot be gainsaid that the physicians' ability to refer to rehabilitation providers in which they are owners (and to deny referrals to facilities in which they do not have an ownership interest) has the real potential to place the best medical interests of the patient at odds with the personal financial interests of the physician.

A study published in the Journal of the American Medical Association in 1992 firmly established that physician-owned physical therapy services in Florida resulted in greater utilization and higher costs. (Mitchell JM, Scott E. Physician Ownership of Physical Therapy Services: Effects on Charges, Utilization, Profits, and Service Characteristics. JAMA. 1992; 268: 19-23). Specific findings of the study included:

- Both gross and net revenue per patient were 30% to 40% higher in facilities owned by referring physicians;
- Percent operating income and percent markup were significantly higher in joint venture physical therapy and rehabilitation facilities;
- Visits per patient were 39% to 45% higher in joint venture facilities;
- Licensed physical therapists and licensed physical therapist assistants employed in non-joint venture facilities spent about 60% more time per visit treating patients than licensed therapists and assistants working in joint venture facilities.

A second study published in the New England Journal of Medicine found that there were higher costs for physical therapy care under the California Workers' Compensation Program when the services were provided by physician-owned physical therapy services. (Swedlow A, Johnson G, Smithline N, Milstein A. Increased Costs and Rates of Use in the California Workers Compensation System as a Result of Self-Referral by Physicians. N Engl J Med. 1992; 327: 1502-1506). According to the authors "this

study demonstrates that self-referral increases the cost of medical care under workers' compensation for each of the three types of service studied [physical therapy, psychiatric, and MRI scans], but by a different mechanism in each instance; by substantially increasing the percentage of injured workers who receive physical therapy (which more than offsets the slight decrease in cost per case)...."

In 1994, the HHS Office of Inspector General (OIG) reported that approximately 78% of physical therapy furnished in physicians' offices did not represent "physical therapy" services as defined by Medicare. The OIG's study concluded that most of the services were palliative in nature or did not involve the complexity required by Medicare's coverage guidelines. (U.S. Department of Health and Human Services, Office of Inspector General, Physical Therapy in Physician's Offices (March 1994)

Another OIG report issued in May 2006 identified additional serious problems with physical therapy services billed by physicians including:

- 91% of physical therapy billed by physicians and allowed by Medicare during the first six months of 2002 did not meet program requirements, resulting in $136 million in improper payments.
- The medical review conducted by the OIG revealed that 26% of the physical therapy was not medically necessary, 34% was undocumented, and 57% was furnished with incomplete plans of care or no plan of care was documented.
- Because of inadequate documentation, OIG reviewers "had difficulty assessing the quality of the physical therapy services." However, according to the OIG, some of the medical records "contained enough documentation for the reviewers to question the quality of care and note that some services 'lacked an objective basis for care.' "
- Most of the medical records which were reviewed "did not indicate the skill level of the individual who rendered the therapy."
- 23 of the 54 beneficiaries in the sample received physical therapy with no plan of care. "In total, physicians for these 23 beneficiaries billed physical therapy for more than eight thousand beneficiaries in 2002 for which Medicare allowed approximately $7.8 million."

The OIG report also identified "questions about physicians' physical therapy billing patterns." For example, the study showed that 4% of all physicians who submitted physical therapy claims accounted for more that half of all allowed claims in 2004. Furthermore, Medicare allowed between $1 million and $7.6 million in physical therapy claims for each of fifteen physicians in 2002, twenty-nine physicians in 2003, and thirty-eight physicians in 2004. (US Department of Health and Human Services, Office of Inspector General, Physical Therapy Billed by Physicians (May 1, 2006)).

Research in other practice settings also indicates that the financial incentives created by physician ownership often result in higher referral rates for services and unnecessary utilization – e.g. durable medical equipment (Hillman, BJ, Joseph, CA, Mabry, MR, Sunshine, JH, Noether, M, "Frequency and Costs of Diagnostic Imaging in

Office Practice-A Comparison of Self-Referring and Radiologist-Referring Physicians, New England Journal of Medicine, Vol. 323, 1990), Outpatient Surgery, Link, W, Longley, C, "The Effect of Physician-Owned Surgicenters on Hospital Outpatient Surgery," Health Affairs, Vol. 21 No. 4, July-August 2002), and Specialty Hospitals (The Lewin Group, "Impact of Limited-Service Providers on Communities and Full-Service Hospitals," Trend Watch, Vol. 6 No. 2, September 2004).

