Submitter : Dr. Sukdeb Datta **Date:** 08/31/2007

Organization : Vanderbilt University Medical Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14483-Attach-1.PDF

CMS-1385-P-14483-Attach-2.PDF

CMS-1385-P-14483-Attach-3.PDF

1385

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.

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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,

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Submitter : Ms. Justine Coffey **Date:** 08/31/2007

Organization : American Society of Health-System Pharmacists

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14484-Attach-1.DOC

CMS-1385-P-14484-Attach-2.DOC

CMS-1385-P-14484-Attach-3.PDF

CMS-1385-P-14484-Attach-4.DOC

#14484 - #1

American Society of
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August 31, 2007

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

Re: CMS-1385-P; RIN 0938-AO65; Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to compendia for determination of medically accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen. ASHP represents pharmacists who practice in hospitals and health systems. The Society's more than 30,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings, including inpatient, outpatient, home care, and long-term-care settings.

ASHP is also the publisher of AHFS Drug Information (DI), a comprehensive, independent reference on the clinical use of medications marketed in the United States. Published continuously for 49 years, AHFS DI is recognized through federal legislation and regulation as an official compendium for information on medically accepted uses of medications.

DRUG COMPENDIA

ASHP commends CMS for proposing a process to determine changes to the drug compendia list, and applauds CMS's interpretation of the Deficit Reduction Act (DRA)

regarding successor versus substitute publication for USP DI. ASHP also commends CMS's decision to consider whether a compendium contains the MedCAC-recommended desirable characteristics when reviewing requests for change to the list of compendia. However, ASHP recommends that the extensive breadth of listings characteristic not be a principal determinant in judging the merits of compendial designation; the quality of review and associated processes, not the quantity of listings, are most important in assessing compendial merits. Additionally, ASHP believes that, in addition to the MedCAC-recommended desirable characteristics, the compendia review process should include a strong emphasis on the need for appropriate processes, including editorial independence, which is essential to a designated drug compendium. Finally, CMS should ensure that its process for review is as rigorous as the Health Care Financing Administration's (HCFA) review was when AHFS became a recognized compendium.

ASHP is also concerned about any reliance by CMS on the Technology Assessment of drug compendia used to determine medically accepted uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen commissioned from the Agency for Healthcare Research and Quality (AHRQ). ASHP submitted comments to CMS regarding the draft report (please see Appendix A, Peer Review Checklist); however, these comments were not addressed in the final report. Additionally, the report focused on the quantity of cited references and did not address the quality of those studies as evidence. Evidence quality should have been measured in order for the report to be considered a useful assessment.

ASHP makes the following specific recommendations to CMS:

- ASHP agrees with CMS that recognition of the USP DI compendium after its name change should not continue if the Secretary determines it is now a substitute publication.

- ASHP cautions CMS in its consideration of extending compendial status for Medicare Part B to Thomson's Drugdex database.

- ASHP strongly recommends that the proposed extensive breadth of listing characteristic not be used as a primary determinant in judging the merits of compendial designation.

- ASHP strongly recommends that CMS add the following characteristic to the list of MedCAC-recommended desirable characteristics of compendia CMS will consider when reviewing requests:
  - Inclusion of safety information for oncology drugs

- ASHP strongly recommends that, in addition to the MedCAC-recommended desirable characteristics, the review process include a strong emphasis on the need for an appropriate process, including editorial independence, which is essential to a designated drug compendium.

- ASHP strongly recommends that CMS add the following characteristics to the list of MedCAC-recommended desirable characteristics of compendia CMS will consider when reviewing requests:
  - High-quality, controlled content development
  - Well-established expert-review process
  - Demonstrated independence from pharmaceutical manufacturers, health insurances, and pharmacy benefits managers
  - Demonstrated evidence-based objectivity

- However, the Society also recommends that CMS ensure that its process for determining changes to the compendia list remains as rigorous as the process used by HCFA when AHFS DI was included as one of the three original drug compendia.

- ASHP strongly recommends that, because AHFS DI went through a rigorous review process prior to its designation, AHFS DI, as well as any other compendium approved under such a rigorous process, should be evaluated by CMS every five years, rather than every year.

Successor v. Substitute Publication

ASHP applauds CMS's interpretation of section 6001(f)(1) of the DRA that amends both sections 1927(g)(1)(B)(i)(II) and 1861(t)(2)(B)(ii)(I) of the Social Security Act (the Act) by inserting "(or its successor publications)" after "United States Pharmacopeia-Drug Information." CMS interprets this DRA provision as explicitly authorizing the Secretary to continue recognition of the compendium currently known as USP DI after its name change, if the Secretary determines that it is in fact a successor publication, rather than a substitute publication.

- **ASHP agrees with CMS that recognition of the USP DI compendium after its name change should not continue if the Secretary determines it is now a substitute publication.**

In 2007, Thomson Healthcare announced that it was replacing the USP DI with its own previously existing DrugPoints database.[1] While Thomson chose to use the term "succeeded" in its press release announcing the change to subscribers,[2] DrugPoints clearly is not a "successor" database since it bears little resemblance to the previous USP DI database in content or editorial oversight by USP's Expert Committees, and it existed

[1] Thomson Healthcare. Important notice: USP DI drug information for the health care professional. Greenwood, CO; 2007 May. Press release No. HC-4684b rev 05/07.
[2] Id.

simultaneously for many years in Thomson's drug database collection. If CMS is unable to determine whether DrugPoints is a successor or substitute publication, ASHP recommends that CMS contact the originator of USP DI, the United States Pharmacopeial Convention (USP), to advise CMS about the nature of DrugPoints relative to USP DI.

- **ASHP also cautions CMS in its consideration of extending compendial status for Medicare Part B to Thomson's Drugdex database.**

Unlike the original three compendia (AHFS DI, AMA DE, and USP DI), Drugdex was never subject to the same rigorous review by Congress and CMS or opportunity for public comment in the *Federal Register*.[3,4,5] Instead, it achieved compendial recognition for Medicaid by amendment to unrelated legislation and for Medicare Part D by reference to the Medicaid language.[6] While not a scientific analysis by any means, in an October 23, 2003 *Wall Street Journal* article, a prominent investigative reporter questioned Drugdex's editorial approach to evidence as well as connections with the pharmaceutical industry (one cited example in the report was the use by Drugdex of a paid pharmaceutical manufacturer consultant to author the gabapentin [Neurontin] monograph).[7] The policy implications on coverage decisions were substantial, costing state Medicaid programs considerable resources.[8] Drugdex subsequently deleted all author attributions in their database (fall 2005), so it is no longer possible to determine the extent to which such authors have been used and still remain. Unfortunately, neither AHRQ's Technology Assessment nor CMS's MedCAC public meeting on March 30, 2006, probed this editorial record.

MedCAC Desirable Compendial Characteristics

ASHP generally agrees with the MedCAC desirable characteristics identified in the Proposed Rule. In addition, ASHP believes that sound, independent, evidence-based policies are the most critical element in establishing compendial merits.

In 2005, assessment of the loss of USP's evidence-based development process for off-label antineoplastic uses led ASHP to consult with oncology experts to develop a codified model for summarizing AHFS' evidence-based analyses of cancer uses for drugs. The

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[3] Armstrong D. How drug directory helps raise tab for Medicaid and insurers. *Wall Street Journal.* October 23, 2003:A1.
[4] Health Care Financing Administration. Medicare program; catastrophic outpatient drug benefit. 21 CFR Part 410. Proposed rule. [BPD-613-P; RIN 0938-AD91] *Fed. Regist.* 1989;54:37190-37208.
[5] Legislative History for compendial designation for Drugdex: 104th Congress Balanced Budget Act of 1995 (vetoed by President) 105th Congress H.R. 3507 Personal Responsibility and Work Opportunity Act of 1996 (not passed)
[6] Id.
[7] Armstrong D. How drug directory helps raise tab for Medicaid and insurers. *Wall Street Journal.* October 23, 2003:A1.
[8] Id.

goal was to develop a model that provided succinct codified conclusions about specific off-label uses that would be readily actionable. Background information was provided to CMS as part of the AHRQ Technology Assessment in 2006. In the intervening year, ASHP has continued to refine its model.

The characteristics of this codified AHFS model are consistent with those identified as desirable by MedCAC, including expanded coverage (listings); quick throughput; provision of detailed evidence tables in support of each individual assessment, including strength of end point; use of pre-specified criteria for weighing evidence; a well-defined expert-review process with clear strengths of recommendation; a publicly transparent process with editorial independence and firewalls; an explicit "not recommended" category that includes therapy considered inappropriate, obsolete, or unproven; an explicit "not fully established" category that includes equivocal evidence and uses with unclear risk/benefit; explicit recommendations concerning sequential and combination therapies; and a process for identification and notification of potential conflicts of interest. ASHP has received favorable comments from CMS, oncology experts, and others regarding this model. Current plans are to roll it out later this year.

Breadth of Listings

ASHP commends CMS's decision to consider whether a compendium contains the MedCAC-recommended desirable characteristics when reviewing requests for change to the list of compendia.

- **However, the Society strongly recommends that the proposed extensive breadth of listing characteristic not be used as a primary determinant in judging the merits of compendial designation.**

While ASHP recognizes the importance of expanding the coverage of off-label anti-cancer uses in its compendium (and has launched a program to address the gap created by USP's exit from focused attention to this therapeutic area), the quality of review and associated processes, not the quantity of listings, are most important in assessing compendial merits. In fact, a principal flaw with CMS's commissioned AHRQ Technology Assessment was its focus on quantifying study citations rather than on assessing the true quality of the evidence that these studies represented.

ASHP believes that a compendium should engage in evidence-based processes that are guided by objective evaluation of the level of evidence according to a well-defined process, and should not to be driven by goals of achieving extensive listings at the expense of quality assessment. The 2003 *Wall Street Journal* report on the effects of overly broad listings of uses documented the severe negative effects of this approach on government expenditures.[9] To require a compendium to have an extensive breadth of

[9] Id.

listings will encourage the listing of off-label uses for which there may be insufficient evidence to either include or exclude.

In the AHRQ Technology Assessment, the emphasis seemed to be on cataloguing all available evidence regardless of quality and merit while discounting the value of editorial process, evidence analysis, expert review, and clinical judgment. Would this approach, i.e., cataloguing all available evidence, be a worthwhile consumption of considerable compendial resources versus emphasizing an ongoing method of reviewing research, evaluating evidence quality, soliciting expert advice about levels of evidence and strengths of recommendation, and then reporting what is relevant according to explicit criteria and reporting methods? ASHP thinks that it would not, and therefore encourages CMS to emphasize the qualitative not quantitative aspects of the process in determining compendial merit.

ASHP remains committed to expanding its timely coverage of off-label anti-cancer uses in a manner that fully embodies the desirable characteristics identified by MedCAC; However, this process should be driven by established principles of evidence-based quality review rather than arbitrary goals of citation quantity. To this end, ASHP's compendial staff is being expanded by at least five full-time employees, including recruitment of a Board Certified Oncology Pharmacist. The result will be an increased breadth of off-label oncology assessment but not one driven by numbers alone.

A basic value among health professionals and the public is that health care practices (including the use of prescription medicines) must be based on evidence of net benefit to the patient (positive outcomes exceeding negative outcomes). Any standard of care lower than this may result in harm to the patient's clinical condition, emotional state, or quality of life, as well as be wasteful of the patient's or society's financial resources. These issues escalate in importance as the cost of a therapy increases. With respect to drug therapy, a too-lax standard for assessing the evidence supporting off-label use could have real consequences for the patient such as delaying or precluding more effective treatment or fostering unfounded hope for improvement in health status.

Safety and Effectiveness

One important desirable characteristic missing from the Proposed Rule that was discussed by AHRQ and MedCAC was inclusion of safety information. In the current environment of increased attention to safe medication use, it is critical, not just desirable, that drug safety issues be weighed in any therapeutic decision. In fact, the strength of recommendation for a given off-label use can be greatly affected by its toxicity profile relative to other therapies and potentially can obscure clinical evidence findings either positively or negatively.

- **ASHP strongly recommends that CMS add the following characteristic to the list of MedCAC-recommended desirable characteristics of compendia CMS will consider when reviewing requests:**

- **Inclusion of safety information for oncology drugs.**

Appropriate Process and Editorial Independence

- **ASHP strongly recommends that, in addition to the MedCAC-recommended desirable characterics, the review process include a strong emphasis on the need for an appropriate process, including editorial independence, which is essential to a designated drug compendium.**

An ideal source for drug information aimed at fostering safe and effective medication use should provide dependable, objective, authoritative information in the context of sound editorial policies; high-quality, controlled content development; a well-established expert-review process; independence from pharmaceutical manufacturers, health insurers, pharmacy benefits managers, and others who may seek to use the source to promote their own interests; an ongoing updating process; a mechanism for correction notification; and broad-based authoritative guideline incorporation. A key aspect of such a resource is the evidence-based objectivity that allows the inclusion of uses and dosages that are not included in the FDA-approved labeling (i.e., off-label/unlabled uses).

- **ASHP strongly recommends that CMS add the following characteristics to the list of MedCAC-recommended desirable characteristics of compendia CMS will consider when reviewing requests:**

  - **High-quality, controlled content development**
  - **Well-established expert-review process**
  - **Demonstrated independence from pharmaceutical manufacturers, health insurers, and pharmacy benefits managers**
  - **Demonstrated evidence-based objectivity**

Recognition of the authority of a drug information source by professional, government, legislative, regulatory, and private-sector groups should be linked to the strength of its editorial process and the dependability of the information it provides. It also is important that the information be free of undue influence of pharmaceutical manufacturers and other third parties who may seek to use the publication to promote their own interests.

An appropriate process for developing authoritative drug information should involve several key steps: information tracking and gathering, evidence-based information analysis, drug information synthesis and development, a review process, and finalization and management of published information; the process should be well documented, transparent and independent. Maintenance efforts should include periodic updating to

accommodate new information and an assertive accessible alerting and correction-notification process.

AHFS DI applies all of these key steps in its process and is widely trusted for its established record in refuting unfounded efficacy claims, its rigorous science-based editorial process, and its independence from the influence of pharmaceutical manufacturers. (See Appendix B, policy relating to editorial independence of AHFS Drug Information approved by the ASHP Committee on Publications and Board of Directors).

Rigorous Review

ASHP commends CMS for its proposal to create a process incorporating public notice and comment to receive and make determinations regarding requests for changes to the list of compendia used to determine medically accepted indications for drugs and biologicals used in anti-cancer treatment.

- **However, the Society also recommends that CMS ensure that its process for determining changes to the compendia list remains as rigorous as the process used by HCFA when AHFS DI was included as one of the three original drug compendia (See Appendix C, Overview of AHFS DI HCFA Review Process).**

This rigorous review by HCFA was an extremely important process, since it ensured that any approved compendium contributed to the information sources available to CMS to determine coverage for appropriate indications. Because of the process AHFS DI went through, CMS should maintain AHFS DI as an approved compendia, and require all other compendia to go through such a rigorous process prior to approval.

- **ASHP strongly recommends that, because it went through this process, AHFS DI, as well as any other compendium approved under such a process, should be evaluated by CMS every five years, rather than every year. In place of an annual review of approved compendia, CMS should consider implementing a certification process that requires approved compendia to certify maintenance of the desirable characteristics during the past year.**

Consensus Opinions vs. Evidence-Based Clinical Trials

ASHP cautions CMS to carefully investigate the independence of a compendia's process, and ensure its process is not biased toward the consensus opinions of its members rather than a rigorous assessment of the evidence from clinical trials and scientific studies. CMS must carefully weigh the outcomes that such a potentially heavily opinion-weighted process may have on its own policies and goals for coverage of off-label uses of drugs and biologics in anti-cancer therapeutic regimens.

CMS versus FDA Standards

CMS should carefully review some of its current standards regarding off-label anti-cancer drug use. For example, as a result of the FDA Modernization Act of 1997, FDA has changed many of its previously stringent requirements for the quality and quantity of evidence required for approval of a new use. [10,11,12] As a result, CMS may be holding coverage of off-label uses for anti-cancer therapies to a higher standard than FDA does for actual approval of labeled uses (e.g., different regimens, different stages, etc).

ASHP appreciates this opportunity to present its written comments on the proposal for a process to determine change to the drug compendia list. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

Justine Coffey

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs

Enclosures/Appendicies

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[10] US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER). Guidance for industry: providing clinical evidence of effectiveness for human drug and biological products. (Clinical 6) 1998 May.

[11] US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER). Guidance for industry: FDA approval of new cancer treatment uses for marketed drugs and biological products. (Clin 7) 1998 Dec.

[12] US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER). Guidance for industry: Clinical trial endpoints for the approval of cancer drugs and biologics. Draft guidance. (Clinical/Medical) 2005 Apr.

#14484 - #2

APPENDIX A

Peer Review Checklist
"Compendia for Coverage of Off-Labels Uses of Drugs and Biologics in an Anti-Cancer Chemotherapeutic Regimen"

Peer Review Checklist
"Compendia for Coverage of Off-Labels Uses of Drugs and Biologics in an Anti-Cancer Chemotherapeutic Regimen"

Name of Reviewer: American Society of Health-System Pharmacists, Inc. (McEvoy, Welsh, Ford)

Title: See Preferred Mailing Address box

Affiliations: ASHP

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Conflicts of Interest: Please disclose any potential conflicts of interest, such as research in progress, consulting arrangements, or other financial involvements.

All members of ASHP's AHFS Drug Information publishing.

Please use this form to guide your comments. Return your separate written review and this completed form **by August 14, 2006 (N.B.: Extension granted by AHRQ because wrong version initially sent to ASHP)** to the attention of the Technology Assessment Program:

E-mail: ahrqtap@ahrq.gov

If there are any questions, please contact Chuck Shih via e-mail cshih@ahrq.gov or by phone at 301-427-1969.

Name of Reviewer: ASHP

Please indicate your answers to the following questions by placing an "x" in the appropriate column, and add a brief explanation of answers and comments in the space provided.

Questions	YES	SOME TIMES	NO
General Comments			
1. Is the purpose of the assessment clear?		X	
2. Is the technology assessment well structured and organized?		X	
Comments: The authors of the report clearly state what was done, but the underlying methodology is overly simplistic. Evaluation of item 3d on p. 6, presence of bias, depends on definition of "equivocal evidence", which was not explicitly defined by authors according to study limitations section on p. 147.			
Scope and Analytic Framework			
3. Is the scope of the report clearly defined?		X	
4. Were all clinically important issues considered?			X
Comments: The report did not adequately address the quality of the evidence considered. Analysis seems to emphasize the number of study citations included more than the quality of evidence. Reporting which unlabeled uses and what supporting evidence was included by each compendium without analysis of *whether* all such information should have been included is not the most optimal measure of compendial quality. There also seems to be a misconception that a compendium is used to catalog all clinical studies for a drug instead of presenting clinically relevant information based on carefully selected studies. One could also argue the clinical impact of the off-labeled uses that were selected as examples.			
Methods			
5. Are the inclusion and exclusion criteria appropriate?			X
6. Is any published literature or work in progress missing?			X
7. Have we included materials that ought to be excluded or down-weighted?	X		
8. Is the method for grading the quality of individual studies appropriate?			X
9. Is the method for analyzing data appropriate and clearly explained?		X	

Questions	YES	SOME TIMES	NO
Comments: Not all studies conducted for a drug provide clinically relevant information. Searching the literature for all studies and checking that against which studies are cited in various compendia is not a valid measure of quality. Method of selecting agent-cancer combinations for study (new and older agents, common and rare cancers, etc.) is likely not consistent with criteria considered important by compendia for prioritizing inclusion of unlabeled uses; i.e., high degree of therapeutic efficacy, lesser toxicity than current treatments, number of patients potentially affected, lack of alternative therapies. Also, many studies were reported as abstracts, which are not optimal for assessing evidence because of deficiencies in reporting of methods and may not be representative of final study results. (See attached references listed under "Problems with using abstracts to assess evidence from clinical trials".) Editorial decisions regarding inclusion of information on unlabeled uses must balance the desire for expediency in reporting with the need for reliable evidence upon which to make recommendations for therapy.			
	YES	**SOME TIMES**	**NO**
Results			
10. Are adverse effects adequately addressed?			X
11. Were the results stated clearly and were the figures, tables and evidence tables clear?		X	
Comments: The various compendia offer information on the adverse effects of each drug based on its labeled uses. The cautions and adverse effects information for a drug is relevant when the drug is used for off-labeled uses too. In addition, when certain risks appear to be uniquely related to or affected by the underlying cancer being treated, they can be described. However, it should be recognized that establishing causal relationships, even from large studies, often is difficult. In the context of the often limited clinical data that is available for emerging off-label uses, establishing causal relationships would be even more difficult. NCCN guidelines are not strictly comparable to other compendia since they do not include adverse event information (Table 1F), which is important for clinicians to consider when deciding whether or not to use a particular drug for a given cancer. Data presentation is sometimes inconsistent or incomplete. For example, there is no summary table for the first 8 agent-cancer combinations as there is in Table 16 for the second 6 combinations. Also, text states that an evidence table was not done for docetaxel in ovarian cancer because the large number of citations (143 total, 57 meeting EPC criteria) "exceeded capacity" (?). However, a similar number of citations was found for some other uses yet they were included in evidence tables, e.g., docetaxel for gastric cancer (132 total, 72 meeting EPC criteria). See additional comments at end of this form.			
Conclusions			
12. Are the major findings clearly stated?	X		

Questions	YES	SOME TIMES	NO
Comments: The major findings are clearly stated, but not particularly helpful. A compendium should be judged on the rigor of its editorial process and the timeliness and clinical relevance of its content. The selection of off-labeled oncology uses for this report does not recognize that publication of certain off-labeled uses may be prioritized based on the strength of the available evidence and the impact the drug will have for the treatment of a particular cancer; there was no attempt to evaluate the quality/strength of evidence in the technology assessment. Many of the off-labeled uses selected for this report, including those for oxaliplatin, irinotecan, rituximab, and erlotinib, have not progressed to phase III trials. In the constraints of existing resources, editorial priority often is driven to add off-labeled uses that have progressed further in clinical trials because there is greater evidence of efficacy and safety to support these uses. There is also no recognition that keeping clinicians up to date on important cautions information on these drugs is an important mission of a compendium. Safety concerns on proper use and management of adverse effects of the drug generally should be given greater priority over citing unlabeled uses that have little or no supporting evidence. First, do no harm.			