Although it does not involve physical therapy services, there is a very recent study which was published in the April 17, 2007 Health Affairs which demonstrates that the exceptions to the Stark physician referral prohibition have resulted in a proliferation of innovative physician self-referral arrangements. (Mitchell J. the Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging. Health Affairs. 2007; 26, no. 3: w415-w424). The study reported that

- 33% of providers who submitted bills for MRI scans, 22% of those who submitted bills for CT scans, and 17% of those who submitted bills for PET scans were classified to be "self-referrals"
- Among them, 61% of those who billed for MRI and 64% of those who billed for CT did not own imaging equipment; instead, they were involved in lease or payment per scan referral arrangements.

The author of the study observed that the exceptions to the physical self-referral prohibition "have resulted in new forms of referral arrangements for advanced diagnostic imaging procedures—arrangements which are specifically designed to take advantage of these exceptions."

The Alliance submits that as long as physical therapy is included as a service which may be excepted from the Stark self-referral ban, physicians will utilize their considerable resources to devise arrangements which meet the qualifying conditions for the exception even though the arrangement may be detrimental to patients, Medicare, and physical therapists. The exceptionally broad construct and definitions of the in-office ancillary services exception certainly facilitates the creation of such arrangements. The relaxation of the contiguous space requirements have resulted in physicians taking the position that therapy services are being provided "in office" even if the physical therapist is located a considerable distance from the physician's office. The "in office" services exception has also been eroded by the proliferation of satellite facilities especially in states such as Florida. The only true solution is to delete physical therapy as a designated health service which is allowable under the in-office ancillary exception. A less comprehensive approach to the problem would be to significantly delimit the services which are in fact "in office."

The Alliance for Outpatient Rehabilitation Quality and Access appreciates this opportunity to comment on this important issue and welcomes the opportunity to be of further assistance to CMS.

THE ALLIANCE FOR OUTPATIENT REHABILITATION
QUALITY AND ACCESS

Physiotherapy Associates, Inc.
Benchmark Rehabilitation Partners, LLC
U.S. Physical Therapy, Inc.
Benchmark Medical, Inc.
Kentucky Orthopedic Rehab Team

Submitter : **Dr. Vaibhave Parikh** **Date: 08/31/2007**

Organization : **Baylor Department of 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
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

As a Baylor College of Medicine Anesthesiology resident 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. Paul Knox** **Date: 08/31/2007**

Organization : **Anesthesia Consultants of St. Petersburg**

Category : **Physician**

Issue Areas/Comments

GENERAL

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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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Thank you for your consideration of this serious matter.

Submitter : Mr. James McNeil **Date:** 08/31/2007

Organization : Sharon Regional Health System

Category : Other Practitioner

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I work for Sharon Regional Health System in Western Pennsylvania. I am a certified athletic trainer licensed by the Pennsylvania State Borad of Medicine and have a masters degree.

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 B. McNeil, MHSA, ATC

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

Organization : **American Academy of Neurology**

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15021-Attach-1.DOC

15C21

August 29, 2007

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Herb Kuhn, Acting Deputy 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: File Code *CMS 1385-P*

Dear Deputy Administrator Kuhn:

The American Academy of Neurology (AAN) is the leading neurological medical specialty society and represents more than 20,000 neurologists and neuroscience professionals. The AAN is pleased to offer the following comments regarding CMS' proposed rule 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* [CMS 1385-P] published in the Federal Register July 12, 2007. Specifically, the AAN would like to comment in the following eight (8) areas:

- Therapy Standards and Requirements
- Payment for IVIG Add-on Code
- Anti-mark up and Reassignment Proposals
- Physician Quality Reporting Initiative (PQRI)
- Budget Neutrality Using Work Adjuster
- Resource-based PE RVUs
- Telehealth Services
- Other Issues: Anticoagulation Management Codes