On the following page, please provide:

- **References for relevant studies that we have missed**
- **Any other comments and suggestions for improving the content and format of this review**

Name of Reviewer: ASHP

Name of Reviewer: ASHP

Peer Review Form

Please use this sheet to provide specific comments about the technology assessment below.

ASHP appreciates the opportunity to provide comments on AHRQ's Draft Report on Compendia for Coverage of Off-label Uses of Drugs and Biologics in an Anti-cancer Chemotherapeutic Regimen May 31, 2006.

General Comments about AHRQ's Draft Technology Assessment

Quality of evidence: Reviewing and selecting studies based on the quality of evidence is more meaningful than citing all studies (phase I-IV) as done in this technology assessment. The authors of this report seem to make assumptions that all studies published for a drug are equally important (hence the searching and tallying) and that numbers of studies translate into clinical importance (not necessarily true). Their methodology seems overly simplistic. The table from the statistics web site (Bandolier: http://www.jr2.ox.ac.uk/bandolier/band139/b139-2.html) supports the arguments for selecting studies based on the quality of evidence. The parenthetically noted JAMA study (PubMed ID: 16014596) shows that an initial randomized trial that is widely cited might be contradicted by a second randomized trial, so confirmatory trials are important. In this study, a sizable percentage (16%) of second randomized trials contradicted the findings of the initial trial.

The technology assessment commented on the reference padding employed by Drugdex; it was notable that in 9 of 14 uses, references included in the bibliography were not cited in the text of the monographs. While not a scientific analysis by any means, a prominent Wall Street Journal investigative report (Armstrong D. How drug directory helps raise tab for Medicaid and insurers. WSJ. 2003 (Oct 23):A1) questioned Drugdex' editorial approach to evidence as well as connections with the pharmaceutical industry (one cited example in the report was the use by Drugdex of a paid pharmaceutical manufacturer consultant to author the gabapentin [Neurontin] monograph). Drugdex subsequently deleted all author attributions in their database (fall 2005), so it no longer is possible to determine the extent to which such authors have been used and still remain. Unfortunately, neither the current technology assessment nor CMS' MCAC public meeting on March 30, 2006 probed this. Table 1C of the Technology Assessment also acknowledge that Drugdex' evidence process is designed to be broad and includes case reports.

It is unclear how the authors of this technology assessment are using "tallying" of study citations, abstracts, and numbers of patients as a measure of efficacy and safety. Phase I trials are intended to establish activity of a drug for a particular cancer and dosing ranges and generally would not represent good evidence. Information on some studies is published at intervals in abstract form (e.g., ASCO abstracts) before publication as a full study, so simply "counting" all of these citations would falsely inflate the number of studies. As mentioned above, the use of abstracts as a sole source of evidence may be particularly troubling because of deficiencies in reporting methods in abstracts and

to start treating their patients would be a misrepresentation of the level of evidence and strength of recommendation. The authors of this report are not recognizing the distinction between research and clinical practice.

By including studies of all design (Phase I-IV) and all studies conducted for a drug for a particular use, the authors of this report fail to acknowledge the diminishing return from less rigorous or irrelevant studies. A reader can simply search Medline or ASCO abstracts or other such sources to obtain unsynthesized information. Is it not an important role of a compendium to sift through the available material, analyze and synthesize it, and attempt to identify and assess what is most useful for the clinician? Unfortunately, the design and tone of the technology report seem to emphasize the tallying of all studies, regardless of quality, rather than this latter evaluative and synthetic process.

Purpose of a compendium: The point of a compendium is to provide a reference for clinicians in which experienced staff have carefully reviewed the medical literature, selected clinically important studies, and then summarized and synthesized this information into discussion that pertains to clinical practice. In this context, evidence tables for key studies can be a useful supplement. But simply pulling all studies and putting the information into evidence tables without any editorial process leaves all the work of evaluation to each clinician. This is an unrealistic expectation.

Despite the considerable time and effort that was put into carefully preparing the detailed evidence tables for all existing studies for each drug/off-label use combination (Appendix detailing the search strategies for the technology assessment), it is not clear how this presentation of the material alone benefits the reader/clinician or dictates what should be reported by a compendium. Unless it is used as a supplement to a discussion that results from an editorial review and synthesis of the literature, this material would leave each reader the unrealistic task of evaluating the entire body of evidence. A compendium is intended to itself serve as a reference containing a summary of the evidence and to provide the reader/clinician with selected bibliographic sources if they wish to pursue the topic in greater detail. While evidence assessments are integral parts of the compendial process in establishing levels of evidence in support of a given use and in soliciting strengths of recommendations from expert reviewers and clinicians, the emphasis on tallying studies (quantitive) in this technology assessment and general lack of assessing the evidence quality could provide the wrong message about the role of compendia.

NCCN is a guideline-based publication for oncology therapy only and distinctly different in approach compared with the other studied compendia. NCCN does not meet the conventional definition of a drug compendium. All of the other compendia provide monographs on the wide variety of prescription drugs in the US addressing a wide array of critical elements needed to safely and effectively use a drug. This is not an equivalent comparison. For example, NCCN does not provide detailed dosage information, information on adverse effects, precautions, warnings, contraindications, etc. In addition, there are other oncology guidelines besides NCCN, such as NIH consensus guidelines, ASCO guidelines, and others. If the intent was to extend the definition of a drug compendium to include to such guidelines, why weren't other such oncology guidelines included in the assessment?

General conclusions: There certainly are useful insights in this report that can be applied by each compendium in improving its process. The discussion section of the document is perhaps most

valuable in this regard. The difficulty in assessing methodological transparency is an important message.

What would have added greatly to the value of this report would have been greater discussion on the importance of assessing evidence quality and on the health policy issues involved, particularly in the context of competing expectations for expeditious evaluation of evidence and more clearly defining thresholds of evidence needed to establish reliable recommendations for therapy. For example, what is the role of a sole meeting abstract in this context? Is evidence truly driving the process or are expectation and opinion?

Perhaps the most valuable health policy conclusion is an implicit one about the overwhelming need for additional resources to address the formidable task of evaluating and synthesizing evidence. For example, what resources were consumed by CMS and AHRQ to simply tally the reported evidence, not even evaluate its quality and make specific recommendations about therapeutic roles, for only 14 uses involving 7 drugs? Now extrapolate this, particularly in the context of clinician and patient expectations.

Specific Comments about AHRQ's Draft Technology Assessment

p 7 (pdf p 9): says source was AHFS 2006 but 2005 edition was used.

Therefore, two *corrections* should be made for unlabeled uses for bevacizumab that appear in January 2006 version of AHFS DI (PDF pages from AHFS can be provided on request.) This discussion is on pdf pp. 28-46 (document pp. 26-44) of the report.

*1. Bevacizumab (Avastin) for treatment of breast cancers - COVERED IN AHFS DI January 2006
*2. Bevacizumab (Avastin) for treatment of lung cancers - COVERED IN AHFS DI January 2006

Tables 2a-c:

bevacizumab - breast cancer

added for AHFS DI January 2006 citing the study of capecitabine vs bevacizumab and capecitabine (Miller J Clin Oncol 2005) and the NCI protocol for a phase III trial of bevacizumab with or without paclitaxel

The discussion in the report is inaccurate because AHFS DI does cover this use and provides current citations for phase III studies.

Tables 3a-c:

bevacizumab - lung cancer (non-small cell lung cancer)

added for AHFS DI January 2006 citing the 2005 ASCO abstract for the Sandler et al Phase II/III trial

The discussion in the report is inaccurate because AHFS DI does cover this use and provides one of the current citations mentioned as supporting evidence.

p 12 (pdf p 14): included all study designs (phase I, phase I/II, phase III or phase IV) - why include phase I studies in a review of evidence?

p 13 (pdf p 15): data extraction done from abstracts: abstracts often contain errors and full text should be requested and reviewed to confirm the information and fully evaluate the study

p 16 (pdf p 18): error - says AHFS DI uses number sign to identify unlabeled use when in fact a dagger is used

p 19 (pdf p 21): Table 1A states that AHFS-DI 2005 was used; why wasn't the 2006 edition, which was available in January, used instead?

Table 1F (p. 24): Clarify that references DO exist for most statements in AHFS monographs, just not published except in electronic version. Material sent for external review is always fully referenced and extensive archival documentation extends back to 1959.

Table 1F (p. 24): Methods for formulating recommendations: Add "External review for comment." This was described in the documentation provided to the Duke Center for Clinical health Policy Research. Unfortunately, this omission was overlooked in the draft reviewed by us in February 2006.

Table 1F (p. 24): Harms: Disagree with comment that harms are not considered in unlabeled uses. Information on adverse effects/precautions is discussed or cross-referenced in uses section when appropriate, e.g., when use in certain patient populations may be associated with increased risk of adverse effects or necessitate additional precautions. In addition, comparative toxicity is typically discussed in Uses section when such information from randomized comparative trials is available. Also, adverse effects info is available in Cautions section from labeled uses of the drug. Toxicity information often is not available if data has only been published in abstract form. Also see earlier discussion under question 10 above.

Table 13b (p. 125). Footnote b under "number of evidence citations" for AHFS DI doesn't correspond to footnote description.

Discussion, p. 144: Contrary to what is stated, AHFS DI often provides information on different therapies for a given condition when alternative therapies are available.

Problems with using abstracts to assess evidence from clinical trials

JAMA. 2006 Mar 15;295(11):1281-7.
Comment in:
JAMA. 2006 Aug 9;296(6):653.

Transition from meeting abstract to full-length journal article for randomized controlled trials.
Toma M, McAlister FA, Bialy L, Adams D, Vandermeer B, Armstrong PW.
The Division of General Internal Medicine, University of Alberta, Edmonton, Alberta, Canada.

CONTEXT: Not all research presented at scientific meetings is subsequently published and, even when it is, there may be inconsistencies between these results and what is ultimately printed. Although late-breaking trials sessions are now integrated into several major scientific meetings and the results are often promptly and prominently communicated, no studies have examined the publication fate and degree of consistency between meeting abstracts or presentations and subsequent full-length article publications for randomized controlled trials (RCTs) presented at these sessions. OBJECTIVE: To compare RCT abstracts presented in the late-breaking trials session vs other sessions at a major scientific meeting and subsequent full-length publications. DESIGN: RCTs were identified by hand searching abstract proceedings booklets and related Web sites for the American College of Cardiology scientific meetings (1999-2002). Subsequent full-length articles were identified via electronic databases. MAIN OUTCOME MEASURES: Publication fate and degree of consistency between meeting abstract results and subsequent full-length publication results. RESULTS: The 86 late-breaking RCTs were significantly larger (median, 2737 patients vs 896; P<.001), were more likely to be preceded by a published design paper (27 [31%] vs 13 [13%]; P = .002), had higher quality scores when eventually published (mean Jadad score 2.69 vs 2.19; P = .01), and were less likely to report favorable results for the intervention than the 100 randomly chosen comparison RCTs presented in other sessions (50 [58%] vs 75 [75%]; P = .01; odds ratio 0.46; 95% confidence interval, 0.24-0.90). RCTs presented at the late-breaking trials sessions were significantly more likely to be published (79 [92%] vs 69 [69%]; P<.001) and appeared earlier after presentation (median 11.5 months vs 22.0 months; P<.001) than RCTs presented in other sessions, an association that persisted even after adjusting for sample size, conclusion of study, and RCT design: adjusted hazard ratio, 1.80 (95% confidence interval, 1.24-2.61). **Sixty (41%) of the 148 RCTs that were subsequently published exhibited discrepancies between the efficacy estimate reported in the meeting abstract vs the one reported in the full-length article for the primary outcome. The mean change in effect was 0.44 SDs and in 20 cases (14%), the point estimate was statistically significant in only 1 member of the pair.** The discrepancy rate was the same for late-breaking RCTs as for RCTs presented in other American College of Cardiology sessions (P = .92). CONCLUSIONS: Late-breaking trials were larger, more likely to be preceded by a design paper, and less likely to report positive results than RCTs presented at other sessions, but **discrepancies between the meeting abstract results and subsequent full-length publication results were common even for late-breaking trials.**

PMID: 16537738 [PubMed - indexed for MEDLINE]

J Clin Epidemiol. 2006 Jul;59(7):681-4.

Reporting of trials presented in conference abstracts needs to be improved.

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OBJECTIVES: To assess how trial information reported in conference abstracts differs to their subsequent full publication. METHODS: Randomized trials reported at the American Society of Clinical Oncology conference (1992) were identified. CENTRAL and PubMed (December 2002) were searched to identify corresponding full publications. A checklist (based on CONSORT) was used to compare abstracts for 37 trials with their full publication. RESULTS: Some aspects were well reported. Ninety-five percent of study objectives, 92% of participant eligibility, 100% of trial interventions, and 84% of primary outcomes were the same in both abstract and full publication. Other areas were more discrepant. **Forty-six percent reported the same number of participants randomized in the abstract and full publication; only 22% reported the same number analyzed (median number analyzed per trial was 96 for abstracts and 117 for full publications). Eighty-two percent of trials were closed to follow-up in the full publication compared to 19% of abstracts. Lack of information was a major problem in assessing trial quality: no abstracts reported on allocation concealment, 16% reported on blinding and 14% reported intention to treat analysis. These figures were 49, 19, and 46%, respectively, for full publications.** CONCLUSION: The information given for trials in conference proceedings can be unstable, especially for trials presenting early or preliminary results, and needs to be improved.

PMID: 16765270 [PubMed - indexed for MEDLINE]

JAMA. 1998 Jul 15;280(3):254-7.

Erratum in:
JAMA 1998 Oct 14;280(14):1232.

Positive-outcome bias and other limitations in the outcome of research abstracts submitted to a scientific meeting.

Callaham ML, Wears RL, Weber EJ, Barton C, Young G.
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mlc@itsa.ucsf.edu

CONTEXT: Studies with positive results are more likely to be published in biomedical journals than are studies with negative results. However, many studies submitted for consideration at scientific meetings are never published in full; bias in this setting is poorly studied. OBJECTIVE: To identify features associated with the fate of research abstracts submitted to a scientific meeting. DESIGN AND SETTING: Prospective observational cohort, with 5-year follow-up of all research submitted for consideration to the major annual 1991 US research meeting in the specialty of emergency medicine. PARTICIPANTS: All research abstracts submitted for consideration at the meeting for possible presentation. MAIN OUTCOME MEASURES: Characteristics associated with acceptance for presentation at the meeting and subsequent publication as a full manuscript. RESULTS: A total of 492 research abstracts were submitted from programs in emergency medicine and other specialties affiliated with 103 US medical schools. A total of 179 (36%) were accepted for presentation and 214 (43%) were published in 44 journals. Of the 179 abstracts accepted for presentation, 111 studies were published. Scientific quality of abstracts or prestige of the journal in which the study was eventually published did not predict either of these outcomes. The best predictors (by logistic regression) of meeting acceptance were a subjective "originality" factor (odds ratio [OR], 2.07; 95% confidence interval [CI], 1.13-3.89) and positive results (OR, 1.99; 95% CI, 1.07-3.84), and, for publication, meeting acceptance (OR, 2.49; 95% CI, 1.49-4.35) and large sample size (OR, 2.26; 95% CI, 1.23-4.31). **Forty-nine percent (241) of abstracts did not report on blinding, and 24% (118) did not report on randomization.** Acceptance and publication were both more likely for positive outcomes (P=.03). Funnel plots showed the classic distribution of positive-outcome ("publication") bias at each of the submission, acceptance, and publication phases. Meeting acceptance predicted publication with a sensitivity of only 51%, specificity of 71%, positive predictive value of 57%, and negative predictive value of 66%. CONCLUSIONS: **Positive-outcome bias was evident when studies were submitted for consideration and was amplified in the selection of abstracts for both presentation and publication, neither of which was strongly related to study design or quality.**

PMID: 9676673 [PubMed - indexed for MEDLINE]

J Orthop Trauma. 2006 Feb;20(2):129-33.

The consistency between scientific papers presented at the Orthopaedic Trauma Association and their subsequent full-text publication.

Preston CF, Bhandari M, Fulkerson E, Ginat D, Egol KA, Koval KJ.
New York University-Hospital for Joint Diseases, New York, NY, USA.

OBJECTIVES: To determine the consistency of conclusions/statements made in podium presentations at the annual meeting of the Orthopaedic Trauma Association (OTA) with those in subsequent full-text publications. Also, to evaluate the nature and consistency of study design, methods, sample sizes, results and assign a corresponding level of evidence. DATA SOURCES: Abstracts of the scientific programs of the OTA from 1994 to 1997 (N = 254) were queried by using the PubMed database to identify those studies resulting in a peer-reviewed, full-text publication. STUDY SELECTION: Of the 169 articles retrieved, 137 studies were the basis of our study after the exclusion criteria were applied: non-English language, basic science studies, anatomic dissection studies, and articles published in non-peer-reviewed journals. DATA EXTRACTION/SYNTHESIS: Information was abstracted onto a data form: first from the abstract published in the final meeting program, and then from the published journal article. Information was recorded regarding study issues, including the study design, primary objective, sample size, and statistical methods. We provided descriptive statistics about the frequency of consistent results between abstracts and full-text publications. The results were recorded as percentages and a 95% confidence interval was applied to each value. Study results were recorded for the abstract and full-text publication comparing results and the overall conclusion. A level of scientific-based evidence was assigned to each full-text publication. RESULTS: The final conclusion of the study remained the same 93.4% of the time. The method of study was an observational case series 52% of the time and a statement regarding the rate of patient follow-up was reported 42% of the time. Of the studies published, 18.2% consisted of a sample size smaller than the previously presented abstract. When the published papers had their level of evidence graded, 11% were level I, 16% level II, 17% level III, and 56% level IV. CONCLUSIONS: Authors conclusions were consistent with those in full-text publications. Most studies were observational, less than half reported on the rate of patient follow-up. **Many abstracts followed by publication had a smaller sample size in the published paper. Half of all studies were graded level IV evidence.**

PMID: 16462566 [PubMed - indexed for MEDLINE]

General Comments About ASHP's Compendial Publishing

American Hospital Formulary Service Drug Information (AHFS DI): ASHP is the publisher of AHFS DI, which is one of 3 drug compendia originally recognized for making determinations about medically accepted indications for anti-cancer chemotherapeutic regimens under Section 1861(t)(2)(B)(ii)(I) of the Social Security Act (SSA). AHFS DI is the only remaining federally recognized drug compendium published by a noncommercial entity—the American Society of Health-System Pharmacists—a nonprofit professional practice and scientific society.

ASHP supports a vision for pharmacy practice in hospitals and health systems in which pharmacists will lead evidence-based medication use programs to implement best practices. Publication of AHFS DI is an important component in achieving this vision.

The mission of AHFS DI is to provide an evidence-based foundation for safe and effective drug therapy. Widely trusted for its established record in refuting unfounded efficacy claims, its rigorous science-based editorial process, and its independence from the influence of pharmaceutical manufacturers, AHFS DI has remained true to this mission for almost 50 years and is the most widely vetted drug compendium. (Background included in documentation provided to Duke.) Recognition of the compendial authority of AHFS has extended over 4 decades.

ASHP holds in high regard the responsibilities attendant to the public and private trust placed in the evidence-based editorial deliberations of AHFS DI. As such, ASHP also considers it essential to protect the integrity and independence of the editorial decisions of AHFS staff by separating the Society's business activities with pharmaceutical manufacturers (e.g., exhibits at educational meetings, journal advertising) from the editorial activities of its drug compendium. Interactions between AHFS staff and pharmaceutical manufacturers are limited to the legitimate exchange of the scientific and medical information needed to fulfill the mission of AHFS DI. Communications are directed to the scientific and medical information areas within the companies; contact with marketing areas is avoided. An editorial independence statement (included in documentation provided to Duke), approved by ASHP's Board of Directors, outlines the principles that AHFS staff apply in ensuring such independence.

ASHP recognizes the challenges of the resource-intensive process involved in conducting evidence-based therapy assessments and remains committed to its vision of fostering evidence-based medication use and publishing its highly regarded drug compendium. The recent loss of USP's evidence-based development process for antineoplastic therapy has prompted the Society to explore opportunities for enhancing its own consideration of such uses via AHFS DI. The codified AHFS evidence rating system that makes use of levels of evidence to reflect strength and quality of existing data as well as recommendation grades is a major initiative aimed at enhancing this effort. As a nonprofit, professional practice and scientific society, resources needed to support such efforts remain a challenge, but our commitment to promoting rational drug therapy through compendial considerations remains steadfast. ASHP remains ready to continue to assist CMS through the Society's authoritative AHFS DI drug compendium in making determinations of medically accepted indications for drugs and biologicals used in anti-cancer chemotherapeutic regimens under Part B of Medicare.

To this end, ASHP continues to work with other nonprofit professional practice and scientific societies such as the Association of Community Cancer Centers (ACCC), American Society of Clinical Oncology (ASCO), American Society of Hematology (ASH), Oncology Nursing Society (ONS), and others in refining its evidence rating system described in the background information provided to the Duke Center for Clinical Health Policy Research.

Appendix B

■ Editorial Independence of AHFS Drug Information

Approved by the American Society of Health-System Pharmacists Committee on Publications and Board of Directors

The mission of *AHFS Drug Information* (*AHFS DI*) is to provide an evidence-based foundation for safe and effective drug therapy. Information included in *AHFS DI* shapes treatment decisions made by clinicians and influences public and private health care policy and decisions. As a result, it is important that the information be authoritative, objective, and free of undue influence from pharmaceutical manufacturers, health insurers, pharmacy benefits managers, and other third parties who may seek to use the compendium to promote their own vested interests. Editorial decisions are evidence-based and made independent of such third parties; final decisions are made solely by the AHFS editorial staff, taking into account the advice of expert reviewers.

Widely trusted for its established record in refuting unfounded efficacy claims, its rigorous science-based editorial process, and its independence from the influence of pharmaceutical manufacturers, *AHFS DI* has remained true to its mission for almost 50 years.

AHFS DI is the only remaining official drug compendium published by a non-commercial entity (i.e., by a tax-exempt ["nonprofit"] professional association). The American Society of Health-System Pharmacists (ASHP) is an IRS 501(c)(6) tax exempt entity. ASHP is the national professional association that represents pharmacists who practice in inpatient, outpatient, home-care, and long-term-care settings. ASHP has a long history of fostering evidence-based medication use as well as patient medication safety—efforts designed to help pharmacists improve their delivery of pharmaceutical care.

AHFS DI is published by ASHP under the authority of its elected Board of Directors. As such, the Board exercises oversight through its ongoing Society considerations as well as through its Committee on Publications. This oversight by the Board also involves review and approval of relevant recommendations originating from its appointed Commission on Therapeutics and the advisory and best practices developments of its Councils, House of Delegates, and other policy-recommending bodies.

In addition, hundreds of experts, principally physicians but also other clinicians, leading medical scientists, pharmacists, pharmacologists, and other professionally qualified individuals, participate in an ongoing extramural review process for *AHFS DI*. Participation is solicited but voluntary, and no honorarium nor other benefit (e.g., complimentary subscription) is provided. These experts must provide full disclosure of interest, including any affiliation with or financial involvement in the manufacturer of the drug(s) under consideration and directly competitive products.

ASHP considers it essential that interactions between AHFS and pharmaceutical manufacturers be limited to the legitimate exchange of the scientific and medical information needed to fulfill the mission of *AHFS DI.* To maintain independence from the undue influence of the promotional interests of pharmaceutical manufacturers, communications are directed to the scientific and medical information areas within the companies; contact with marketing areas is avoided.

ASHP holds in high regard the responsibilities attendant to the public and private trust placed in the evidence-based editorial deliberations of AHFS. As such, ASHP also considers it essential to protect the integrity and independence of the editorial decisions of AHFS staff by separating the Society's business activities with pharmaceutical manufacturers (e.g., exhibits at educational meetings, journal advertising) from the editorial activities of its drug compendium. AHFS staff apply the following principles of editorial independence in weighing the propriety of their conduct.

1. AHFS staff should avoid participating in business discussions with pharmaceutical manufacturers and other ASHP staff should avoid engaging AHFS staff in such discussions.

2. AHFS staff must disclose any potential financial conflicts of interest or other external activities that may affect their editorial decisions on specific drugs. AHFS staff should not hold financial interests that conflict or may influence the conscientious performance of their editorial duty.

3. AHFS staff may not solicit or accept any gift or other item of monetary value from any individual or entity seeking official action or influence from the compendium nor from those whose interests may be substantially affected by the performance or nonperformance of the staff's editorial duties.

4. AHFS staff have an obligation to act impartially and not give preferential treatment to any interested individual or organization that might influence their editorial decisions.

5. AHFS staff should avoid actions that might create the appearance that they are violating these principles of ethical conduct and editorial independence. Any such behavior shall be judged from the perspective of a reasonable individual in a similar situation with knowledge of the relevant facts. When necessary, the expert advice of other staff (e.g., professional practice, corporate counsel) should be sought.

6. On occasion, ASHP may determine that the Society's interest in the staff's participation in a particular activity or discussion outweighs any concern that a reasonable individual might question the integrity of the activity.

7. AHFS staff members with questions about their activities that are not addressed by these principles on editorial independence shall refer their questions to the Vice President of Publishing and Editor of AHFS.

APPENDIX C
Overview of AHFS DI HCFA Review Process

The mission of AHFS Drug Information (DI) is to provide an evidence-based foundation for safe and effective drug therapy. AHFS DI is widely trusted for its established record in refuting unfounded efficacy claims, its rigorous science-based editorial process, and its independence from the influence of pharmaceutical manufacturers. AHFS DI is one of the three Compendia listed under Section 1861(t)(2)(B)(ii)(I) of the Act that may be used in determining the medically accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen.

In January 1989, HCFA began developing regulations to implement section 202 of the Medicare Catastrophic Coverage Act of 1988 aimed at establishing standards for prescribing outpatient drugs based on accepted medical practice. In establishing these standards, HCFA required ASHP to describe the extent to which AHFS DI met each of the criteria outlined in the Congressional Conference Report relating to the legislation.

HCFA was required by Congress to designate as official only those compendia that based such medical practice standards on review of published scientific and medical information, that provided for a public comment and review process, and that provided adequate assurances that the panelists who establish standards were free of financial (or other) conflicts of interest.

In March 1989, ASHP participated in a public hearing conducted by HCFA's Bureau of Eligibility, Reimbursement, and Coverage on the use of authoritative compendia to determine prescribing standards for the new Medicare outpatient drug coverage.

In September 1989, HCFA published its determination that AHFS DI, along with AMA-DE and USP DI, met the selection criteria as an official compendium in the Federal Register, and requested public comment, thus subjecting its determination to broad-based public scrutiny.[1]

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[1] Federal Register, Vol. 54, No. 172, Thursday, September 7, 1989, 37190, Medicare Program; Catastrophic Outpatient Drug Benefit; Proposed Rule.

Submitter : **Ms. Shannon White** **Date: 08/31/2007**

Organization : **Ms. Shannon White**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Sincerely,

Shannon White

Submitter : Ms. Meganne Gourley **Date:** 08/31/2007

Organization : Gilbert Public Schools

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a board certified athletic trainer as well as a National Registered and Licensed Emergency Medical Technician. I received my Bachelor of Arts degree in Athletic Training from Augustana College and am now pursuing my Master of Science Degree in Athletic Training at A.T. Still University. In addition, I am the assistant athletic trainer at Desert Ridge High School in Gilbert, AZ. As the assistant athletic trainer, I assist the head athletic trainer with a variety of tasks and provide quality care to each athlete through my assessment, prevention, and rehabilitation skills.

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 concerncd 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,

Meganne Gourley, ATC, NREMT-B

Submitter : **Dr. Gary Palman** **Date: 08/31/2007**

Organization : **Maine Society of Anesthesiologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.
Thank you for your consideration of this serious matter.

Gary E. Palman, D.O.
President, Maine Society of Anesthesiologists

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

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I'm Lynn Swiggum, I have a masters degree and have been doing rehabiliation for physically active people of all ages for 17 years. The outcome studies done on Certified Athletic Trainers (ATC) providing rehabilitation services vs other professionals (PT/OT) show that ATC's have better outcomes and use less time and visits to provide these satisfactory outcomes. I find it hard to understand how a government agency can limit the practice of one allied health professional (ATC) over another (PT/OT). This is what your past ruling have done and your future actions are looking at further restrietions. Have you ever questioned why those other health professionals have apposed ATCs providing these services? It has nothing to do with qualifications! While PT/OT spend one semester studying orthopacdics and musculoskeletal disorders, ATCs spend two years and go into significantly more depth. Hence, the reason for our excellent outcome studies. I would strongly urge you to consider all aspect before further limiting the livelyhood of one allied health profession (ATC) to enhance the livelyhood of others (PT/OT). ATC have been recognized by all physicians as allied health professionals for years and we still have to battle for our rights to provide services we are more than qualified and educated to provide. These limitations also take rights away from the consummer to make an informed decision and receive the best possible service.

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,

Lynn R Swiggum, MS, ATC

Submitter : Mr. MICHAEL TORNERO **Date:** 08/31/2007

Organization : Mr. MICHAEL TORNERO

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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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. Terry Wilson **Date:** 08/31/2007

Organization : Boise State University

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a Graduate Assistant at Boise State University. I am working towards a degree in Athletic Administration while serving as an Athletic Trainer to BSU, working with its varsity athletes. This will be my second year at BSU, and my second year as a Certified Athletic Trainer.

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

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

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

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

Sincerely,

Terry Wilson, ATC
Boise State University

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

Organization : LINDA MCKENZIE

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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

LINDA MCKENZIE

14492

August 30, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, D.C. 20201

Re: CMS 1385-P: 2008 Medicare Fee Schedule
Coding- Multiple Procedure Payment Reduction for Mohs Surgery

Dear Acting Administrator Kuhn:

As a fellowship trained Mohs Surgeon who specializes in the treatment of skin cancer in the state of South Carolina I am deeply concerned by the proposed Multiple Payment Reduction for Mohs Surgery. In my opinion this reduction is not justified and will result in a dramatic shift in treatment patterns for skin cancer. This treatment pattern shift will result in substandard care for patients and an increased net cost to Medicare.

Currently when a patient is seen in my office, I have the ability to treat their skin cancer in a single visit while also performing all necessary reconstruction. This allows the patient to have their removal, pathology and repair all performed in a single visit thus saving Medicare the additional costs of pathology fees, additional reconstructive surgeon's consult fees, hospital/facility fees and anesthesia fees. With the proposed Multiple Procedure Reduction I will not be able to justify the cost in time and materials to perform my patient's reconstruction. That is why many surgeons, including myself, will simply refer many reconstructions to hospital based plastic surgeons, thus dramatically increasing the net cost of skin cancer treatment to CMS. In addition, we will be burdening our elderly population with additional office visits and delayed medical care.

Secondly, there is no significant justification for the Multiple Procedure Reduction with Mohs Surgery. Each skin cancer that is treated via the Mohs technique requires complete repeated performance of each aspect of the procedure. When a second skin cancer is treated on a patient there is no less time and cost spent on the second lesion than the first. The second cancer requires just as much prep and surgical time. The second skin cancer specimen requires the same amount of time and cost in its laboratory technical processing and the second set of slides produced for the second cancer requires the same amount of time to read and analyze. Essentially the Multiple Procedure Reduction reimburses the Mohs surgeon at 50% for an activity that entails 100% reproduction of their time and their lab's time and costs.

The financial ramifications of this reduction will result in the delay of treatment of skin cancer. Surgeons will be forced to address only one skin cancer with each visit and thus additional cancers will be treated at a later date. This delay in treatment will most

importantly put patients at risk, but will also have significant negative financial ramifications for Medicare. The delay in treatment caused by the Multiple Procedure Reduction will result in:

i. larger tumors requiring greater number of layers for tumor clearance and increase in the utilization of the 17312, 17314 and 17315 codes
ii. larger tumors that will require reconstruction with both flaps and grafts rather than less expensive linear closures or "no cost" secondary intention healing.
iii. an increase in the number of secondary referrals for reconstruction resulting in increased hospital, facility and consult fees.

Overall, in my humble opinion, the implementation of the Multiple Procedure Payment Reduction for Mohs Surgery will have a negative impact on patients, physicians and Medicare. I don't see how anyone benefits from this proposal. That is why I would like to ask CMS to reconsider their decision to apply the multiple reduction code to the Mohs codes and instead preserve the long standing exempt status of Mohs Surgery.

Sincerely,

James R. DeBloom, II. M.D.
President, South Carolina Skin Cancer Center

Submitter : **Ms. Michelle Anderson** **Date: 08/31/2007**

Organization : **Ms. Michelle Anderson**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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

Thank you for your consideration of this serious matter.

Sincerely,

Michelle Anderson

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

Organization : Lynda White

Category : Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See attachment.

CMS-1385-P-14494-Attach-1.PDF

MVP
PHYSICAL THERAPY
Orthopedic • Work • Sports

August 30, 2007

Mr. Kerry N. Weems
Administrator - Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018.

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

I am a licensed physical therapist in the state of Washington who has been practicing since 1993. I am employed by a physical therapist-owned outpatient therapy company with multiple locations. I would like to encourage you and your colleagues to remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.

My reason for this request can best be provided by specific example. We have clinics located in clusters serving particular geographical regions. In one of these areas, a large medical practice opened its own multi-specialty clinic with 80 physicians providing healthcare services to greater than 250,000 residents of the area. The physicians now own their own surgical facilities, physical therapy practice, diagnostic center, and other miscellaneous services housed within the same mega-size building with a mega-size parking lot that is always full.

These same physicians formerly referred to outpatient physical therapy practices within the region. Since opening their facility, our former patients have reported they are no longer able to attend physical therapy at our facilities because the physicians have requested they get their services from their own clinic instead. This direction of care into their own therapy practice is reinforced by a referral system that uses computer generated referrals within the physician clinic system. The patient does not receive a written referral that can be taken at their will to other physical therapy providers. Since the opening of this facility, our patient volume has decreased to 40% of its prior level.

By contrast, in another geographical area, we have a large orthopedic practice that owns its own medical plaza where space is leased to independent medical practitioners including those providing physical therapy, radiology, and durable medical equipment. The patients receive written physical therapy referrals that allow the patient to go to any provider of their choice. This arrangement allows the patient access to the best of both

7308 Bridgeport Way W, Suite 203 Lakewood, WA 98499 253-582-8500 www.mvppt.com

worlds in that physical therapy services are available within the same building allowing for ease of access AND the patients retain the ability to seek care elsewhere if desired.

In summary, I strongly encourage Medicare to eliminate physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws. It is clear that patients can receive convenient access to physical therapy services WITHOUT physicians owning the practice. In addition, this guarantees that referrals for physical therapy will be written based upon patient need rather than for physician financial gain.

Please close this "in-office ancillary services" loop-hole and eliminate inherent financial incentive to refer their patients to the practices they have invested in and to over-utilize those services for financial reasons. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, over-utlization of physical therapy services under the Medicare program, and enhance the quality of patient care.

Thank you for your consideration of my comments and specific experience with this very important issue.

Respectfully,

Lynda White PT.

Lynda White PT
Physical Therapist
Phone: 206 271 0458

Submitter : Mr. Aaron Nelson **Date:** 08/31/2007

Organization : Phoenix Suns

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Aaron Nelson and I am the head athletic trainer for the Phoenix Suns. ((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 thesc 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 cxperience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to pcrform these services and these proposed regulations attempt to circumvent those standards. Many individuals, either sports affliated or the recreational exerciser, count on athletic trainers to help them either prepare for activity(prevention) or aid them in rehabilitation of injury. No matter the setting we work, whether high school, college, professional, or clinical, ATCs are counted on by millions to aid in their quest for a healthy, mobile life. I am sure you, a family member, and/or a friend have counted on the expertise of an athletic trainer at more than one point of your life.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
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Sincerely,

Aaron Nelson, MS, ATC-L, PES, CES
Head Athletic Trainer
Phoenix Suns

Submitter : **Dr. Alexander Kim** **Date: 08/31/2007**

Organization : **University of New Mexico Health Science Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

Thank you for your consideration of this serious matter.

Sincerely,
Alexander Kim, M.D.

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

Organization : JULI MCKENZIE

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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Thank you for your consideration of this serious matter.
JULI MCKENZIE

CMS-1385-P-14498

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

Organization : Urology Associates of Mobile, P.A.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14498-Attach-1.DOC

Urology Associates of Mobile, P.A.
168 Mobile Infirmary Boulevard
Mobile, Alabama 36607

A. Greer Megginson, M.D.
G. Coleman Oswalt, M.D.
Charles F. White, Jr., M.D.
Dino N. Frangos, M.D.
S. Harbour Stephens, III, M.D.
Paul A. Scott, Sr., M.D.

August 30, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, Maryland

Dear Ladies and Gentlemen,

My name is Dr. Paul A. Scott, Sr. I am a urologist practicing in Mobile, Alabama in a private group practice. This letter is in addendum to the letter offered by my partner Charles White, M.D., dated August 21, 2007 on behalf of the entire practice. We are involved in a joint venture partnership providing lithotripsy services within Mobile and Baldwin counties in Alabama; however, we also provide service to patients in numerous rural counties in both Alabama and Mississippi.

Prior to the formation of our partnership, lithotripsy services were controlled by a for-profit hospital who determined whether or not a patient was offered treatment. Since their unit was a fixed unit, this limited geographically where a patient could have his or her treatment.

The proposed new regulations regarding physician fee schedules cause great concern to urologists, and threaten access to care for many of our patients.

Particularly of concern, regarding under-arrangement contracting, by sharing the services of our mobile lithotripsy equipment among several hospitals, this actually lowers costs. By providing mobile lithotripsy services, this provides access to services that smaller rural hospitals cannot afford. When the physicians own the equipment, we are more likely to remain up-to-date with technological advances in equipment, which allows patients access to this state-of-the-art therapy. Regarding concerns of over-utilization, with treatment of urinary stones, there is an easily identifiable diagnosis of a stone, which doesn't lend itself to the abuses of diagnostic procedures. The same argument can be made for provision of laser services for treatment of benign prostatic hypertrophy. These are not subjective issues, but objective findings.

Submitter : Dr. Patrick Pickett **Date:** 08/31/2007

Organization : Dr. Patrick Pickett

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14500-Attach-1.DOC

14500

Leslie V. Norwalk, Esq.

Acting Administrator

Centers for Medicare and Medicaid Services

Attention: CMS-1385-P

P.O. Box 8018

Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

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

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation—a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services.

I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

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

Thank you for your consideration of this serious matter.

Sincerely,

Patrick M. Pickett, MD
Case Western / University Hospitals
Anesthesiology Resident, PGY-1

Submitter : Mrs. HELEN TORNERO **Date:** 08/31/2007

Organization : Mrs. HELEN TORNERO

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Organization : **Lahey Clinic**

Category : **Physician**

Issue Areas/Comments

Medicare Economic Index (MEI)

Medicare Economic Index (MEI)

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.