Therapy Standards and Requirements

The AAN supports the CMS proposal to drop recertification requirements at 30-day intervals. Although we have reservations that less supervision by MDs may lead to overuse in some cases, it seems reasonable that physicians order therapy for a defined length of time or request the professional opinion of the therapist regarding the duration and intensity of therapy. Non rehabilitation physicians are more likely to rely on therapist professional opinion and the routine signature of certification plans does not necessarily indicate appropriate utilization. The AAN is comfortable with the proposed change to 90-day certification given the other safeguards outlined by CMS in the proposed rule against over utilization.

Coding – Payment for IVIG Add-on Code

The AAN believes that the new codes for different IVIG liquid products do not adequately respect the market and actual acquisition cost of the drug for the average

Neurology practice. Although the office of Inspector General (OIG) reports that 59% of physicians are able to purchase IVIG below the Medicare ASP+6 percent payment rates, this does not appear to be true in the market place. The 59% includes all providers, and mostly applies to hospitals or physicians that belong to Group Purchase Organizations (GPO). Given that most Neurologists do not belong to GPOs and are forced to purchase IVIG either from distributors or at retail prices directly from manufacturers, the asserted lower pricing for IVIG is not accessible for most Neurology practices.

Even if neurologists could obtain IVIG at ASP+6%, this reimbursement does not also cover handling costs or overhead costs associated with storing the drug, infusion facilities, equipment, and billing. The administration reimbursement also does not cover costs. As a result few, if any, neurology practices are able to administer this drug in the outpatient setting, shifting the costs to the hospitals. Now we hear from neurologists that hospitals have begun to restrict the use of IVIG to avoid financial losses of their own. This practice has already started leading to barriers to access for this treatment.

IVIG was left out of the CAP with concerns for escalating use of this expensive treatment. Widely acknowledged is the fact that IVIG is commonly used for an expanding number of off-label indications. This use includes both neurological and non-neurological diseases. The scientific rationale for these uses is unclear in many, but not all, instances.[1-3] This uncertainty requires that the provider community monitor and scrutinize future IVIG utilization.

A recent report on IVIG by the OIG stated, "Recent increases in the use of IVIG for off-label indications may strain the tight supply of this product."[4] And in their response to the OIG report, CMS agreed, "In a tight market, increased demand generated by factors, such as additional off-label use, has an impact on IVIG availability for Medicare beneficiaries. It would be helpful to know more about the surge in off-label use, its effectiveness, and the current and planned research in this area." The AAN strongly supports learning more about the scientific rationale and effectiveness of off-label IVIG use. The off-label indications are becoming expansive and heterogeneous; however, it is not clear whether off-label neurological uses have increased as much as non-neurological uses. Also undetermined is the level of scientific evidence underlying many of the newer IVIG indications.

The AAN is in favor of gathering and tracking utilization data separately for neurological and non-neurological conditions. We request that CMS assign separate HCPCS codes for neurological and non-neurological (infectious diseases, allergy-immunological, oncology-hematological and transplant medicine) IVIG uses. Separate HCPCS codes will lay the groundwork for identifying, tracking and learning more about the "surge" and "effectiveness." Data generated through such tracking will assist CMS and individual academic societies in generating educational guidelines and research towards appropriate IVIG practice.

The AAN is pleased with the CMS proposal to continue, for one more year, the add-on payment designed to compensate physicians for difficulty associated with the acquisition of IVIG for in-office administration. As an incentive, we suggest that continuance of add-on payments beyond that period be contingent on reporting and data collection based on separate HCPCS codes.

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[1] Dalakas MC. Intravenous immunoglobulin in autoimmune neuromuscular diseases.JAMA. 2004 May 19;291(19):2367-75. Review.

[2] Gurcan HM, Ahmed AR. Efficacy of various intravenous immunoglobulin therapy protocols in autoimmune and chronic inflammatory disorders. Ann Pharmacother. 2007 May;41(5):812-23. Epub 2007 Apr 17. Review.