-Dr. David A. Shaff

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

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Physical Therapy as one of the services to be added to the Stark III physican self referral policy under CMS

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

Organization : JOHN MCNERNEY

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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JOHN MCNERNEY

Submitter : **Mr. David Bouska** **Date: 08/31/2007**

Organization : **Mr. David Bouska**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Serviees
Attention: CMS-1385-P
P.O. Box 8018
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Sincerely,

David Bouska

Submitter : Mr. MICHAEL TORNERO **Date:** 08/31/2007

Organization : Mr. MICHAEL TORNERO

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P
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Submitter : JUDY MCNERENY **Date:** 08/31/2007

Organization : JUDY MCNERENY

Category : Health Care Professional or Association

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

Submitter : **Dr. Peter Koranyi** **Date: 08/31/2007**

Organization : **Dr. Peter Koranyi**

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

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Thank you for your consideration of this serious matter.

Sincerely Yours,
Peter Koranyi, M.D.

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

Organization : HealthTronics, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14509-Attach-1.DOC

14509

HealthTronics.

August 31, 2007

Via Electronic Mail

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

http://www.cms.hhs.gov/eRulemaking

RE: Comments to 2008 Proposed Revisions to Medicare Physician Fee Schedule ("Proposed Regulations")

Ladies and Gentlemen:

HealthTronics Inc. is the largest provider of lithotripsy services in the United States, with over 65 affiliated lithotripsy ventures currently operating in over 35 states. HealthTronics is also involved in approximately 19 affiliated ventures that provide laser services that treat patients with benign prostate hyperplasia ("BPH"). Most of these affiliated ventures are co-owned with urologists that actively use the ventures' technologies in the treatment of their own patients ("Physician Ventures"). These Physician Ventures have greatly expanded patient access to state-of-the-art medical technologies that have significantly improved the quality of patient care, and reduced costs to the Medicare program. Despite these clear benefits to patients and the Medicare program, the Center for Medicare and Medical Services ("CMS") has determined, without justification, that these types of physician-owned arrangements pose a threat to the Medicare program, and they have issued the Proposed Regulations to address that threat. The purpose of this letter is to address those provisions of the Proposed Regulations that threaten the high-quality, accessible patient care provided by the Physician Ventures sponsored by HealthTronics.

I. Services Furnished Under Arrangements

The Medicare statute permits providers, such as hospitals, to furnish services to beneficiaries "under arrangements" with third-party vendors. Lithotripsy and BPH laser services are commonly provided by urologist-owned vendors, such as our Physician Ventures, that contract under arrangements with hospitals. Historically, CMS interpreted "entity" under the Stark Statute to only mean the entity billing for the service in an under arrangement contract, which would be the hospital. The Stark financial interest in such circumstances would be a

compensation arrangement between the hospital and physician-owned vendor, and our Physician Ventures have historically relied on the Stark indirect compensation arrangement to comply with the Stark law. The new Proposed Regulations intend to change the Stark definition of entity to mean not only the hospital that bills for the services, but also the person or entity that either provides the DHS (e.g., our Physician Venture) or "causes a claim to be presented" for the DHS.

If a physician vendor contracting with a hospital is interpreted to be the entity "performing" the DHS service or "causing" the claim for DHS to be presented, then the physicians' ownership interest in the vendor could also require a Stark ownership exception. As there is no applicable Stark ownership exception under such circumstances, the proposed rule could be interpreted to prohibit a physician vendor from contracting under arrangements with hospitals for DHS Services.

Historically, CMS recognized that physician ventures contracting under arrangement with hospitals created an indirect compensation arrangement that could be addressed with the Stark indirect compensation arrangement exception, and acknowledged that a separate Stark ownership exception was not required. Under the Proposed Regulations CMS is now reversing its position on this issue that it took only six years ago. CMS was not alone in historically not requiring an ownership exception for under arrangement contracts, as Congress also expressly recognized that an under arrangement contract only required a compensation exception in a 1989 Stark Phase I statutory exception. This clear expression of Congressional intent on this issue raises questions whether CMS has the authority to promulgate regulations that would contradict that intent.

The proposed change in the characterization of "entity" raises numerous other questions. Under what circumstances would an under arrangement provider be deemed to be "causing a claim to be presented" by the hospital to Medicare? Our Physician Ventures usually only contract with hospitals to be paid a set price for their services, and they are not involved in whether or how a hospital will seek reimbursement.

Further, it would seem clear from the judicial decision American Lithotripsy Society v. Thompson, 215 F. Supp. 2d 23 (D. D.C. 2002), that CMS cannot apply these proposed under arrangement rule changes to lithotripsy, since the court clearly held that lithotripsy provided under arrangement at a hospital was not a designated health service ("DHS") under the Stark Statute. As stated by the court in that case, "the lack of any mention of lithotripsy in the Stark II Statute itself, the legislative history of the statute, and the statutes purpose demonstrate a clear intent on the part of Congress not to subject lithotripsy to the ban on self-referrals by including it in 'inpatient and outpatient hospital services.'" Given this judicial decision, our lithotripsy Physician Ventures cannot be characterized as an "entity" under the Stark Statute, therefore they cannot be required to meet a Stark ownership exception.

In its Commentary to the Proposed Regulations, CMS seems primarily concerned with imaging services furnished under arrangements, which services would be DHS whether provided in or outside of a hospital setting. If a physician-affiliated imaging vendor contracting under arrangements with a hospital is deemed to be the "entity" directly providing the service, then the vendor would be in the same position as if it was directly providing the service, i.e., a provider of

a DHS service without a Stark ownership exception. Before the proposed changes to the definition of entity, under arrangement contracting effectively allowed physician-affiliated imaging ventures to do indirectly what Stark would prohibit them from doing directly. This is not the case with therapeutic services such as lithotripsy and BPH laser services that are only characterized as DHS when performed as a hospital inpatient or outpatient hospital service. Consequently, if a Physician Venture is deemed to be directly providing the service under the new definition of entity, what would be the nature of the service provided? The Physician Venture is not a hospital, so it cannot perform hospital services. Clearly if the venture is deemed performing the services, then it is performing lithotripsy or BPH laser services, which are not DHS services. In ALS vs. Thompson, the court held that lithotripsy should not be characterized as a "hospital inpatient or outpatient service" merely because that is how it is billed. The court recognized that it was not medically necessary for lithotripsy to be performed in a hospital, and consequently it should not be labeled as a hospital service for that reason alone. The same logic also applies to BPH laser services. As a matter of fact, pursuant to other new CMS regulations, beginning in 2008 lithotripsy technical fees will be reimbursed by the Medicare program at ambulatory surgery centers. BPH laser services currently are reimbursed at both ambulatory surgery centers and physician offices under the Medicare program. Lithotripsy and BPH laser services deemed directly performed by Physician Vendors should not be DHS inpatient or outpatient hospital services for which a Stark ownership exception would otherwise be required.

The conclusion reached by CMS that all physician under arrangement contracts are abusive fails to recognize the clear benefits of such contracts and the low risk of overutilization for therapeutic operations such as lithotripsy and BPH laser services. We note that many of the factors that led the Office of Inspector General ("OIG") to provide safe harbor protection for ASCs are present in our Physician Ventures. In contrast to the other investment interest safe harbors, the ASC safe harbor was established to protect payments to investors in ASCs who refer patients directly to an ASC and perform surgery themselves on such patients. The OIG noted that legitimate business reasons exist for physician ownership of an ASC, such as "convenience, professional autonomy, accountability, and quality control." Notwithstanding the OIG's unwillingness to extend this safe harbor to entities other than ASCs, the principles of the extension of practice concept apply equally to physician owners in HealthTronics' Physician Ventures, as the lithotripsy and BPH laser systems are an integral part of the physician owners medical practices.

The OIG concluded that physician investment in ASCs was not likely to lead to overutilization and increased health care costs. Similar to surgery, therapeutic services, such as lithotripsy and BPH laser services, generally are not subject to overutilization abuse and are not likely to cause increased health care costs. Unlike diagnostic services, the need for therapeutic services can be determined objectively, based upon the underlying illness or disease. Moreover, therapeutic services are furnished to patients as an integral part of the referring physician's services. In the case of diagnostic services, a physician's anxiety about malpractice and a patient's anxiety about symptoms, real or imagined, can create an inclination to over prescribe diagnostic tests, and this inclination may be exacerbated by the physician's investment in the diagnostic facility. Such a dynamic is not present in the case of lithotripsy and BPH laser services because they are relatively discrete clinically and it is relatively straightforward to

determine need objectively. On several occasions, CMS has recognized that overutilization of lithotripsy services is unlikely because the need for such therapeutic services can, in most cases, be determined objectively. 63 Fed. Reg. 1682 (Jan. 9, 1998).

We also note that, in many cases, patients of the physician owners of our Physician Ventures presenting appropriate symptoms will not receive services provided by our technology. Approximately, 75 to 90% of all stones pass spontaneously, usually within three to six weeks, and require little or no clinical or surgical intervention. Further, HealthTronics' Compliance Plan ("Compliance Plan") and its Quality Assessment & Performance Improvement Plan ("Q/A Plan") establish medical necessity requirements to document the presence of a stone and the need for lithotripsy services. The Compliance Plan requires that all prospective lithotripsy patients first receive a kidney, ureter and bladder ("KUB") x-ray or equivalent abdominal x-ray image in order to ensure that each prospective patient is properly evaluated prior to treatment. Prospective patients must undergo an intravenous pyelogram ("IVP"), Nuclear Renal Scan, or CT Scan to document the presence of a kidney stone, its size and position. Patients also are screened for contraindications for lithotripsy. In addition, even when a kidney stone is documented, there are multiple factors that influence the clinical decisions for managing the stone, including the stone size, location in the urinary system, the composition of the stone, the presence or absence of infection, and pain related to the stone's passage. Treating physicians often consult with their patients about treatment alternatives using criteria that has been developed by the American Urological Association and incorporated into HealthTronics' Compliance Plan and Q/A Plan. Similar medical necessity screening guidelines are followed prior to initiation of BPH laser services, such as imaging of the prostate, digital rectal exams and urine flow rate studies.

It is also worth noting that both an influential Congressional representative and even the State of Florida have recognized that lithotripsy services are not particularly vulnerable to abuse. U.S. Representative Fortney Pete Stark, author of the Stark Law, confirmed in the *Congressional Record* that the self-referral ban contained in the law that bears his name was not intended to apply to physician-owned lithotripsy facilities that furnish services under contract with hospitals. 139 Cong. Rec. H6238 (daily ed. Aug. 5, 1993) (statements of Rep. Rose and Rep. Stark). Florida, the first state to enact a patient self-referral act in 1992, specifically exempted orders by urologists for lithotripsy services from its definition of "referral" by a health care provider. Florida believed that the involvement of the specific category of specialists in assuring their patients access to quality therapeutic care was controlling, and the specialists' investments in such therapeutic entities would not reduce access to competitive alternatives, cause overutilization, or contribute to increased costs to the health care system. We understand that in formulating this exception, Florida legislators reviewed certain state empirical studies that demonstrated that physician-owned ventures did not cause overutilization of lithotripsy services by patients of the physician owners. In the Stark I law legislative history, it was also clear that Congress initially intended that the law was to cover a much broader range of services other than clinical laboratory services, but even at that time lithotripsy services were specifically excluded because it posed no threat of overutilization.

CMS should target physician-owned diagnostic ventures that pose a real threat of program overutilization and attendant increased costs, and should exclude beneficial physician-

owned therapeutic ventures, such as lithotripsy and BPH laser, that improve patient access to quality services and pose no threat of overutilization.

We are also concerned with whether CMS has fully considered the consequences of its Proposed Regulations. Hospitals often are unable or unwilling to spend money on state-of-the-art medical technologies. Due to their close relationships with their patients, physicians are willing to make this financial commitment in order to improve the quality of patient care. By providing mobile services to many hospitals, our Physician Ventures are able to share technology with many hospitals that no one hospital alone could afford based upon its isolated patient volume. This mobile Physician Venture access to the best medical technology is most apparent in poorer rural markets. The Proposed Regulations would deny access to medical technologies, leaving a significant gap in care in many communities. If a lithotripter is unavailable in a community, patients may have to travel long distances to another community to receive care. Alternatively, the patient may have to undergo surgery to remove a kidney stone, thereby exposing the patient to significantly higher surgical risks under general anesthesia, and costing the Medicare program substantially more funds for a long-term hospital stay. Further, thirty-six states have certificate of need laws, and many of these states would prohibit or significantly restrict the introduction of new technologies into the state. We are aware of at least one large population state where all lithotripters in the state are owned by physician vendors, and the state health plan prohibits the introduction of any new lithotripters. Where will patients in such states go for treatment of kidney stone disease if these sole physician vendors can no longer provide services at hospitals? Beginning in 2008, lithotripsy services can be provided as ASCs, but many communities have no access to ASCs. CMS has not thoughtfully considered the absolutely disastrous consequences to accessible quality patient care that will likely result if the Proposed Regulations become effective.

II. Per Procedure Leases

Most services and leasing arrangements involving medical technology between physician vendors and hospitals provide for payment on a per procedure basis. This is also the case for most of the lithotripsy and BPH laser services arrangements between our Physician Ventures and hospitals. Current Stark exceptions for space and equipment leases (and personal services) allow for payment on a per procedure basis. Under the Proposed Regulations, the Stark equipment lease and space rental exceptions would be modified to prohibit per unit of service rental charges between an individual physician equipment lessor and a hospital lessee. Under the recently published Stark III final regulations, the per procedure lease prohibition in the Proposed Regulations would be extended to historical indirect compensation arrangements as well. Under the new Stark III regulations, a physician in a joint venture that leases equipment to a hospital will now be treated as if the physician is directly leasing the equipment to the hospital (i.e., the joint venture entity is ignored). Consequently, the Proposed Regulations read in conjunction with the Stark III final rule could prohibit our Physician Ventures from contracting with hospitals on a per procedure basis.

Again, the consequences of this proposed rule will likely deny patient access to state-of-the-art technology, and increase the costs of providing services to hospitals. Hospitals are risk

adverse, and often loathe to acquire new medical technologies or enter into fixed payment monthly leases where procedure volumes to recover such costs are uncertain. Physician lessors of medical technology appreciate the importance of innovations in medical technology to patient care, and are more willing to incur these capital risks. Per procedure lease payments allow physician lessors to assume the capital risks of the leased technology. If procedure volume is not sufficient to recover the cost of leased technology, it is the physician lessor and not the hospital lessee that assumes this risk in a per procedure lease arrangement. Rural hospitals will particularly be unlikely to have the resources to buy the latest in medical technology, nor would they have the certain procedure volume to be able to lease medical technology on a fixed monthly basis. Per procedure leasing of technology from physician vendors with an interest in treating their own patients in such rural markets may be the only way for rural patients to have access to such technology.

CMS acknowledges in its Commentary to the Proposed Regulation that per unit of service rental charges were specifically allowed six years ago in its Stark final rule because "We . . . concluded that Congress intended that time-based or unit of service based payments be protected." 66 Fed. Reg. 876 (Jan. 4, 2001). Specifically, the House Conference Report No. 103-213 states that:

> the conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of the time-based or unit of service rates does not fluctuate during the contract period based upon the volume or value of referrals between the parties to the lease or arrangement.

Given the clear Stark legislative history to permit per procedure lease payments, the Proposed Regulations would violate the Administrative Procedure Act as the regulations would exceed CMS' statutory authority and are arbitrary and capricious. 5 U.S.C. § 706(2)(A) and (C). Based upon the analysis in Chevron U.S.A. Inc. v. Natural Resources Defense Counsel, 467 U.S. 837 (1984), if Congress has spoken on the issue in legislative history, then an agency's interpretation of a statute "contrary to clear congressional intent" as expressed in a regulation must be set aside. Id. at 843 n.9. Given the clearly expressed intent by Congress to allow per procedure rent payments that is acknowledged by CMS in its own Commentary, the per procedure prohibition cannot survive serious challenge.

The reasons given by CMS for the per procedure lease ban are also questionable when applied to therapeutic ventures, such as those providing lithotripsy and BPH laser services. CMS stated in its Commentary that it believes "such arrangements are inherently susceptible to abuse because the physician lessor has a incentive to profit from referring a higher volume of patients to the lessee . . . ." We have already addressed this overutilization concern in Section I of this letter, so we will not belabor the point here. Suffice it to say, however, overutilization concerns may be present in diagnostic equipment leasing ventures where referrals may be linked to the subjective judgment of a referring physician lessor. Those risks are not present with therapeutic equipment leases where the underlying medical condition can be objectively determined; i.e., either a renal stone exists or it doesn't, or the prostrate is enlarged or it is not. Physician

ownership in an equipment lessor will not impact the utilization of these therapeutic technologies.

III. Restriction on Percentage Fee Payments

Several important Stark exceptions require that compensation be "set in advance;" e.g., personal service arrangements, fair market value compensation, and the office and equipment lease exceptions. Historically, CMS interpreted the "set is advance" requirement to permit percentage fee payments. In the Proposed Regulations, CMS would change the "set in advance" definition to prohibit percentage based fees, except for professional services. The Proposed Regulations would prohibit an individual urologist from directly leasing equipment to a hospital in exchange for a percentage fee. As previously discussed in Section II herein, the Proposed Regulations together with the new Stark III final rule would also prohibit physician equipment lessors from leasing equipment to hospitals on a percentage fee basis.

It is unclear why CMS is concerned about percentage payment arrangements. Our Physician Vendors have seen public and private insurance reimbursement rates for lithotripsy and BPH laser services vary significantly over time. Further, reimbursement rates vary widely by private insurer. Medicare rates are generally always lower than privately insured rates, and changes in patient population can often result in material shifts in public and private payor mixes in a given market. Percentage fee arrangements allow Physician Ventures and hospitals to share the risks inherent in potential reductions in reimbursement or shifts in payor mix. Percentage fee arrangements also insure a hospital that it will never make a rental payment that is greater than the reimbursement it receives for the service from even the lowest benefit provider. Percentage fee arrangements also allows both hospitals and Physician Vendors to share the cost burden of treating indigent and self pay patients. Eliminating percentage fee arrangements would likely increase costs for services to hospitals, and deny access to services for indigent and self-insured patients.

In conclusion, CMS must separate beneficial therapeutic physician joint ventures which are not directly performing DHS, from questionable diagnostic ventures that pose true overutilization risk for the Medicare program. Our Physician Ventures have clearly improved the quality of patient care, broadened access to new innovative medical technologies and brought efficiencies to the market that have resulted in substantial savings to CMS and the Medicare program.

We appreciate your time and thoughtful consideration to our comments expressed herein.

Respectfully,

HealthTronics, Inc.

By: _____

James S. B. Whittenburg
President & CEO

Submitter : Dr. HARESH PATEL **Date:** 08/31/2007

Organization : CAPE ANESTHESIA AND PAIN MANAGEMENT

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
HARESH C PATEL M.D.

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

Organization : Scott Hadden

Category : Health Care Professional or Association

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

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Scott Hadden

Submitter : Mr. MARK TORNERO **Date: 08/31/2007**

Organization : NORTHEASTERN OHIO UNIVERSITIES COLLEGE OF MEDICINE

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Organization : BRENT MEFFORD

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Serviees
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.
BRENT MEFFORD

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

Organization : **Pam HADDEN**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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

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

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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. Thomas Wilder **Date:** 08/31/2007

Organization : America's Health Insurance Plans

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1385-P-14515-Attach-1.DOC

CMS-1385-P-14515-Attach-2.PDF

CMS-1385-P-14515-Attach-3.PDF

CMS-1385-P-14515-Attach-4.PDF

America's Health Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org

#14515-#1

September 10, 2007

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

Re: Proposed Revisions to Payment Policies Under the
Physician Fee Schedule – Recalls and Replacement Devices

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments regarding the Proposed Revisions to Payment Policies Under the Physician Fee Schedule published in the *Federal Register* on July 12, 2007 (72 Fed. Reg. 38122) and, in particular, with respect to issues related to Medicare reimbursement for costs associated with recalls of and replacements for medical devices.

AHIP is the national association representing nearly 1,300 health insurance plans providing coverage to more than 200 million Americans. Our members offer a broad range of products in the commercial marketplace including health, long-term care, dental, vision, disability, and supplemental coverage. AHIP's member health insurance plans also have a strong track record of participation in Medicare, Medicaid, and other public programs.

As noted in the Proposed Revisions, recent recalls of implantable cardioverter-defibrillators (ICDs) have resulted in significant costs for public and private payers including, for example, hospitalization, surgery or other medical procedures to repair or replace the recalled device, physician consultation and follow-up visits, and lab tests. AHIP believes the manufacturers of these devices should be responsible for medical expenses associated with such recalls, in addition to the cost of any replacement device. We have enclosed prior correspondence with the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration regarding this issue.

AHIP supports efforts by CMS to identify expenditures by the Medicare program in connection with the recall of medical devices, such as ICDs, and actions to recover any expenses from the manufacturers of the devices. We do not believe the costs should be the responsibility of federal programs, such as Medicare, private payers or the general public.

Please feel free to contact me at (202) 778-3255 if you have any questions regarding this important issue.

Sincerely,

Thomas J. Wilder

Thomas J. Wilder
Senior Regulatory Counsel

Enclosures

- **Responsibility for Medical Costs.** AHIP suggests that FDA, working with other appropriate policymakers, consider the responsibility that medical device manufacturers should bear for medical expenses associated with both voluntary and involuntary device recalls. These costs are separate from the replacement cost of the device itself. We believe that – in addition to taking responsibility for the replacement cost of a recalled device – a manufacturer should take responsibility for associated medical expenses. Medical expenses may include, for example, hospitalization, surgery or other medical procedures to repair or replace the recalled device, physician consultation, and necessary lab tests. If manufacturers of recalled medical devices do not voluntarily assume these medical costs, the costs will be shifted to working families who pay for health insurance through forgone wages and taxpayers who fund public programs. Such expenses only compound the health care financing burdens already faced by employers, consumers, and public programs. At present, if a device manufacturer does not voluntarily opt to pay for medical costs associated with recalled devices, the only recourse to recover payment is through litigation, which is an inefficient and costly process. We urge the FDA to lend its significant expertise to the health care community to fashion a better solution to this problem and to work with CMS as it considers whether Medicare beneficiaries and taxpayers should bear the burden of these costs.

- **Facilitating the Flow of Recall Information.** Until such time that there has been a broader policy resolution concerning the allocation of responsibility for medical costs associated with recalled devices, AHIP asks FDA to consider ways to facilitate the flow of key information about recalled devices (*e.g.*, model number, serial number, identifying patient information) from medical device manufacturers to public and private payers. Although this information is already tracked by the manufacturers and voluntarily shared with providers, it is not currently provided to public and private payers. At present, there is no simple way for both health insurance plans and public programs, such as Medicare and Medicaid, to identify consumers who have received a recalled device for purposes of allocating medical costs.

AHIP appreciates the significant role FDA plays in maintaining patient safety and promoting quality health care, and looks forward to a continuing dialogue with you on these important issues. We will call your office to schedule an appointment to discuss AHIP's concerns and ways we can move forward to address these critical cost, quality, and safety issues.

Sincerely,

Karen Ignagni

Karen Ignagni

c: Mark McClellan, M.D., Ph.D.
Janet Woodcock, M.D.

#14515 - #3

AHIP
America's Health
Insurance Plans

August 17, 2005

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

We write today to call to your attention our concerns regarding the recent recalls of certain implantable defibrillators and pacemakers by Guidant Corporation and the impact of these recalls on the Medicare and Medicaid programs and our member health insurance plans. In our view, these recalls highlight several important public policy issues that should be addressed by CMS, and we are anxious to work closely with the agency as it addresses these issues.

As the result of advances in medical knowledge and improvements in the delivery of care, CMS and health insurance plans are providing coverage for more new technology than ever before. In particular, CMS' decision to expand its coverage of implantable devices will likely increase their use in the Medicare program. Recent information about internal defibrillators raises new and important questions about safety, effectiveness and costs for both private and public purchasers of medical devices.

As you explore these questions, we have two recommendations. The first is to urge a broader policy discussion about ultimate responsibility for medical expenses involved with device recalls. The second relates to the urgent need for better data sharing between medical device manufacturers and public and private payers and consumers, including steps to enable collection of medical device information by payers.

Responsibility for Medical Costs:

AHIP suggests that CMS consider developing a reasonable and equitable means to allocate responsibility to medical device manufacturers for the medical expenses associated with device recalls. We believe that a manufacturer should bear not just the replacement cost of a recalled device, but also the associated medical expenses. Those expenses may include hospitalization, surgery or other medical procedures to repair or replace the recalled device, physician consultation, and necessary lab tests. At present, it appears that medical device manufacturers have assumed that Medicare and private payers will bear the considerable medical expenses associated with defective device recalls.

For example, Guidant Corporation has offered to reimburse only patients themselves who receive certain replacement devices up to $2,500 for out-of-pocket medical expenses remaining after Medicare and health insurance coverage. Strikingly, it has not offered to reimburse Medicare or private health insurers for medical expenses surrounding its recalled devices. It also appears that Guidant's policy

guidelines would result in hospitals being paid by Medicare for a device that Guidant Corporation is replacing at no charge. Thus, Guidant has published a list of appropriate CPT and ICD-9 codes associated with recall-related medical expenses which specifically advises providers that: "When billed, Medicare is expected to pay providers the full Diagnosis Related Group (DRG) or Ambulatory Payment Classification (APC) rate for the replacement procedure *without discounting that amount by the value of the replaced device.*"[1]

It is troubling if manufacturers of recalled devices are pursuing policies that result in shifting of costs associated with their recalled devices to working families who pay for health insurance through forgone wages and taxpayers who fund public programs. Such expenses only compound the health care financing burdens already faced by employers, consumers, and public programs. AHIP stands ready to work with CMS and others in the health policy community to develop a fair policy for allocation of these costs.

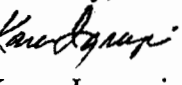
Facilitating the Flow of Device Information:

Unfortunately, today neither public nor private payers are able to efficiently collect critical information about devices at the time of implantation, resulting in an information vacuum where payers are left in the dark about when and whether additional medical costs are attributable to a replacement of a defective device. Manufacturers, however, routinely track this information and voluntarily share it with providers at the time of a recall, but it is not currently provided to public and private payers. At present, there is no simple way for both health insurance plans and public programs like Medicare and Medicaid to identify consumers who have received a recalled device for purposes of allocating medical costs.

Until such time that there can be a broader policy resolution concerning the allocation of responsibility for medical costs associated with recalled devices, AHIP asks CMS to work with AHIP's members, the FDA, and device manufacturers to consider ways to facilitate the flow of key information about recalled devices (*e.g.*, model number, serial number, identifying patient information) from medical device manufacturers to public and private payers. We also understand that CMS will be collecting registry information on internal defibrillators in connection with the expanded coverage of these devices. We urge CMS to work with AHIP and others to facilitate the collection of this important information so that costs can be properly allocated.

AHIP appreciates the significant role CMS plays in working with AHIP's members and assuring coverage for medical devices for Medicare and Medicaid beneficiaries. We look forward to a continuing dialogue with you on an issue critical to both public and private payers.

Sincerely,



Karen Ignagni

c: Lester M. Crawford, Ph.D., DVM
Leslie Norwalk, Esq.

---

[1] *See* http://www.guidant.com/reimbursement/guidelines.pdf; *see also* Ch 16§40.4 – Items Covered Under Warranty, Medicare Benefit Policy Manual, http://www.cms.hhs.gov/manuals/102_policy/bp102c16.pdf; Medicare transmittal http://www.cms.hhs.gov/manuals/pm_trans/R599CP.pdf

America's Health Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org

#14526 - #4

March 14, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
United States Food and Drug Administration
Office of the Commissioner
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: The Medical Device User Fee Modernization Act of 2002 – Docket No. 02N-05341

Dear Dr. von Eschenbach:

I am writing on behalf of America's Health Insurance Plans (AHIP) representing 1,300 member companies providing health insurance coverage to more than 200 million Americans to provide comments on the Medical Device User Fee Modernization Act and to follow-up on previous discussions with your staff about collaborative initiatives to improve the safety and efficacy of pharmaceutical products and medical devices.

Our comments are designed to urge you to consider analyzing the long-term safety and effectiveness of prescription drugs, biological products, and medical devices as part of FDA's enforcement activity and to set aside funding for ongoing effectiveness analysis and comparisons across available treatments. We believe the agency has an important role to play in facilitating the transition to a more evidence-based, safe, and effective health care system and we are making five recommendations to help achieve these goals.

1. Require and Adequately Fund Post-Market Studies of Prescription Drugs, Biological Products, and Medical Devices

The FDA has committed significant resources to pre-market testing of prescription drugs, biological products, and medical devices through funding available under the Prescription Drug User Fee Act and the Medical Device User Fee Act. As the population ages and the number of individuals with multiple chronic diseases increases, it is critical that FDA expand its activities to include post-marketing surveillance that focuses on the long-term effects of drugs, biologics, and devices.

We believe that FDA should require manufacturers to conduct selected post-market studies of their products, including situations where safety concerns have not been raised, to determine if the drug, biologic, or device is safe, effective, and fulfilling its intended purpose. In addition, FDA should seek adequate support for its post-market surveillance activities through user fee funding. The Prescription Drug User Fee Act and the Medical Device User Fee Act provide critical resources to conduct cost-effective and efficient review of new prescription drugs, biological products, and medical devices. We support reauthorization of these two important laws, which are scheduled to expire next year, and urge the earmarking of specific user fee funds for both pre- and post-market studies of prescription drugs, biological products, and medical devices.

2. Develop Public-Private Partnerships to Conduct Post-Marketing Studies of Drugs and Devices

An overwhelming majority of Americans have their health care financed through or administered by health insurance plans. As a result, health insurance plans have comprehensive data sets that could be used in evaluating safety and effectiveness. We recommend that FDA work with health plans and other key stakeholders to design post-marketing studies that will draw upon these de-identified data. We would be delighted to bring together representatives of health plans and FDA staff to discuss this issue.

The Centers for Medicare & Medicaid Services (CMS) also can provide important information about drug, biologic, and device usage for older Americans and for the disabled. These data, coupled with information available from health insurance plans, could provide an expanded view of how prescription drugs, biological products, and devices impact patient outcomes.

We recommend that FDA work with CMS to establish appropriate protocols to utilize Medicare data in the development of post-marketing studies. We are available to participate in this dialogue to ensure that data sets available from health insurance plans can be integrated into data available from CMS.

3. Provider Early Warning Monitoring Through Linkages to the National Health Information Infrastructure

Health plans have taken a leading role in using information technology to improve health quality and care outcomes through activities such as electronic prescribing, creation of personal health records, and development of decision support tools for consumers and caregivers. These initiatives are part of a larger effort by the health care community to create an electronic "health information highway" to link physicians, hospitals, health plans, state and federal governments, and consumers.

We recommend that FDA consider ways to monitor drug and device safety through linkages with public and private health data systems. Such linkages will provide the tools to obtain early indications of potential problems with prescription drugs, biologics, and medical devices that impact patient safety.

4. Establish Procedures to Track Implanted Medical Devices

FDA's Center for Devices and Radiological Health (CDRH) recently published a report (*Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program*) discussing its process for post-market surveillance of medical devices. One important issue raised in the report is the lack of complete documentation in health care records at the time devices are implanted which results in an inability to monitor device performance. Unlike prescription drugs, which have a National Drug Code identifier, there is no currently reliable system to track medical devices.

We recommend FDA work with health plans, health care providers, standards organizations, and other stakeholders to establish procedures to track medical devices. This process should include the development of unique identifiers for medical devices that can be used for health reporting purposes and in the claims and payment process (such as the UB 04, HCFA 1500, and HIPAA 837 claim forms). In

addition, a process should be developed to identify medical procedures that are performed as a result of device failures.

5. Encourage Accountability for Device Failures

Recent recalls of implantable defibrillators and pacemakers highlight the impact of device failures on patient safety and the cost of medical care. If device manufacturers are not held accountable for medical expenses associated with voluntary and involuntary device recalls, these costs are shifted to the public at large. We believe that manufacturers are responsible for all expenses related to a recall, including replacement costs, hospitalization, surgery, and other medical procedures to replace or repair the device. We recommend FDA use its existing authority to establish a process for medical device manufacturers to assume the cost of voluntary and involuntary device recalls. We have previously shared with FDA's General Counsel an analysis of this authority and would be happy to discuss this issue with you.

We believe the Food and Drug Administration plays an essential role in protecting patient safety and promoting quality health care for all Americans and we look forward to continuing our dialogue on how health plans can assist the FDA in this critical endeavor.

Sincerely,

Karen Ignagni

Karen Ignagni

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

Organization : TAMYRA MEFFORD

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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Thank you for your consideration of this serious matter.
TAMYRA MEFFORD

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

Organization : **Judy Johnson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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Judy Johnson

Submitter : Dr. Michael Axley **Date:** 08/31/2007

Organization : Dr. Michael Axley

Category : Physician

Issue Areas/Comments

Background

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Thank you for your consideration of this serious matter.

My best regards,

Mike Axley, MD

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

Organization : **Don Johnson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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Don Johnson

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

Organization : JIM MELTON

Category : Health Care Professional or Association

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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JIM MELTON

Submitter : Dr. john Salvo **Date:** 08/31/2007

Organization : Cooper University Hospital

Category : Physician

Issue Areas/Comments

GENERAL

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see attachment

CMS-1385-P-14521-Attach-1.WPD

14521

August 29, 2007

To whom it may concern,

My name is John Salvo. I am an Orthopaedic surgeon and the Director of Sports Medicine at Cooper Bone and Joint Institute, a center of excellence at Cooper University Hospital. I am writing on behalf of my fellow sports medicine colleagues here at Cooper Bone and Joint Institute.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the physician self-referral provisions proposed in 1385-P. Initially, I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting. CMS seems to have come to these proposed changes without clinical or financial justification, and without the input of various healthcare professionals, especially the physicians who will be tasked with hiring enough staff to adequately treat our patients with rehabilitation needs.

The workforce shortage to fill rehabilitation positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans to further restrict their ability to receive those services.

However, I am more concerned that these proposed rules will create additional lack of access to quality health care for patients in my facility. The current standards of staffing in hospitals and other rehabilitation facility's flexibility are pertinent in ensuring patients receive the best, most cost-effective treatment available. As a physician and administrator, it is my duty to see that these jobs are filled by the most qualified individuals, regardless.

Current hospital Conditions of Practice, state law and hospital medical professionals have given me and my fellow physicians and administrators the authority to determine who is qualified to provide rehabilitation services. These proposed regulations attempt to circumvent those standards and force new ones on my clinical practice.

I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B rehabilitation facility.

14521

Sincerely,

John P. Salvo, MD
Director, Sports Medicine
Cooper Bone and Joint Institute
Cooper University Hospital

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

Organization : **Theresa Miles**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Theresa Miles

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

Organization : **LIZ melton**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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LIZ MELTON

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

Organization : **David Miles**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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David Miles

Submitter : **Dr. Marsha Wakefield** **Date: 08/31/2007**

Organization : **Dr. Marsha Wakefield**

Category : **Physician**

Issue Areas/Comments

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Thank you for your consideration of this serious matter.
Thank you for working for better healthcare in the U.S.

Sincerely,
Marsha L Wakefield

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

Organization : **Medical Imaging & Technology Alliance**

Category : **Device Association**

Issue Areas/Comments

GENERAL

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Please see attachment.

CMS-1385-P-14526-Attach-1.PDF

#14526

MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

1300 North 17th Street • Suite 1752
Arlington, Virginia 22209
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Fax: 703.841.3392
www.medicalimaging.org

August 31, 2007

VIA HAND DELIVERY AND ELECTRONIC MAIL
www.cms.hhs.gov/regulations/eRulemaking

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health & Human Services
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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

Dear Acting Deputy Administrator Kuhn:

The Medical Imaging and Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA), is pleased to submit comments regarding the proposed rule entitled "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008."[1] MITA is the leading trade association representing companies whose sales comprise over ninety percent of the global market for medical imaging. We are pleased to provide the Centers for Medicare and Medicaid Services (CMS) our perspective on ways to enhance the physician payment system to ensure continued access to the transformative medical imaging technologies that are improving diagnostic and therapeutic interventions for Medicare beneficiaries.

Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, diagnostic ultrasound, and nuclear medical imaging, including positron emission tomography (PET) and magnetic resonance imaging (MRI). Imaging is used both to diagnose and treat patients with disease and offers physicians the ability to view soft tissue and organs, often reducing the need for costly and invasive medical and surgical procedures.[2] In addition, imaging equipment is used in some procedures to guide physicians as they carry out a medical or surgical intervention, such as device placement, to ensure high-quality clinical results for the patient.[3]

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[1] 72 Fed. Reg. 38122 (July 12, 2007).

[2] Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., New England Journal of Medicine, Vol 352, No 17; pp1760-1768, April 28, 2005.

[3] Jelinek, JS et al. "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." *Radiology*. 223 (2002): 731 - 737.

The trade association, AdvaMed, commissioned United Biosource Corporation (UBC) to analyze and provide a report evaluating the survey done by MedPAC.[6] UBC determined that, "...the methods and sampling frame used [by MedPAC] were insufficient to reach a level of validity needed to use the results as evidence for policy and/or reimbursement decision-making on a national level." Also, surveys that focus solely on MRI and CT services do not capture the full range of imaging utilization rates for all imaging modalities.[7]

As outlined above, many sources were used to attempt to assess accurate equipment utilization rates. Neither CMS nor UBC were able to establish an appropriate methodology to determine equipment utilization rates across all imaging modalities and relevant settings. The array of modalities, the array of potential uses to which they can be applied clinically, and the array of sites in which they are employed create a highly complex set of usage algorithms. Therefore, MITA agrees with CMS that the empirical data are insufficient to validate an alternative methodology to determine equipment utilization rates for all imaging modalities. We stress to CMS that it is important to move cautiously in this area, and if an alternative methodology is considered, that the Agency allow the public the opportunity to comment on any proposed changes to the formula in a future notice of public rulemaking prior to implementation.

B. Equipment Interest Rate

In the proposed rule, CMS makes reference to the possibility of revising the equipment interest rate used in determining payment rates for physicians. After reviewing the Small Business Administration (SBA) data on loans and applicable interest rates, CMS found that interest rates were comparable to the current equipment interest rate utilized in the payment rate-setting methodology.

MITA agrees with CMS's decision to not propose an alternative equipment interest rate and maintain the equipment interest rate at 11 percent.

II. Resource-based Practice Expense (PE) Relative Value Units (RVUs)

By submitting supplemental survey data to CMS, specialty societies play an important role in determining appropriate scaling factors used to calculate physicians' practice expenses. The primary purpose of these surveys is to ensure that Medicare payment for the indirect practice expenses of various specialties accurately reflect the indirect practice expenses of the various specialties.

In the proposed rule, CMS proposes to revise the practice expense per hour (PE/HR) values associated with radiology, based on an analysis presented by the ACR and reviewed by The Lewin Group which determined that weighting the ACR survey data by practice size more appropriately accounted for the small high cost entities in the final PE/HR. MITA believes that CMS has taken the right approach by modifying the weighting

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[6] This report may be found on the AdvaMed web site: http://www.advamed.org/NR/rdonlyres/A91FD8B6-8A45-4B17-8633-FC3935035593/0/medpacsurvey062007.pdf. (accessed on August 6, 2007).

[7] Id.

methodology used to integrate the ACR data into the fee schedule methodology, and we appreciate CMS's willingness to work with these societies to ensure accurate payment for radiology services.

MITA supports the use of the adjusted ACR supplemental survey data for radiology practice expense values.

III. RUC Recommendations for Direct Practice Expense (PE) Inputs and Other PE Input Issues For Specific Procedures

At the February and April 2007 meetings, the American Medical Association's Practice Expense Review Committee (PERC) reviewed numerous CPT® codes to assist in recommending direct practice expense inputs for new and existing CPT® codes. These recommendations were reviewed by CMS.

MITA cautions CMS in adopting some of the recommendations suggested by the PERC. For example, we disagree with the PERC's recommendation for revisions to CPT® codes, 77080-77082, for dual energy x-ray absorptiometry (DXA), the clinical gold standard for detecting osteoporosis. A high level of skill and physician's time is needed to accurately interpret DXA scans; this is critical for accurate diagnosis and determining subsequent therapy for the patient.