[3] Kumar A, Teuber SS, Gershwin ME. Intravenous immunoglobulin: striving for appropriate use. Int Arch Allergy Immunol. 2006;140(3):185-98.

[4] Report by Levinson, DR Inspector General April 2007 OEI-03-05-00404. Department of Health and Human Services OFFICE OF INSPECTOR GENERAL INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY < http://oig.hhs.gov/oei/reports/oei-03-05-00404.pdf, Last accessed 07-21-2007.

Anti-mark up and Reassignment Proposals

CMS' proposal to extend the anti-markup rule to the professional component of diagnostic tests and its expansion of the definition of supplier to encompass physicians who are less than full-time employees or independent contractors to the billing practice violates the Medicare statute and, as such, constitutes illegal agency rulemaking. In addition, the proposal would result in the elimination of legitimate arrangements and loss of access to care for Medicare beneficiaries.

1. Extension of the Anti-Markup Rule to the Professional Component of Diagnostic Tests

We find no legal authority for expanding the anti-markup rule to physician professional services. Section 1848 of the Social Security Act mandates that physician services be paid the lesser of the billing physician's actual charge or the physician fee schedule amount. CMS cannot, through regulation, impose a different methodology for determining payment for physician services.

Moreover, there is nothing in Section 1842(n) which would permit the anti-markup rule to be applied to services other than diagnostic tests. That law specifically states that the policy applies to billing for a "diagnostic test described in section 1861(s)(3). The physician interpretation of a diagnostic test is NOT a service described in 1861(s)(3). Physician services are described in section 1861(s)(1). [1] Congress, in enacting section 1842(n), specifically limited the applicability of the anti-markup provision to diagnostic tests and did not act to include any other services. Therefore, CMS has no authority under Section 1842(n) to extend the anti-markup rule to physician service services. The proposal to do so is inconsistent with the plain meaning of the law and contrary to the clear intent of Congress.

2. Applicability of the Anti-Markup rule to Services Provided by Employees and Contractors

CMS also proposes to redefine outside supplier under the purchased diagnostic test rule to include anyone who is not a full-time employee of the billing physician or medical group. The agency's authority for the purchased diagnostic test rule comes from section 1842(n) of the Act. That section limits the applicability of the anti-markup rule to charges for diagnostic tests "for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who (sic) shares a practice personally performed or supervised the performance of the test. . . ." Thus, the anti-markup rule does not apply where the services are provided by a physician who "shares a practice" with the billing physician or group. The clear intent of this section is to limit the prohibition on markups to services actually purchased from a third party or entity. One does not purchase services from one's own employees.

Consequently, CMS' definition of "outside supplier" to include employees of a group practice is inconsistent with the plain meaning of the statute. Section 1842(n) is clear that the anti-markup rule does not apply if the diagnostic test is performed or supervised by either the billing physician or another physician with whom that physician "shares a practice." A physician who is an employee of a professional corporation, whether or not he is also an owner of the practice, clearly "shares a practice" with other physician employees. This relationship does not change simply because the physician may work part-time. For this reason, we believe the proposed definition of outside supplier in section 414.50 is inconsistent with section 1842(n).

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[1] CMS has specifically addressed this issue in a previous fee schedule notice in which the agency stated: [d]iagnostic services that have physician work RVUs are not "other diagnostic tests" covered under section 1861(s)(3) of the Act but physician services and services incident to a physician's services covered under sections 1861(s)(1) and 1861(s)(2)(A) of the Act. See Final 1998 Physician Fee Schedule Rule at 62 Fed. Reg. 59048, (October 31, 1997).

Also, the AAN does not believe the anti-markup rule should apply to services performed by physicians who have a contractual rather than employment relationship with a physician practice and provides services on the premises of the billing practice and shares office space, overhead, clinical and administrative personnel and equipment with the billing practice. In such a situation, the independent contractor is "sharing a practice" within the meaning of section 1842(n).

3. Impact on Neurology Practices

If implemented, the proposed rule would result in the elimination of a number of legitimate arrangements and would reduce access to care for Medicare beneficiaries.