Reimbursement for DXA is projected to drop to approximately $36 a scan by January 1, 2010, a decline of 71 percent compared to 2006 levels.[8] Screening for bone density, such as DXA, is already underutilized. Most bone diseases disproportionately affect the elderly, many of whom already experience substantial problems with frailty, reduced functional capacity, and even life-threatening fractures that can lead to hospitalization and long-term care expenses. In fact, there have been a number of Federal initiatives that have attempted to target and increase the number of Medicare beneficiaries who are screened for osteoporosis, such as the United States Preventive Services Task Force, the National Osteoporosis Foundation, and the Surgeon General's Report on Bone Health and Osteoporosis. The universal promotion of screening with DXA is clearly at odds with both the changes to the Physician Fee Schedule and the objectives of the Deficit Reduction Act of 2005 (DRA), which takes aim at reducing the volume of all imaging services, except mammography.

Because most screenings are done in the physician's office, MITA is concerned that an additional reduction to direct practice expense (PE) inputs, by the PERC, may force physicians to no longer provide bone mass measurement screenings to Medicare beneficiaries, leading to higher fracture rates, more expensive hospitalizations and greater economic impact on the Medicare program. It is imperative that CMS properly value the current DXA technology utilized in physicians' offices and properly reflect those costs in the reimbursement rate.

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[8] According to the International Society for Clinical Densitometry: http://www.iscd.org/Visitors/positions/publicpolicy.cfm (accessed August 28, 2007).

We believe it is in the public's and the Medicare program's best interest to ensure that access to and promotion of screening services for bone mass measurement remain available and affordable. We ask that CMS reconsider its decision to implement the PERC's recommendation regarding bone mass density testing using DXA.

IV. Additional Codes for the 5-Year Review of Work RVUs

MITA is extremely concerned with CMS's proposal to package the Medicare payment for color flow Doppler, CPT® code 93325, into all echocardiography procedures. As noted in the proposed rule, CMS justifies this action by stating that color flow Doppler has become "intrinsic to the performance of other echocardiography services."

CMS's justification for eliminating additional payment for color flow Doppler is unsound. Although color flow Doppler may be done concurrently with other echocardiographic tests, it is not intrinsic to the performance of all echocardiography procedures. The performance and interpretation of color flow Doppler increases the sonographer time and equipment time that are required for a study, thereby adding additional resources to the procedure.

Currently, the CPT® coding system includes different descriptors for different types of ultrasound services, based on how and why ultrasound is performed by various clinical specialties. For example, color flow Doppler is treated as an "add-on" code in cardiac ultrasound, but not vascular ultrasound. After our review of the Medicare claims data, provided by a highly competent and reliable researcher through medical societies to CMS, MITA believes that it would be inappropriate to bundle color Doppler into all "base" echocardiography codes. Based on this review of Medicare claims data, it appears that color flow Doppler is not truly "intrinsic" to all echocardiography procedures. That review found that color flow Doppler is actually used less than 50 percent of the time concurrent with other echocardiographic procedures. This is not a sufficient linkage to determine that color flow Doppler is "intrinsic" to echocardiography services. In addition, CMS has not articulated a proposed definition or standard, or a clear threshold in regards to what would constitute appropriate bundling of this procedure.

It is our understanding that a proposal to potentially bundle adult transthoracic echocardiograms, color flow Doppler, and spectral Doppler into one CPT® code has been approved by the American Medical Association's (AMA) Editorial Panel. Thoughtful, selective and clinically appropriate bundling of services, as this may be, is a more supportable pathway over time. MITA supports the medical societies' rationale for not bundling color Doppler across the board on all base echocardiography codes, and we urge CMS to reconsider the proposed packaging of color flow Doppler scans into all echocardiography services.

V. TRHCA -- SECTION 101(b): Physician Quality Reporting Initiative (PQRI)

The Tax Relief and Health Care Act of 2006 - Medicare Improvements and Extension Act of 2006 (Pub. L. 109-432, also known as TRHCA or MIEA-TRHCA) requires that "as part of the publication of proposed and final quality measures for 2008 PQRI the Secretary

shall address a mechanism whereby an eligible professional may provide data on quality measures through an appropriate medical registry.".

MITA believes that use of registries for 2008 and beyond is of critical importance to the PQRI, as well as to physicians and other health care professionals. The use of clinical data residing in a registry or an electronic health record (EHR), without the need for special claims-based codes for performance measure numerators, will enhance clinical and billing workflow and increase the accuracy of the reported measures. MITA encourages an approach to data gathering and reporting through registries that does not impose burdens on physicians and other health care professionals who would be utilizing specific registry options to fully satisfy their PQRI obligations.

Furthermore, MITA asks that CMS issue the invitation to self-nominate in the testing of the registry-based quality data submission mechanism as soon as possible so that registries have a full opportunity to evaluate and prepare their responses, and to determine and implement any technical changes needed to meet CMS requirements under the PQRI program.

Looking to the future of the PQRI program, MITA urges CMS to propose measures with ample advance notice to give physicians and vendors sufficient time to plan for use of these measures, and to ensure that the necessary data collection, measure computation, and quality programs are in place.

Lastly, MITA asks that as CMS moves forward with the initial expansion of these quality measures, as well as future measures, that CMS be cognizant of the need for appropriate recognition of imaging technology within these measures. MITA is pleased that CMS has considered and incorporated imaging services within relevant quality measures. However, in doing so, we caution CMS to provide for ongoing innovation of imaging technology, and medical practice when adopting measures for various diseases and conditions. As technology advances and techniques for utilizing equipment improve, it is imperative that physicians be able to deploy the most advanced and medically appropriate imaging technology to diagnose and treat patients. Quality measures should focus on the range of modalities available in the context of the measure, while providing latitude to address emerging imaging advances. Imaging technologies are undergoing rapid specification advances that physicians should be able to incorporate based on their medical decision-making.

MITA looks forward to working with CMS and others as measures that involve imaging procedures are developed, adopted, or modified under the PQRI program.

VI. Physician Self-Referral Provisions

In the proposed rule, CMS outlines several issue areas and a subset of actual proposals to regulatory policy broadly governed by the Omnibus Budget Reconciliation Act of 1993 (commonly referred to as the Stark Law)[9] that relate to physician self-referral rules. CMS

[9] SSA §1877 codified at 42 U.S.C. §1395nn.

has proposed regulatory policies in several areas and invited comment on other related areas, without specific proposals on the latter. In general, MITA believes that it is highly inadvisable for CMS to propose significant new interpretations and policies regarding current physician leasing, and referral arrangements in the context of the Medicare physician fee schedule. Rather, MITA strongly urges CMS to develop any specific proposals governing permissible arrangements within the context of separate proposed rules promulgated to update the Stark Law requirements. That appears to be the more appropriate arena in which to propose changes in the policies that govern permissible arrangements, which in turn set the foundation upon which to propose modified reimbursement rules.

MITA notes that many of the proposals under discussion in this notice penetrate deeply into how physicians, and for that matter, hospitals, structure their working relationships. In fact, in one area under the "in-office ancillary services" discussion, CMS seems to be entering into an especially troubling area, which is to suggest setting policy regarding which types of physicians are qualified to perform which services. This is an area fraught with issues and which is impacted upon by state licensure and scope of practice laws, and individual physician training and acquired practice skills. We think it is not necessary for CMS to wade into those issues to advance its program objectives. Separately, it is not clear that CMS has adequately investigated the common leasing and interactive service contractual relationships in the market, which can be practical and cost-efficient, in compliance with Stark Law requirements, and not necessarily abusive or leading to excessive utilization of services. Therefore, we believe that it would be prudent to proceed cautiously and within the right legal framework for defining what is permissible and what is not, and then to determine how best to structure any Medicare reimbursement changes.

It appears that CMS's underlying real concern is that many of the arrangements may be leading to inappropriate utilization of imaging services. In the CY 2007 Physician Fee Schedule Proposed Rule, CMS states that, "We [CMS] are concerned that allowing physician group practices or other suppliers to purchase...diagnostic testing services...may lead to patient and program abuse in the form of over-utilization of services and result in higher costs to the Medicare program."[10] Although CMS expressed concern regarding the possible existence of arrangements that were not intended under the physician self-referral rules, it is important to note that **self-referral is not a widespread practice in Medicare**, and accounts for only a modest percentage of all referrals for imaging services.[11]

MITA commissioned a study utilizing CY 2005 Medicare claims data to examine self-referral rates. Based entirely on Medicare claims data, we found that the majority of referrals for imaging services are made by physicians who do not stand to realize any financial gain from making the referral.[12] These are physicians (usually family practitioners

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[10] 71 Fed. Reg. 49054 (August 22, 2006).

[11] According to an analysis by Direct Research, LLC of 2005 Medicare claims data. The full analysis is attached for CMS's review.

[12] Id.

or doctors of internal medicine) who order the tests, but are in no way connected to the physicians who then perform the test. For example, referrals for CT, MRI, PET and SPECT services are made on average 94-percent of the time to physicians who do not order the tests. *The data show, in each imaging modality, that the physicians who most often perform the tests are radiologists, who typically are not in a position to refer or self-refer the imaging studies.* This clear separation between the ordering and performing physicians is illustrated, in our analysis, for each major imaging modality.

According to the MITA-commissioned analysis of the 2005 claims data, most imaging for Medicare patients is done in hospitals, primarily in hospital outpatient departments. For instance, 81.3 percent of CT imaging is done in hospitals (including outpatient facilities) whereas 16 percent is in physician offices. Most MRIs are also performed in hospitals; only 34 percent are done in physician offices. We have attached our detailed analysis for CMS's review.

With respect to selected other issues raised by CMS, MITA understands CMS's intentions of preventing inappropriate referrals within the Medicare system, but feels the definition of a "centralized building" needs to be outlined in a more concise manner to ensure that appropriate, cost-effective, mobile radiology services and teleradiology services are not disrupted. It is our view that if CMS has identified one or two clearly questionable situations, the Agency should act on those specific matters rather than propose broader-scope rules that may inadvertently disrupt legitimate service arrangements in imaging.

A. Unit of Service Payments in Space and Equipment Leases

In the proposed rule, CMS proposes to prohibit "time-based or unit-of-service-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity."[13] Specifically, section 1877(e)(1) of the Social Security Act provides an exception to the prohibition of physician referrals for space and equipment leases, but CMS has expressed their concern with these types of lease arrangements, and notes that the Agency believes that "such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee..."[14] MITA recognizes CMS's concern, but it is our opinion that such arrangements may be clearly permissible under current statute and regulations, therefore, we believe CMS should conduct a further analysis prior to moving forward with any specific changes.

Although the proposed restrictions discussed above would not apply where the entity is the lessor, CMS also seeks comments regarding whether the Agency should prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee. Based on Congress' intentions, as long as the lease arrangement meets the requirements, and the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner, it should continue

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[13] Id.

[14] 72 Fed. Reg. 38122 (July 12, 2007).

to be allowed.[15] For many solo practitioners, it may be difficult to justify purchasing expensive equipment for their office that may be used only on a part-time basis. Arrangements between physicians and facilities, such as the ones discussed above, also allow physicians to better extend their services to Medicare beneficiaries in rural areas, without adding significant cost to their individual practices. This ensures beneficiaries have access to state-of-the-art imaging equipment, yet the services remain cost-effective for all parties. MITA urges CMS to not prohibit these types of time-based or unit-of-service-based lease arrangements.

VII. Other Issues

Although not formally discussed in the proposed rule, MITA continues to believe that application of the multiple procedure discount policy in the Physician Fee Schedule is redundant and excessive in light of the Deficit Reduction Act of 2005 (DRA) cap. Enacted January 1, 2007, the DRA provision caps the technical component reimbursement for non-hospital outpatient imaging to the lesser of the Hospital Outpatient Prospective Payment System (HOPPS) payment amount or the Medicare physician fee schedule payment amount. Imaging services affected by this provision include CT, MRI and ultrasound procedures.

MITA urges CMS to remove the multiple procedure discount policy from the Physician Fee Schedule for those services held to the "lesser of" rule. The HOPPS rates serve as the basis for the cap, and these rates already factor in the effects and economies of performing multiple imaging procedures during the same session. To apply the multiple procedure discount policy in the Physician Fee Schedule, and then to apply the DRA cap, is essentially "over-adjusting" payment levels to account for economies in multiple procedure imaging.

MITA also asks CMS for clarification regarding the extent to which the DRA cap will be imposed on procedures that are either (a) bundled into other principal procedures under the HOPPS system (e.g. ultrasound guidance procedures); or (b) only one component of a broader package that includes other items and services (e.g. myocardial perfusion (SPECT) procedures whose Ambulatory Payment Classification (APC) rates also include add-on services and radiopharmaceuticals. In the absence of guidance from CMS, we presume that the DRA "cap" will not apply to services, like ultrasound-guidance services and dependent ancillary services (i.e. "add-on" codes) that are not separately payable under HOPPS.

VIII. Conclusion

In closing, we ask CMS to develop policy decisions that accurately recognize that the majority of the growth in imaging services emerges from the genuine medical benefit and clinical support that physicians recognize that they receive from employing imaging technologies in diagnosing and treating injury and disease. Many applications in use today did not exist a mere decade ago. MITA believes that these transformative imaging

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[15] 42 U.S.C. §1395nn.

technologies are major contributors to improvements in patient care, and over time are generating off-setting savings through less-invasive care, and quicker recovery and fewer complications for patients. These crucial benefits are often overlooked in assessments of growth in imaging spending. A better approach to managing this growing utilization is to rely upon sound evidence of clinical benefit and practice guidelines developed by physicians so that clinically optimal medical protocols are in place.

Imaging advocacy groups, such as MITA, also feel it is necessary to implement guidelines to promote proper equipment maintenance and utilization. MITA looks forward to sharing its ideas with CMS in the upcoming months. Finally, we urge CMS to look to the future, as developments in molecular, cellular, functional and genetic imaging promise a new era of prediction and prevention of disease, not just diagnosis and treatment.[16]

We strive to continue working with CMS on these matters under the Medicare Physician Fee Schedule. If you have any questions or would like to discuss these matters further, please contact me at 703-841-3279.

Respectfully Submitted,

Andrew Whitman
Vice President

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[16] "Advances in Biomedical Imaging," Tempany MC, McNeil BJ, *Journal of the American Medical Association,* 2001, Vol. 285: 562-567.

MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA
www.medicalimaging.org

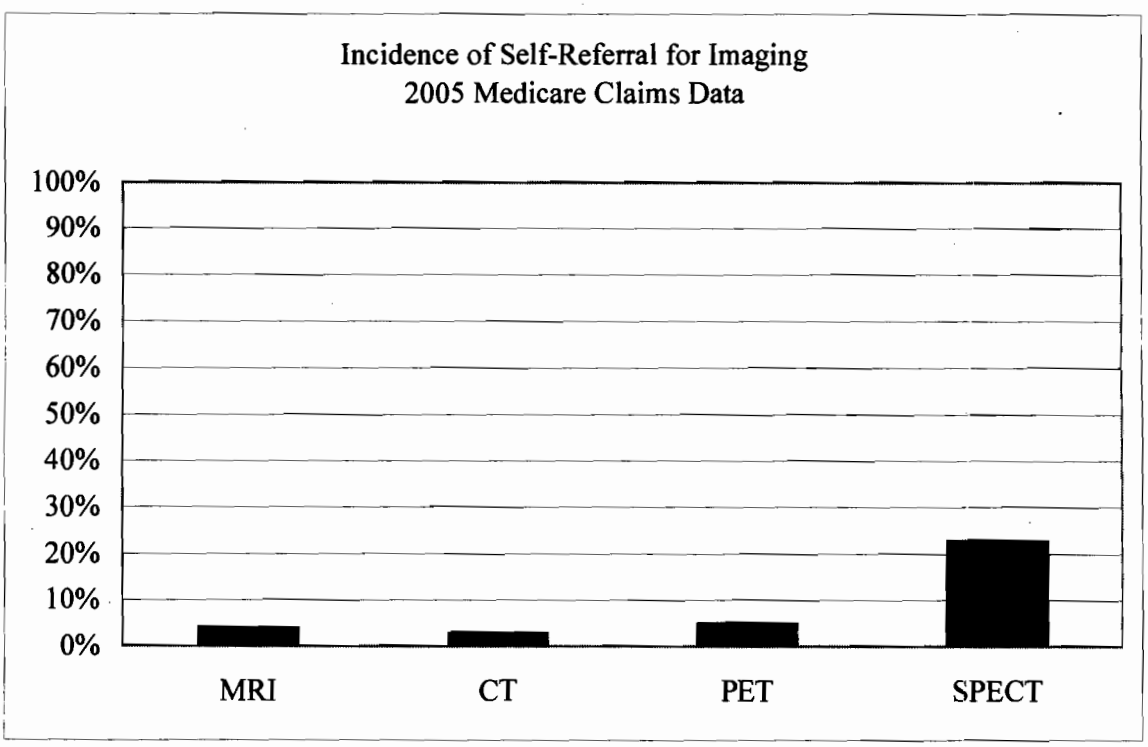
Medicare Data Analysis
Self Referral Rates in Medical Imaging are Low

The term "self referral" is used to describe the practice whereby a physician performs a medical service that he or she has ordered. Although CMS recognized the validity of this practice when done as a part of the rest of the care that a physician provides to a patient in his or her office, discussions of whether the opportunity to self-refer leads to the provision of unnecessary imaging services continue.

According to an analysis by Direct Research, LLC of 2005 Medicare claims data; self-referral is not a widespread practice in Medicare, and accounts for only a modest percentage of all referrals for imaging services.

- The 2005 Medicare data suggest several conclusions about how imaging is used and by which physicians.
  - Referrals for CT, MRI, PET and SPECT are made on average 94% of the time to physicians who do not order the tests.
  - Most physicians who refer patients for imaging scans do not experience economic gain from the referral.
  - Self-referral is not a dominant trend in Medicare for medical imaging; in fact, it occurs in only a small percentage of cases.

- In 2005, the proportion of imaging studies in which the referring physician and the providing physician were one-in-the-same, i.e., in which physicians were self-referring, was 3.9% for MRI services, 2.8% for CT services, 5% for PET services, and 22.8% for SPECT services. On a weighted average basis, fully 94% of imaging studies cannot be described as self-referral.



- The majority of referrals for imaging services are made by physicians who do not stand to realize any financial gain from making the referral, according to the 2005 Medicare data. These are physicians (usually family practitioners or doctors of internal medicine) who order the tests, but are in no way connected to the physicians who then perform the test. The data show in each imaging modality, that the physicians who most often perform the tests are radiologists, who typically are not in a position to refer or self-refer the imaging studies. This clear separation between the ordering and performing physicians is illustrated by the 2005 Medicare data for each major imaging modality.

- Imaging is used for diagnosing, monitoring and guiding treating of common medical conditions, such as stomach pain, back problems, cancer, and heart disease.
  - Top CT procedures by volume are for diagnosing abdominal pain (12%) and lower respiratory diseases (8.2%).
  - Top MRI procedures are for back (27%) and joint disorders (7.3%).
  - Top PET procedures are for cancer (lung 22.2%; non-Hodgkin's lymphoma 13.3%)
  - Top SPECT procedures are for heart disease (38.8%) and chest pain (32%).

- Most imaging for Medicare patients is done in hospitals, primarily in hospital outpatient departments, according to the analysis of 2005 Medicare data.
  - 81.3% of CT imaging is done in hospitals (48.5% of that in the outpatient setting); 16% is in physician offices.
  - 52.6% of MRIs are done in hospitals (34.4% in the outpatient setting); 34.1 percent of MRIs are done in physician offices.
  - 39.2% of PET scans are done in physician offices, while 38.9% are done in hospitals (34.2% of that is in the outpatient setting); 20.7% is done in independent diagnostic testing facilities.
  - 64.5% of SPECT scans are done in physician offices, while 34.3% are done in hospitals (20.3% of that in the outpatient setting).

Memorandum

To: Andrew Whitman, Vice President
Medical Imaging & Technology Alliance (MITA)
From: Christopher Hogan, Direct Research, LLC
Subject: Advanced Imaging Self-Referral Analysis

This report briefly summarizes Medicare carrier-paid claims for MRI, CT, and PET/SPECT services in the US, for 2005 to determine the incidence of self-referral of imaging services as reported in the Medicare carrier-paid claims data.

1. Methodology

- Start from the Medicare 2005 5 percent sample standard analytic file, limited dataset version, carrier claims file.
- Summarize entire file by encrypted Unique Provider Identification Number (UPIN) and specialty to provider a roster of encrypted UPINs.
- Extract MRI and CT services, defined as claims lines with Berenson-Eggers Type of Service (BETOS) codes I1A, I2B (CT) or I2C, I2D (MRI). For PET/SPECT, the codes were extracted by CPT code, as they may be located in any of several BETOS categories.
- Match the UPIN registry to the claim line, by referring UPIN, to identify the specialty of the referring physician.
- Compare the beneficiary state of residence to the provider's state, to flag patients who crossed state borders for care.
- Match to patient counts from the 5 percent LDS denominator file to determine per-capita use rates. (Include only fee-for-service beneficiaries with Part B coverage.)
- Summarize line diagnosis by the Agency for Healthcare Research and Policy (AHRQ) Clinical Classification System (CCS) disease categories to show what the MRIs were used for.
- Define place of service as hospital inpatient, hospital OPD or ER, IDTF (independent diagnostic testing facility), physician office, and other.
- Exclude technical component only claims when counting services per capita.
- Summarize referring and performing specialty, diagnosis, and other aspects of care.

2. Results

This section presents the results of the analysis, with tables of data and conclusions. Results are presented in five tables.

Table 1 shows the most common specialties performing each type of advanced imaging service profiled here. The four advanced imaging services differ markedly in terms of performance by radiologists and freestanding radiology facilities. For MRI and CT, roughly 90 percent of services are performed by radiologists. For PET, if nuclear medicine specialists are included, about 80 percent of services are performed by radiologists. For SPECT, by contrast, cardiologists perform two-thirds of the services.

Table 1: Medicare Advanced Imaging Claims, Most Common Performing Physician Specialties, 2005

	Service Count, 5% Sample	Percent of Claims
CT		
Total	1,062,351	100.0%
Diagnostic radiology	952,463	89.7%
Interventional radiology	28,748	2.7%
IDTF	27,330	2.6%
Radiation oncology	10,910	1.0%
Internal medicine	7,446	0.7%
General/Family practice	5,901	0.6%
Hematology/ oncology	5,245	0.5%
MRI		
Total	391,303	100.0%
Diagnostic radiology	300,767	76.9%
Independent Diagnostic Testing Facility (IDTF)	50,878	13.0%
Orthopedic surgery	9,239	2.4%
Interventional radiology	7,405	1.9%
Neurology	5,836	1.5%
Nuclear medicine	2,589	0.7%
General/Family practice	2,306	0.6%
Internal medicine	2,072	0.5%
Radiation oncology	1,852	0.5%
PET		
Total	4,814	100.0%
Diagnostic Radiology	2,296	47.7%
Independent Diagnostic Testing Facility (IDTF)	998	20.7%
Nuclear medicine	525	10.9%
Cardiology	505	10.5%
Hematology/ oncology	153	3.2%
Radiation oncology	70	1.5%

Table 1: Medicare Advanced Imaging Claims, Most Common Performing Physician Specialties, 2005		
	Service Count, 5% Sample	Percent of Claims
Interventional radiology	64	1.3%
Medical oncology	60	1.2%
Internal medicine	33	0.7%
Neurology	23	0.5%
SPECT		
Total	181,623	100.0%
Cardiology	124,503	68.6%
Diagnostic radiology	31,647	17.4%
Internal medicine	11,009	6.1%
Nuclear medicine	7,829	4.3%
Independent Diagnostic Testing Facility (IDTF)	2,087	1.1%
General/Family practice	1,363	0.8%
Interventional radiology	857	0.5%
Source: Analysis of 5% sample physician/supplier SAF, LDS version.		
Notes: CT defined as BETOS I1A, I2B. MRI defined as BETOS I2C and I2D. PET and SPECT identified by CPT codes for those services. Includes all carrier-paid bills (including TC-only bills)		

Table 2 gives the same breakout by the specialty of the referring (ordering) physician. Diagnostic radiologists ordered slightly more than 1 percent of PET scans. For the other three categories, diagnostic radiologists accounted for less than 1 percent of the services ordered.

Table 2: Medicare Advanced Imaging Claims, Most Common Referring (Ordering) Physician Specialties, 2005		
	Service Count, 5% Sample	Percent of Claims
CT		
Total	1,062,351	100.0%
Internal medicine	227,721	21.4%
Emergency medicine	169,350	15.9%
General/Family practice	141,493	13.3%
No UPIN match/Unk.	102,944	9.7%
Hematology/ oncology	61,405	5.8%
General surgery	42,131	4.0%
Urology	41,321	3.9%
Pulmonary disease	34,972	3.3%
Gastroenterology	28,701	2.7%
Medical oncology	28,192	2.7%
Cardiology	28,068	2.6%
Otolaryngology	13,821	1.3%
Neurology	13,459	1.3%

Neurosurgery	12,929	1.2%
Orthopedic surgery	12,037	1.1%
Diagnostic radiology	**10,775**	**1.0%**
Nephrology	9,663	0.9%
Radiation oncology	8,156	0.8%
Vascular surgery	7,822	0.7%
Obstetrics/ gynecology	7,124	0.7%
Thoracic surgery	5,628	0.5%
MRI		
Total	391,303	100.0%
Internal medicine	83,985	21.5%
General/Family practice	57,117	14.6%
Orthopedic surgery	46,852	12.0%
Neurology	42,817	10.9%
No UPIN match/Unk.	31,506	8.1%
Neurosurgery	13,485	3.4%
Hematology/ oncology	13,452	3.4%
Emergency medicine	8,617	2.2%
Cardiology	8,563	2.2%
General surgery	7,069	1.8%
Physical medicine and rehabilitation	6,146	1.6%
Otolaryngology	6,023	1.5%
Medical oncology	5,943	1.5%
Rheumatology	5,824	1.5%
Pulmonary disease	5,699	1.5%
Nephrology	4,170	1.1%
Gastroenterology	4,169	1.1%
Anesthesiology	3,352	0.9%
Diagnostic radiology	**3,267**	**0.8%**
Radiation oncology	3,009	0.8%
Podiatry	2,807	0.7%
Ophthalmology	2,752	0.7%
Urology	2,511	0.6%
Vascular surgery	2,483	0.6%
PET		
Total	4,814	100.0%
Hematology/ oncology	1,023	21.3%
Internal medicine	586	12.2%
Cardiology	541	11.2%
Medical oncology	482	10.0%
Pulmonary disease	318	6.6%
Neurology	290	6.0%
No UPIN match/Unk.	283	5.9%
General/Family practice	262	5.4%
Radiation oncology	167	3.5%
Otolaryngology	141	2.9%
General surgery	137	2.8%
Thoracic surgery	78	1.6%

Hematology	65	1.4%
Diagnostic radiology	**53**	**1.1%**
Gastroenterology	50	1.0%
Emergency medicine	34	0.7%
Psychiatry	26	0.5%
Cardiac surgery	23	0.5%
Critical care (intensivists)	22	0.5%
SPECT		
Total	181,623	100.0%
Cardiology	66,439	36.6%
Internal medicine	53,745	29.6%
General/Family practice	33,897	18.7%
No UPIN match/Unk.	8,736	4.8%
Emergency medicine	2,752	1.5%
Pulmonary disease	1,737	1.0%
General surgery	1,618	0.9%
Nephrology	1,332	0.7%
Orthopedic surgery	1,008	0.6%
Gastroenterology	962	0.5%
Nurse practitioner	670	0.4%
Endocrinology	664	0.4%
Vascular surgery	616	0.3%
Diagnostic radiology	**535**	**0.3%**
Source: Analysis of 5% sample physician/supplier SAF, LDS version.		
Notes: CT defined as BETOS I1A, I2B. MRI defined as BETOS I2C and I2D. PET and SPECT identified by CPT codes for those services. Includes all carrier-paid bills (including TC-only bills)		

Table 3 shows imaging by place of service, counting each bill (professional component, technical component, or total) as one service. SPECT is primarily an office-based service, with about two-thirds of services taking place in physician offices. Both PET and MRI have a significant volume in independent diagnostic testing facilities (IDTFs).

Table 3: Advanced Imaging Services by Location, 2005							
Col Pct	1:Inpatient	2:OPD/ER	3:Office	4:IDTF	5:Other	Total	Services, 5% Sample
1:CT	32.8%	48.5%	16.0%	2.6%	0.2%	100.0%	1,062,351
2:MRI	18.2%	34.4%	34.1%	12.9%	0.4%	100.0%	391,303
3:PET	4.7%	34.2%	39.2%	20.7%	1.2%	100.0%	4,814
4:SPECT	14.0%	20.3%	64.5%	1.2%	0.1%	100.0%	181,623
Source: Analysis of 5% sample physician/supplier SAF, LDS version.							
Notes: CT defined as BETOS I1A, I2B. MRI defined as BETOS I2C and I2D. PET and SPECT identified by CPT codes for those services. Includes all carrier-paid bills (including TC-only bills)							

Table 4 shows the diagnosis reported on the claim line for the service, grouped by the Agency for Healthcare Research and Quality Clinical Classification System (CCS) categories. The data clearly show the main uses for PET (cancer staging) and SPECT (assessment of cardiovascular problems). CT and MRI, by contrast, are more general purpose tools, used for a broad array of underlying problems.

Table 4: Services by Clinical Classification System Diagnosis Category			
CCS	CCS label	Services, 5% sample	Pct of Services
CT			
Total	Total	1,062,351	100.0%
251	Abdominal pain	127,377	12.0%
133	Other lower respiratory disease	87,226	8.2%
244	Other injuries and conditions due to external causes	35,874	3.4%
84	Headache; including migraine	34,027	3.2%
155	Other gastrointestinal disorders	33,445	3.1%
109	Acute cerebrovascular disease	32,245	3.0%
146	Diverticulosis and diverticulitis	27,459	2.6%
205	Spondylosis; intervertebral disc disorders; other back	27,402	2.6%
151	Other liver diseases	27,297	2.6%
259	Residual codes; unclassified	26,032	2.5%
MRI			
Total	Total	391,303	100.0%
205	Spondylosis; intervertebral disc disorders; other back	105,489	27.0%
204	Other non-traumatic joint disorders	28,395	7.3%
109	Acute cerebrovascular disease	20,670	5.3%
95	Other nervous system disorders	15,639	4.0%
84	Headache; including migraine	11,606	3.0%
211	Other connective tissue disease	11,415	2.9%
110	Occlusion or stenosis of precerebral arteries	11,361	2.9%
111	Other and ill-defined cerebrovascular disease	10,675	2.7%
225	Joint disorders and dislocations; trauma-related	9,780	2.5%
112	Transient cerebral ischemia	9,659	2.5%
PET			
Total	Total	4,814	100.0%
19	Cancer of bronchus; lung	1,067	22.2%
38	Non-Hodgkin`s lymphoma	640	13.3%
101	Coronary atherosclerosis and other heart disease	498	10.3%
68	Senility and organic mental disorders	345	7.2%
133	Other lower respiratory disease	318	6.6%
14	Cancer of colon	284	5.9%
11	Cancer of head and neck	254	5.3%
15	Cancer of rectum and anus	201	4.2%
102	Nonspecific chest pain	153	3.2%
22	Melanomas of skin	119	2.5%

SPECT			
Total	Total	181,623	100.0%
101	Coronary atherosclerosis and other heart disease	70,437	38.8%
102	Nonspecific chest pain	58,059	32.0%
117	Other circulatory disease	16,665	9.2%
133	Other lower respiratory disease	10,750	5.9%
106	Cardiac dysrhythmias	5,412	3.0%
108	Congestive heart failure; nonhypertensive	2,843	1.6%
256	Medical examination/evaluation	2,040	1.1%
98	Essential hypertension	1,660	0.9%
104	Other and ill-defined heart disease	1,494	0.8%
237	Complication of device; implant or graft	1,427	0.8%
Source: Analysis of 5% SAF LDS physician/supplier claims, 2005			
Note: Disease entity is line diagnosis code crosswalked to AHRQ CCS category.			

Finally, Table 5 gives summary statistics on performance by radiologists (either diagnostic radiology or IDTF), self-referral, and services and service users per capita. SPECT stands out in terms of self-referral, presumably by cardiologists. For the other services, self-referral rates (as measure by matching UPINs for performing and referring physician) range from about 3 to 5 percent. Almost none of that is self-referral by radiologists -- as noted above, radiologists ordered 1.2 percent of PET scans and 1 percent or less of all other types of imaging.

In terms of users and services, about one in ten PET or SPECT users have multiple bills for those services (other than TC-only bills) during the year. For MRI, about a third of users have more than one (non-TC) MRI bill. For CT, almost two-thirds have multiple (non-TC) bills for CT services over the course of the year.

Table 5: Comparison of Specialty and Use Rates, Advanced Imaging, 2005

	1:CT	2:MRI	3:PET	4:SPECT
Percent of carrier-paid bills with:				
Radiologist or IDTF as performing physician	92.2%	89.9%	68.4%	18.6%
Radiologist or IDTF as referring (ordering) physician	1.0%	0.8%	1.2%	0.3%
With UPIN-based self-referral (referring UPIN matches performing UPIN)	2.8%	3.9%	5.0%	22.8%
Services per capita and users per capita:				
Total including TC	0.61	0.23	0.003	0.11
Total excluding TC	0.59	0.21	0.002	0.10
Fraction of carrier bills TC only	0.03	0.09	0.12	0.08
Users per capita, any service	0.235	0.126	0.0022	0.088
Users per capita with multiple services	0.142	0.046	0.0002	0.007
Source: Analysis of 5% SAF physician/supplier and denominator, 2005, LDS version				

Submitter : **Mr. Kenneth Rude** **Date: 08/31/2007**

Organization : **Pine Plains Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

PINE PLAINS PHYSICAL THERAPY
PO Box 490 2980 East Church Street, Pine Plains, NY 12567
Phone: (518) 398-7506 Fax: (518) 398-1143
pineplainspt@taconic.net

August 31, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medieare and Medicaid Services
U. S. Department of Health and Human Services
Attention: CMS-1385-P
P. O. Box 8018
Baltimore, MD 21244-8018

Subject:
Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Purpose:
Physician Self-Referral Issues

Dear Mr. Weems,

I wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically upon the proposed amendment to the Stark exceptions defining which in-office ancillary services may be permitted for physician self-referral.

I own a small Physical Therapy private practice in a rural community in upstate New York. I have been a physical therapist for 20 years, and have owned this practice for the past five years. The clinic is small, and I am the only therapist. There are no other physical therapy options within a half-hour s travel from here.

Recently, a hospital in our county built a new wing to accommodate a large orthopedic surgical practice that wanted to expand its area of service. This orthopedic group is by far the largest within several adjacent counties, and the surgeons now perform many of their procedures in this new setting. All of the community was happy to have their services locally available now, as were my patients and myself.

However, the surgical group soon opened their own in-house physical therapy clinic in the facility the hospital had just built. The surgeons own the PT practice, not the hospital, and the vast majority of their PT patients were referred by the surgeons themselves. Reports I and other therapists have heard indicate that the surgeons are urging their patients attend their PT practice and not any other. (Incidentally, the surgical group opened their PT practice despite an already-existing PT department providing community services in the hospital. One can marvel at these surgeons ability to persuade.)

In the past, my clinic received a large percentage of its referrals from this orthopedic group. Since this group opened its PT practice and began self-referring, my clinic has seen its revenues drop by about a third. My post-surgical treatments from this group have almost completely vanished.

A system which allows referral for profit invites abuse. The persuasive powers of a surgeon can be close to irresistible, and when he or she suggests the patient will get better care at the surgeon s PT clinic, it can be hard for a patient to consider other, and possibly better, options. Residents of my community, who would otherwise receive physical therapy close to home, now subject their injured and sutured bodies to three hours a week of car travel, and several trips across a large parking lot, on the instruction of surgeons who stand to profit from the inconvenience. (By way of comparison, the trip from car to treatment table in my clinic is 37 feet.)

The significance of this story doesn t rest on one businessman s woes. My clinic has been reduced from a once-prosperous enterprise to one that now struggles to get by, and our continued existence is no longer certain. If we shut down, our rural community will lose a valuable health-care resource, with nothing to fill the void for many miles. The losers would be the elderly, the infirm and the injured of this community, and the only beneficiaries would be an already-wealthy medical group. Ours would be a classic case of the rich getting richer at the community s expense.

I do not believe that the intention of the Stark exception to the referral-for-profit laws was to countenance the formation of regional health-care monopolies. The exceptions are wiscly specifie

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

Organization : **Mandi Miles**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Rc: CMS-1385-P
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To cnsure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Mandi Miles

Submitter : **Mr. Hugh O'Neill** **Date: 08/31/2007**

Organization : **sanofi-aventis**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14529-Attach-1.PDF

14529

sanofi aventis

Because health matters

Hugh M. O'NEILL
Vice President

August 31, 2007

VIA ELECTRONIC SUBMISSION

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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]

Dear Acting Deputy Administrator Kuhn:

Sanofi-aventis appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to payment policies under the proposed 2008 Medicare physician fee schedule published in the Federal Register on July 12, 2007 (Proposed Rule).[1] Sanofi- aventis is a research-based pharmaceutical company with over 18,000 employees in the United States and a leader in developing innovative therapies to help Medicare beneficiaries lead longer, healthier, and more productive lives. As a pharmaceutical company backed by world class research and development, we are developing innovative therapies to help Medicare beneficiaries lead longer, healthier, and more productive lives. We are pursuing leading positions in seven major therapeutic areas: oncology, cardiovascular disease, thrombosis, diabetes, central nervous system, internal medicine, and vaccines.

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1 72 Fed. Reg. 38122 (July 12, 2007).

Sanofi-aventis is committed to the fight against disease throughout the world. In the new millennium, we have taken up the major challenges of discovering new compounds that are essential to the progress of medical science and launching pharmaceutical products all over the world that constitute real therapeutic progress for patients. Our mission is to discover, develop, and make available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs.

Of particular importance for sanofi-aventis is our fight against cancer. We invest millions of dollars each year in this battle, and it is crucial for the patients we serve to have timely access to cutting-edge therapies that offer their best hope in combating the disease. Accordingly, our comments focus on our concerns regarding providing timely beneficiary access to innovative cancer therapies. Specifically, our comments focus on the need to add to the list of compendia for determination of medically accepted indications, and we urge the agency to act promptly on applications for authoritative drug compendia that currently are pending such that additions are made by the end of the year. We look forward to working with the agency as it revises the compendia process to ensure that our patients and your beneficiaries have appropriate and timely access to state-of-the-art cancer care.

In addition, we believe that patients should have access to high quality care and offer several comments relating to the Physician Quality Reporting Initiative (PQRI). Many of the proposed measures for 2008 affect therapeutic areas in which sanofi-aventis has therapies that can and do improve the lives of beneficiaries. As such, we have engaged with CMS and the quality measure developing and endorsing organizations to ensure measures are appropriate to ensure high quality care for Medicare beneficiaries. In particular, sanofi-aventis supports CMS' efforts to require data reporting to improve the quality of physician care. We urge CMS to adopt an agenda that provides for periodic revision of measures to ensure their continued validity and also includes the development of measures that address urgent medical needs among the Medicare population, such as identification and testing for Peripheral Arterial Disease (PAD) and the prevention of venous thromboembolism (VTE) in all hospital patients, both surgical and medical. We also ask CMS to encourage the development of additional measures to encourage greater coordination of care among providers. Finally, we applaud CMS' efforts to develop a mechanism for receiving registry data to avoid duplicative reporting requirements. These comments are discussed in depth below.

I. Compendia for Determination of Medically Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen [DRUG COMPENDIA]

A. Background

In 1993, Congress, recognizing the importance of scientific compendia, amended the Social Security Act (SSA) to add to the definition of drug for purposes of coverage, "any drug or

biological used in an anticancer chemotherapeutic regimen for a medically accepted indication."[2] Additionally, Congress specified three scientific publications in its amendment that shall be considered to be scientific compendia.[3] The statute states:

> the term "medically accepted indication", with respect to the use of a drug, includes any use which has been approved by the Food and Drug Administration for the drug and includes another use of the drug if—(i) the drug has been approved by the Food and Drug Administration; and (ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, The American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia.[4]

The statute clearly reflects Congressional intent for Medicare contractors to have at least three compendia as scientific resources when making coverage decisions that allow Medicare beneficiaries timely access to innovative cancer therapies. Currently, only the American Hospital Formulary Service-Drug Information (AHFS-DI) publishes a statutorily specified compendium, however, as the American Medical Association Drug Evaluations (AMA-DE) is no longer in publication and United States Pharmacopoeia-Drug Information (USP-DI) is now published by Thomson Micromedex® under the name DrugPoints®.[5] Fortunately, the statute permits the Secretary to revise the list of compendia as appropriate for identifying medically accepted indications for drugs, and we urge the agency to do so by the end of the year.[6]

To gain a better understanding of the compendia, CMS held a Medicare Coverage Advisory Committee (MCAC) meeting on March 30, 2006, entitled, "Compendia for Coverage of Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen" to discuss evidence and hear presentations regarding the desired characteristics of published authoritative compendia that may be used by CMS to determine medically accepted indications of drugs and biologicals in an anti-cancer chemotherapeutic regimen.[7] In preparation for the MCAC meeting, CMS reviewed the legal authority governing the addition and removal of compendia, assessed the functionality of the compendia, and acknowledged that it has received requests for official recognition of additional compendia. Since the MCAC seventeen months

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2 SSA § 1861(t)(2)(A).
3 SSA § 1861(t)(2)(B).
4 *Id.*
5 http://www.micromedex.com/products/uspdi/v1/
6 SSA § 1861(t).
7 71 Fed. Reg. 4589 (Jan 27, 2006).

ago, CMS has continued its evaluation process leading to the publication of this proposed process in the Proposed Rule.