Impact on Employed Neurologists and Their Practices

CMS would require that a practice charge Medicare for the TC and PC of an EMG the amount it is charged by the performing physician if that physician is not a full-time employee of the practice. Failure to include such a charge on the claim would result in denial of the claim. With respect to part-time employees, in most cases it will be impossible to determine what that charge is since employed physicians do not generally charge their own practices for their services. Employed physicians are paid a salary which can be adjusted based on productivity and which may include profit sharing. They are not paid a fixed amount for each service. As such, it will be impossible to determine what the "charge" is for the TC or PC of an EMG. Yet, if such a "charge" is not reflected on the claim, payment will be denied. However, including a "charge" on the claim when it does not exist would subject a practice to liability under the False Claims Act. Thus, the proposed rule puts practices in an entirely untenable position with respect to their part-time employees. The only prudent option would be for the part-time physician to bill Medicare him or herself for such services, rather than reassign to his or her group even though the group bills for other services provided by the physician. This is likely to result in a number of billing and administrative headaches for both physician practices and the Medicare program without any apparent countervailing benefit.

Given the nature of procedural arrangements, this scenario could be very common. In fact, many physicians involved in these studies have arrangements that would be affected by the CMS proposal. This is particularly true of physicians just starting out in a practice or who have been out of training a relatively short period of time, but is true of other physicians, as well. In addition, many neurologists provide MRIs in the office and read these MRIs themselves as part of their diagnosis of the patient. For the same reasons, as is the case with EMGs, the CMS proposal would create significant problems for neurology practices that have neurologists wanting to read MRIs that work less than full time.

Impact on Contracted Neurologists

It is not uncommon for neurologists to work a half day or full day in the office of an orthopedic surgeon or neurosurgeon performing nerve conduction studies and EMG. These arrangements can increase access to services especially in rural or other areas where there may be a shortage of physicians able to provide these highly specialized services. Such services are furnished on the premises of the billing practice (i.e. not in a centralized building) and utilize the billing practice's overhead, clinical and administrative personnel and supplies. The neurologist may be paid a per diem or may be paid per test. If payment is on a per diem basis, there is no assigned "charge" for the contract physician's services and thus, for the same reasons as discussed above, with respect to employees, practices are forced to come up with a "charge" and risk False Claims Liability or not be paid for the procedure.

Certainly if payment is on a per test basis, then a charge can be determined. However, that charge reflects the fact that the billing practices incurs practice expenses such as clinical labor, supplies and equipment. Thus, for example, a contract physician might be paid $100 for a service for which the practice charges and is paid $200. Under the proposal, Medicare would only pay $100 for the service and the billing practice would be significantly under compensated for its practice expense costs – costs that are otherwise recognized by CMS as appropriate and paid for under the physician fee schedule. Even if CMS had legal authority to impose such a policy, to do so would be extremely punitive.

If CMS moves forward with its proposal, fewer practitioners may be willing to participate in these arrangements; there may be a decrease in the number of procedures themselves; beneficiaries may have difficulty accessing these services, especially in a timely fashion; and the cost may be higher overall when these studies are actually available.

We understand that there are abuses that CMS is attempting to eliminate and we do not disagree that certain arrangements such as those involving so-called "pod laboratories" should be curtailed. However, the proposed solution has such a broad brush, that a great many legitimate non-abusive arrangements such as those discussed above would also be eliminated. We believe these abuses could be more appropriately addressed through changes to the Stark law definition of "centralized building."

4. Prohibition on Reassignment of the TC if Billing Practice Does Not "Directly Perform" the PC

We oppose the changes to section 484.40(d) (3) for the same reasons we oppose the changes in the anti-markup regulation, as set forth above. We are also concerned about the particular impact of the proposed new 424.80(d)(3)(iii) on EMGs which are somewhat unique among diagnostic tests because the physician generally performs both the TC and the PC. That section states that if a group is billing under a reassignment from a physician who performs the technical or professional component of the service and is not a full-time employee of the practice, then:

> *To bill for the technical component of the service, the physician or medical group must directly perform the professional component of the service.*

As explained above, a physician performs both the TC and the PC of an EMG on the premises of the billing practice. If that physician is not a full-time employee of the billing group, then this provision would work to entirely prohibit the reassignment of the TC of EMGs since the billing group would not have performed the "professional component" of the service. This creates the odd situation that the group could bill for the PC of an EMG performed by a part-time employed or contractor neurologist, under the reassignment rules, but could not bill for the TC since it was also performed by the part-time employee.

The AAN strongly advocates that CMS clarify this provision to state that it would not apply where the physician performs both the TC and the PC such as is the case with EMGs, EEG studies, and MRI or CT imaging studies.

TRHCA—Section 101(b): PQRI

Background on Consensus Organizations

As CMS discusses the "consensus-based process for developing quality measures," the AAN requests that the use of "consensus" be clear. The process used to develop measures themselves

should ideally be based on the best available evidence and not consensus-based. Measures based solely on consensus should be subject to formal validation.

The proposed rule references the important role the AQA Alliance plays in the adoption and implementation of measures. If the AQA is to continue to be used to adopt measures, then CMS should require the AQA to be more transparent about its voting process and the process utilized for adopting and implementing measures. There is no defined membership for determining a quorum for the AQA. If there is a need for coordination of implementation, then work in this area should commence and the AQA should be transparent in its processes relating to the coordination of implementation of measures.

As the PQRI continues, it is important that CMS continue to acknowledge measure developers. Measure developers should be recognized as the owners and maintainers of measures. The measure developers' processes should also be transparent and, in particular, should be made available to those being measured. The AAN would like to stress the importance of including a public comment period in the development of the measures and especially allowing a formal review and comment period for measure specifications.

Proposed 2008 PQRI Quality Measures

The AAN supports the proposed expansion of measures for the 2008 PQRI.

Regarding the specifications for existing measures in the PQRI, AAN would like to request that office consult codes (99241-99245) be added to the denominators for Measure #4 Screening for Future Fall Risk, Measure #46 Medication Reconciliation, and Measure #47 Advance Care Plan.

With the planned continuation of the PQRI in 2008, the AAN requests that CMS provide a justification of the PQRI effort and progress toward quality goals; evaluate the meaningfulness of measures of quality and the utility of the PQRI program; and the degree to which the Medicare program needs are met as well as the functionality in terms of the ability to be collected and calculated in the PQRI program. The ability of CMS to collect and calculate the data in the PQRI program should be evaluated. The AAN also requests that CMS provide PQRI data and feedback reports on the measurement sets to the measures developer work groups and specialty societies in order to evaluate that the use and interpretation of the measures as well as the rate of participation of the various specialties.

Submission of Data on Quality Measures via a Medical Registry or Electronic Health Record

The AAN supports the testing phase for registry-based reporting of PQRI measures with attention to the following recommendations:

- CMS should commit to a long term vision in supporting registries
- CMS should clearly state its accepted level of performance for each of the five registry options
- CMS should be clear about the criteria it will use to determine the preferred option (e.g., 100% match of linkages, highest percent of match from the registry data to the claims, no difference between rate calculations in the registry versus PQRI, validity of data capture, reliability of data capture)
- Rate comparisons and an acceptable margin of error should be established
- CMS should explicitly state the time period used to evaluate the options (e.g. July - December 2007 claims)
- Testing should be done on a variety of measures and/or the most generalizable
- Evaluation results should be collected from the supplier and receiver of registry data
- CMS should use the following parameters when evaluating self-nominated registries: transparency to algorithms, written protocols, standard operating procedures, user training

materials, documentation of standard data dictionary, entry verification, validity and reliability plans

The AAN supports CMS exploring EHR-based submission of measures as an alternative to claims-based reporting for the PQRI.

TRHCA—Section 101(d): Physician Assistance and Quality Initiative (PAQI) Fund

The AAN opposes CMS using the $1.35 billion PAQI fund toward bonus payments for the 2008 Physician Quality Reporting Initiative (PQRI). The MIEA-TRHCA legislation allows CMS to use the fund to buy down the negative update to the fee schedule. With a scheduled 9.9% cut in the conversion factor, the AAN strongly supports CMS directing the money toward the payment update.

Budget Neutrality/Five-Year Review Work Adjuster

In the 2008 proposed rule, CMS announces an increase from -10.1% to -11.8% to the Five-Year Review Work Adjuster. The AAN continues to believe that applying budget neutrality to the work RVUs to offset the improvements in E/M and other services is undesirable.

In 1997, following the first Five-Year Review of the RBRVS, CMS modified the approach to apply budget neutrality and implemented a separate work adjuster. This approach was short-lived as CMS converted this adjustment to the conversion factor in 1999. CMS later stated that the creation of the work adjuster was not effective:

> "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).

From 1998 to 2007, CMS implemented all work neutrality adjustments by adjusting the Medicare conversion factor. We request that CMS consider the history and these additional arguments in its consideration of this issue:

- Adjusting the conversion factor does not affect the relativity of services reflected in the recommended RVUs. Adjusting the RVUs has the potential to inappropriately affect relativity. If the work RVUs continue to be adjusted, it will dampen the improvements to the E/M services valuation. CMS has publicly lauded the RUC for recommending these increases to E/M and we would surmise that the agency would want to achieve the full benefit of these improvements.

- An adjustment in the Medicare conversion factor is preferable because it has less impact on other payers who use the Medicare RVUs. That is, an adjustment in the Medicare conversion factor will not necessarily affect the payment rates of other payers who use the Medicare RVUs and their own conversion factors. However, adjustments in the RVUs impact the payment rates of such payers. The payment rates of payers who peg their rates to a percentage of Medicare will be affected regardless. CMS must consider such "ripple effects" as it decides how to continue to adjust for work neutrality.

- A conversion factor adjustment is preferable because it recognizes that budget neutrality is mandated for monetary reasons. As the monetary multiplier in the Medicare payment formula, the conversion factor is the most appropriate place to adjust for budget neutrality.

- Applying the work neutrality adjustment to the conversion factor would coincide with CMS' current mission of making the Medicare payment transparent.

The AAN agrees with comments from the Relative Value Update Committee (RUC) dated August 31, 2007: "The constant re-scaling also impede[s] the process of establishing work RVUs for new and revised services. The RUC argue[s] that any budget neutrality adjustments deemed necessary should be made to the conversion factor."

The AAN feels strongly that the continued use of a work adjuster to account for budget neutrality is a step backward and therefore compels CMS to eliminate the work adjuster and apply necessary budget neutrality adjustments in 2008 to the conversion factor instead.

Resource-based PE RVUs

The AAN shares the opinion of the RUC that the 50% utilization rate assumption for all medical equipment is not an accurate. Some medical equipment is typically used much less, and other medical equipment may be used much more. For example, some equipment is used less then 5 hours per week in a typical practice, whereas some expensive equipment is used 80 hours per week.

We are strongly in favor of an independent survey of typical equipment utilizations rates. Subsequently, CMS should provide an opportunity to specialty societies to provide data to support lower or higher rates, if appropriate, based on clinical or geographic factors.

The AAN further agrees with the RUC that interest rates on medical equipment should more accurately reflect the current market rates. An increase in the utilization rate assumption should redistribute practice expense relative values to all services within the RBRVS.

Medicare Telehealth Services

The AAN is supportive of the CMS proposal to add neurobehavioral status exam (96116) to the list of Medicare telehealth services.

Other Issues: Anticoagulation Management Codes

In the 2008 proposed Fee Schedule, CMS maintains its decision to bundle anticoagulation management codes (99363 & 99364) into existing evaluation and management (E/M) service codes. The AAN strongly disagrees with this CMS position. The initial impetus for the creation of the codes was a statement by CMS that these services were not managed as well as they should be and that the existing coding structure failed to provide incentives to optimize care. The AAN worked in cooperation with other medical societies to find the best way to define the services performed by physicians managing this very serious medication regimen. The complete range of this work is not paid under the current system. During the creation of the codes, the Current Procedural Terminology (CPT) editorial panel and the Relative Value Scale Update Committee (RUC) were very careful to create protections that would prevent anticoagulant management work from being included in selecting the level of the E/M service. CMS did not offer any explanation for its decision to bundle these codes into E/M services when it published the final rule for the physician fee schedule for 2007 and there is still no explanation articulated in the 2008 proposed rule.

Chronic disease management is important in preventing more costly future interventions and in improving patient quality of life. Patients receiving anticoagulation therapy require extensive

medical work and attention from physicians. In many cases, physicians are forced to either give this care away or refuse to accept patients who require this therapy into their practice. Results of research on this issue show the striking impact of the management of this drug on the healthcare system. It is estimated that there are more than 43,000 adverse drug events treated in the emergency room each year related to anticoagulation therapy. Many of those treated in the emergency room will also end up admitted to the hospital, further degrading the health of the patient and adding to unnecessary spending.

Anticoagulation management services involve extensive work and are an important responsibility; one that the AAN believes should be recognized by CMS with separate payment.

Thank you for your attention to our remarks. If you have questions or require further information, please contact Katie Kuechenmeister, AAN Staff, at 651-695-2783 or kkuechenmeister@aan.com.

Regards,

Stephen M Sergay

Stephen M. Sergay, MB BCh, FAAN
President, American Academy of Neurology

Submitter : **Ms. Rebecca Lopez** **Date: 08/31/2007**

Organization : **University of Connecticut**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I have been a certified athletic trainer for over 9 years. I am currently pursuing a PhD in Exercise Science at the University of Connecticut, where I conduct research as well as teach in the undergraduate Athletic Training Education 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.

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,

Rebecca M. Lopez, ATC, H/FI
Clinical Laboratory Instructor/ Research Assistant
Rebecca.Lopez@uconn.edu

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

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a patient I was told by my MD that I needed physical therapy in order to recover fully from my surgery. The MD told me I was requried to go to a particular physical therapy clinic. I discovered on my first visit the clinic he requested me to receive therapy from was owned by he and his partners. I called the MD and asked to have a prescription to go to physical therapy closer to home and he replied with one visit was suficient enough, even though the orginal prescription requested that I go to physical therapy three times a week for four weeks. The next surgery the MD performed he told my husband I would need to go to therapy at the the same particular clinic as before. My husband requested that I go to therapy again closer to home. The MD replied he prefered me go to that clinic beeause of their quality. He never mentioned to me or my husband that he owned that clinic, and would make money off of his request for me to receive therapy. He refused on this occassion to write a specific prescription for physical therapy provided by someone other than the clinic he owned. He would not release my surgical report to any other clinic. I had to get my own copy of surgical reports so that I may have them for the therapist whom I chose.

Submitter : Dr. David Bryce **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15024-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.

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,

David Bryce, MD
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Joan Reed** **Date: 08/31/2007**

Organization : **Emory University**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Joan Reed and I am the Head Athletic Trainer at Emory University. Prior to taking the position in December 2000 I served as the Assistant Athletic Trainer at Emory since September 1998. Before joining the Emory Sports Medicine Team I was employed at HealthSouth, Mariner Sports Medicine and Pinnacle Sports Medicine, all of which are located in Atlanta. I am originally from Steubenville, Ohio, and hold a Masters of Arts in Teaching from the University of Louisville (1990). At Louisville I served as Graduate Assistant Athletic Trainer, and received a Bachelors of Science in Athletic Training from Ohio University in 1988.

In conjunction with serving as the Head Athletic Trainer at Emory, I have been a guest lecturer at Georgia State University in the Graduate Sport Medicine Program and have been a guest lecturer for the Emory University Physical Therapy Program. I have been a presenter at multiple symposiums in the past. I have also worked part-time for the United States Soccer Federation from 1991-2004. I was a volunteer athletic trainer at the United States Olympic Training Center in Colorado Springs in the summer of 1994 as well as the 1996 Summer Olympics in Atlanta.

I've been a certified member of the Athletic Training profession since 1988. I also am a certified member of the National Strength and Conditioning Association and a licensed 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 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,

Joan C. Reed MAT, ATC, CSCS
Assistant Director of Athletics for Sports Medicine