B. Medicare Beneficiaries Rely on Compendia to Access State-of-the-art Cancer Therapies

It is imperative that both CMS and Medicare contractors ensure that coverage policies keep up with the pace of innovation and clinical discovery to allow beneficiaries timely access to the most appropriate treatment options in their battles against cancer. As a leading research-based pharmaceutical company, sanofi-aventis knows that cancer treatments constantly evolve through new clinical research. Many new treatment options involve the use of drugs and biologicals for indications not initially approved by the Food and Drug Administration (FDA). New clinical uses of FDA-approved therapies offer patients and physicians new hope and greater choice in fighting illness and can be particularly important for patients with advanced stages of cancer.[8] We also know that as scientific advances are publicized through peer reviewed publications, however, scientific compendia often incorporate peer reviewed information before it appears on the FDA label. Thus, compendia are an important resource for physicians when determining the most appropriate treatment regimen for their patients. Similarly, Medicare beneficiaries rely on the physician's ability to access compendia for cutting-edge cancer treatments to assist them in their fight against cancer. Therefore, sanofi-aventis urges CMS, consistent with Congressional intent, to recognize additional compendia by the end of the year to help Medicare beneficiaries' access state-of-the-art cancer care.

Additionally, in order to enhance Medicare beneficiary access to cutting-edge cancer treatments, the Medicare statute further requires the Secretary to issue guidance instructing Medicare contractors to use supportive clinical evidence in peer reviewed medical literature to determine additional medically accepted uses of drugs.[9] Recently, contractors have issued decisions that explicitly state that they will no longer proactively evaluate peer reviewed medical literature when making coverage decisions, however.[10] Sanofi-aventis is very concerned about the potential impact these polices have on access to cancer treatments, and we urge the agency to remind the carriers of their obligation to proactively use peer reviewed journals when making coverage decisions for drugs.

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[8] Off-Label Use of Anticancer Therapies: Physician Prescribing Trends and the Impact of Payer Coverage Policy, Sept. 2005, at 5, available at http://www.bio.org/speeches/pubs/CovanceReport.pdf.

[9] 1861(t)(2)(B)(ii)(II).

[10] http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=24296&lcd_version=2&basket=lcd%3A24296%3A2%3ADrugs+Used+Incident+to+a+Physician%27s+Service+and+Their+Covered+Diagnoses%3AMAC+%2D+Part+B%3ANoridian+Administrative+Services+%2803102%29%3A.

C. *Sanofi-aventis Urges CMS to Improve Beneficiary Access by Completing the Current Process for Pending Compendia While Finalizing its Proposed Process*

CMS has acknowledged that at least one other publication has requested to be added as an official compendium. Obviously, any compendium that has applied did so prior to the discussion of the proposed process. In fact, those that applied already went through a CMS process. As stated previously, the March 2006 MCAC was convened to assess the desirable characteristics of a compendium. In preparation for the MCAC, CMS commissioned a technology assessment from the Agency for Healthcare Research and Quality (AHRQ) to summarize the process by which anticancer drugs are added to various compendia, as well as the evidence collection methodology for listed drugs and their indicated uses.[11] AHRQ evaluated the following six publications: AHFS-DI; USP-DI; DRUGDEX Information System; Facts & Comparisons; National Comprehensive Cancer Network Drugs and Biologics Compendium; and, Clinical Pharmacology and provided a detailed analysis regarding the evidence grading system, the methods for communicating information and the comprehensiveness of each compendium. The MCAC members heard presentations from each compendium and discussed in great detail the value of compendia and each desirable characteristic before voting. Either as a result of or before the MCAC, CMS has received requests from the stakeholder community for recognition of additional compendia giving the agency plenty of time to evaluate those compendia that have already applied during this process. Sanofi-aventis believes that the compendia that were evaluated by the MCAC and applied for recognition already have participated in a process that attempts to achieve many of the goals contained in the process detailed in the Proposed Rule.

We appreciate that CMS wants to establish a new transparent and predictable process before adding or removing any compendia; however, given the fact that there is only one statutorily recognized compendia currently in the marketplace and the important role that compendia have in affording patient access to innovative cancer care, we urge CMS first to add the compendia that already have applied for recognition and then to focus efforts on establishing a new process and identifying additional compendia that Medicare carriers could use to determine medically accepted indications. We urge CMS to take this action by the end of the year. If the compendia with pending applications are rejected, we encourage CMS to clearly outline the specific changes that need to be made as well as an expedited timeline for reevaluation in order for the compendia to be added as soon as possible but later than 60 days. We believe that adding these compendia promptly is essential to ensuring Medicare beneficiary access to state-of-the-art cancer care.

Even though all of the compendia are evidence-based, the content of the compendia may vary due to differences in publication schedules, priorities, review processes, local practices, and methods of describing the evidence for each listing. Therefore, to improve the chances of a treatment option being recognized by a compendium in a timely manner, we recommend that CMS continue to recognize multiple compendia for use in Medicare's coverage decisions and to

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[11] https://www.cms.hhs.gov/mcd/viewtechassess.asp?where=index&tid=46

allow each compendium the needed flexibility to add new indications. Recognition of additional compendia is an important step towards protecting beneficiary access to advanced cancer therapies.

D. Sanofi-aventis Recommends Flexibility in the Proposed Process

The Proposed Rule provides, for the first time, a detailed process for modifying the list of recognized compendia.[12] Within this process, CMS proposes a definition for compendia, desirable characteristics of a compendium, and the complete application process.[13] Sanofi-aventis appreciates CMS' detailed approach and urges the agency to maintain a great deal of flexibility in this process because compendia serve as a vital tool for both physicians and Medicare beneficiaries to access cutting-edge therapies. We also encourage the agency to reexamine the timeline of this process and shorten it wherever possible. Additionally, we believe that should CMS deny an application at the conclusion of the process, the agency should clearly articulate why and provide a roadmap for acceptance for the compendia to complete within 60 days. Sanofi-aventis does not believe that the rejected compendia needs to go through the entire process again as this will delay the ability for the compendia to be added, in turn hampering Medicare beneficiary access to state-of-the-art therapies.

Sanofi-aventis agrees with many of the specific characteristics that the MCAC and CMS recommend for compendia. Our research also revealed that practicing physicians would find value in a description of the evidence reviewed for every individual listing as well as a an understanding of the process each compendia uses in making its recommendation and recommend that CMS require these characteristics of each compendia. We also urge the agency to consider that each product has a FDA approved Product Insert (PI) containing detailed scientific and clinical information that need not be duplicated by any individual compendia, however. Rather, each compendium simply can provide a link to the FDA website that contains the PI simplifying and streamlining the presented information. The compendia should not be required to duplicate this information in an attempt to create a "one-stop" resource. A simple link will make available the information without overwhelming the presentation or requiring compendia to provide and update duplicative information. Further, this will allow the compendia to focus resources on meeting the other desirable characteristics presented. We urge CMS to meet with each of the compendia that have been subject to the MCAC process and have applied for recognition to establish the parameters for approval or conditional approval by the end of this year.

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12 72 Fed. Reg. at 38178.

13 *Id.*

II. Sanofi-aventis Urges CMS to Adopt Quality Reporting Requirements and Measurements That Are Scientifically Valid and Consensus Based [TRHCA—SECTION 101(b): PQRI]

As we understand it, CMS is interpreting section 1848(k)(2)(B)(i) of the Tax Relief and Health Care Act of 2006 to require that each quality reporting measure be both developed by a consensus-based process and adopted or endorsed by a consensus organization.[14] CMS further indicates that the statute requires the consensus organizations to consider at least some measures proposed by physicians or specialty organizations.[15] CMS proposes that the statute requires physicians or organizations that develop measures to obtain the endorsement of a consensus organization, such as National Quality Forum (NQF), the Ambulatory Care Quality Alliance (AQA), or another similarly consensus based organization that considers the viewpoints of a broad range of stakeholders (if such an organization exists), in order for the measure to qualify for consideration for inclusion in the PQRI measure set.[16] Sanofi-aventis supports these interpretations as foundational principles of the measure development and adoption process.

Consistent with these interpretations, CMS is proposing to include measures developed via the AMA-Physicians Consortium for Performance Improvement (PCPI) as well as measures under development by the American Podiatric Medical Association (APMA), provided such measures are endorsed by NQF or adopted by AQA prior to November 15, 2007.[17] Sanofi-aventis supports the inclusion of measures developed by specialty societies participating in PCPI or by individual specialty organizations like the APMA, subject to endorsement by NQF or AQA. We urge CMS to work with both the NQF and AQA or other consensus organizations that may exist or be created in order to ensure that they meet the standards necessary for consensus organizations and can continue to endorse or adopt measures for inclusion in the PQRI, as mandated by the statute.

III. CMS Should Set an Agenda and Prioritize Measure Development, Endorsement, and Periodic Revision for Diseases and Conditions of Importance to the Medicare Program [TRHCA—SECTION 101(b): PQRI]

Sanofi-aventis urges CMS to take a leadership role in developing an agenda for developing, adopting, and revising measures for its quality reporting programs in a manner that prioritizes conditions of importance to seniors. In order to implement its agenda, CMS should work with multiple organizations to ensure the development and endorsement of quality measures in an expeditious fashion. As part of this agenda, sanofi-aventis encourages CMS to periodically review and revise quality measures so that they remain current and reflect evolving clinical guidelines and standards.

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14 *Id.* at 38196-97.
15 *Id.* at 38197.
16 *Id.* at 38197-99.
17 72 Fed. Reg. at 38201-02.

A. CMS Should Update the Acute Myocardial Infarction (AMI) Measures

Sanofi-aventis encourages CMS to consider updating the AMI measures to reflect current scientific literature. In particular, the measure should require the administration of antiplatelet therapy (clopidogrel, aspirin) for patients with coronary artery diseases, as endorsed by the NQF and recommended by the American College of Cardiology and American Heart Association guidelines for unstable angina and Non-ST Elevation Myocardial Infarction.[18] Further, CMS should communicate its desire to update this measure, among others, to the measure developing and endorsing organizations as part of its measure development and update agenda for 2008.

B. CMS Should Revise the Hemoglobin A1c Control Standard

CMS also should consider revising the Hemoglobin A1c control standard for patients with Type I or Type II diabetes mellitus[19] to be consistent with clinical guidelines established by the American Diabetes Association (ADA). These guidelines, supported by a broad collection of public health experts and medical societies, recommend lowering A1c to less than seven percent for people with diabetes in order to reduce the microvascular and neuropathic complications of diabetes.[20] PQRI measure #1 only requires documentation of A1c more than nine percent.[21] In the proposed rule regarding the Hospital Outpatient Prospective Payment System for CY2008, CMS indicated that the Hemoglobin A1c >9.0 percent measure is "an intermediate outcome measure that has not been risk-adjusted," and proceeded to describe its rationale for selecting the diabetes outcome measure.[22] In PQRI, sanofi-aventis believes that the measure specifications should be modified to emphasize the current clinical guidelines, and we urge CMS to include revisions to this measure as part of its quality agenda for 2008 and beyond.

We acknowledge that, in the absence of an appropriate risk-adjustment, the nine percent measure is useful as an interim measure, but we believe that the measure could be better understood by physicians, consumers, and payers if it were rewritten as a positive goal to be achieved. In other words, rather than setting a target representing poor control (>9.0 percent), it might be easier for physicians, patients, and payers to monitor quality if the measure is rewritten to reflect good control (<7.0 percent). The NCQA Diabetes Physician Recognition program, for example, has diabetes recognition measures that set goals for the percentage of patients with

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18 NQF, National Voluntary Consensus Standards for Ambulatory Care: An Initial Physician-Focused Performance Measure Set at 10 (May 2006), available at http://www.qualityforum.org/; J. Anderson *et al.*, ACC/AHA 2007 Guidelines for the Management of Patients With Unstable Angina/Non–ST-Elevation Myocardial Infarction, J. Am. Coll. Cardiol. Vol. 50, No. 7, e45 (Aug. 14, 2007), available at http://content.onlinejacc.org/cgi/reprint/50/7/e1.

19 72 Fed. Reg. at 38199.

20 ADA, *Standards of Medical Care in Diabetes 2006*, Diabetes Care, 29:1 (Jan. 2006).

21 CMS, 2007 Physician Quality Reporting Initiative Specifications Document at 2 (June 18, 2007), available at http://www.cms.hhs.gov/apps/ama/license.asp?file=/PQRI/downloads/Measure_Specifications_061807.pdf.

22 72 Fed. Reg. 42628, 42800-01 (Aug. 2, 2007)

good control (A1c <7.0 percent) and those with poor control (A1c >9.0 percent).[23] We believe acceptance of the 7.0 percent threshold by NCQA and its inclusion in HEDIS suggests the measure should be considered for endorsement by NQF or AQA. By stating the measure as a positive goal, CMS also would improve the consistency of the diabetes measures. The other two diabetes measures, which consider blood pressure and low density lipoprotein control, both consider the percentage of patients that achieve a threshold level representing good control of the indicator at issue. Thus, although all three measures for diabetes establish targets for the percentage of patients achieving a certain level of control, they are inconsistent because for one a lower percentage of patients meeting the threshold standard is a good outcome, whereas the opposite will be true for the other two measures. More specifically, for the A1c measure, a lower percentage of patients meeting the target level of control is better because the threshold is for poor control of A1c. This differs from the aim of the other two measures, for which a higher percentage of patients meeting the target level of control is preferable because the threshold is for good control of blood pressure or cholesterol. If the A1c measure can be rewritten to focus on good control of A1c, this problem can be eliminated and physicians and patients will be able to more easily assess when they are meeting the threshold for good control of the relevant health indicator. We encourage CMS to continue to work with measure developing and endorsing organizations to expeditiously review and update the measure to reflect current guidelines and improve the ease of its interpretation.

C. CMS Should Continue to Encourage the Development of PAD Measures

We applaud CMS for proposing to adopt a new measure ("Diabetic Foot and Ankle Care, Peripheral Arterial Disease: Ankle Brachial Index (ABI) Measurement") for PAD,[24] a silent disease that affects over 12 million people, including about 12 to 20 percent of individuals over the age of 65.[25] Once an individual develops PAD, that person is at high risk of developing coronary heart disease (CHD).[26] Early detection of PAD, however, can prevent devastating complications including heart attack, stroke, amputation, and death. Although diabetes is a risk factor for PAD, there are numerous other risk factors, including smoking, obesity, physical inactivity, high blood pressure, and high cholesterol.[27] We encourage CMS to continue to work with the APMA, NQF and AQA, and stakeholders such as the PAD Coalition, the American College of Cardiology, and the American Heart Association, to expand this measure beyond diabetes to address other relevant risk factors and cover all Medicare beneficiaries. If an

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[23] NCQA and ADA, Recognizing Physicians for Excellence in Diabetes Care, 3, available at http://web.ncqa.org/LinkClick.aspx?fileticket=JXm2ViUPgog%3d&tabid=139&mid=860&forcedownload=true.

[24] 72 Fed. Reg. at 38202.

[25] American Heart Association, Peripheral Artery Disease, available at http://www.americanheart.org/presenter.jhtml?identifier=3020242 (last visited Aug. 30, 2007).

[26] National Cholesterol Education Program, National Heart, Lung and Blood Institute, National Institutes of Health, Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), II-46 (2002), available at http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf (identifying PAD as a CHD risk equivalent).

[27] American Heart Association, PAD Risk Factors and Possible Complications, available at http://www.americanheart.org/presenter.jhtml?identifier=3020256 (last visited Aug. 30, 2007).

expanded measure cannot be included in the 2008 PQRI measures, we ask that CMS take the lead in developing a broader measure for 2009 and adopt the more narrow proposed measure for 2008.

D. CMS Should Include Additional VTE Measures in the PQRI Measure Set

Sanofi-aventis applauds CMS' proposal to continue to include PQRI measure #23, Perioperative Care: VTE Prophylaxis (When Indicated in All Patients) in 2008.[28] This measure complements the Surgical Care Improvement Measures (SCIP-VTE 1 and SCIP-VTE 2) adopted by CMS in the hospital inpatient reporting program that require hospitals to report on appropriate prophylaxis of surgical patients at risk for VTE in the hospital setting. The continued use of these measures for physicians and hospitals reporting quality data will help to improve quality of care for Medicare beneficiaries and reduce the risk of post-operative complications associated with VTE. VTE is an all-too-common risk for patients after surgery, but the risk can be mitigated through the administration of prophylactic treatment.

Like PAD, VTE disproportionately affects the elderly, including both surgical patients *and* patients who are hospitalized for acute illness. Sanofi-aventis urges CMS to take the lead in requesting that the measure developing and endorsing organizations prioritize the VTE measure set for prophylaxis of medical patients at risk for VTE. This measure set is included in the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) toolbox for hospitals and should be implemented in conjunction with corresponding measures for physicians.[29] This is consistent with NQF-endorsed safe practices that include:

- The evaluation of each patient upon admission, and regularly thereafter, for the risk of developing deep vein thrombosis (DVT)/VTE. Use clinically appropriate methods to prevent DVT/VTE.
- The use of dedicated anti-thrombotic (anti-coagulation) services that facilitate coordinated care management.[30]

For patients admitted to the hospital who are at risk of developing VTE, evaluation and appropriate prophylactic treatment can reduce the risk of this life-threatening and often fatal condition. Current CMS reporting initiatives only include measures for VTE prophylaxis in surgery patients. Sanofi-aventis believes CMS should expand the measures to include a measure for prophylactic treatment of medical patients at risk for VTE.

E. CMS Should Encourage the Development of Measures of Coordination of Care

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[28] 72 Fed. Reg. at 38200.

[29] Eight VTE measures are being pilot tested, and JCAHO hopes that the final VTE measures can move forward for approval and endorsement by NQF by 2008. JCAHO, National Consensus Standards for Prevention and Care of Venous Thromboembolism (May 7, 2007), available at http://www.jointcommission.org/PerformanceMeasurement/PerformanceMeasurement/VTE.htm.

[30] NQF, Safe Practices for Better Healthcare: A Consensus Report at VII, available at http://www.qualityforum.org/ (last visited June 7, 2007).

Finally, CMS should work with measure developing organizations and stakeholders, including groups such as the National Transitions of Care Coalition (NTOCC), to continue to include measures relating to care coordination in all of its the quality reporting programs, including the PQRI. The NTOCC is a coalition supported by sanofi-aventis that is dedicated to further care coordination via the development of appropriate tools, metrics, and policies. Patients frequently are transferred between care settings, such as between primary care and specialty physicians, different departments in the hospital, or multiple facilities. During these transitions, it can be difficult to ensure sufficient communication between providers or across care settings in order provide continuity of care to a patient and ease the burden borne by patients and their families with regard to follow-up care. CMS has begun to adopt measures that facilitate coordination among treating physicians (for example, PQRI measure #24 - Osteoporosis: Communication with the Physician Managing Ongoing Care Post Fracture and measure #46 – Medication Reconciliation).[31] We applaud CMS for adopting these reporting requirements and encourage CMS to work with the measure developing and endorsing organizations, and groups such as the NTOCC, to continue to develop measures and requirements that further care coordination.

NQF has identified care coordination as a "priority area." NQF has endorsed a standard definition of care coordination and a framework for measuring it, but to our knowledge has endorsed only one specific standard for care coordination.[32] We request that CMS encourage the development and endorsement of care coordination measures to address the areas that NQF has identified as essential, namely:[33]

- Medical home for each patient;
- Proactive plan of care and follow-up for each patient;
- Use of standardized, integrated information systems;
- Standardized data elements for patient's personal medication record;
- Standardized data elements for medication reconciliation; and
- Standardized care guidelines for transitions between care settings that include medication reconciliation and care plan and communication plan between medical team members, patients, and caregivers.

IV. Registries – CMS Should Establish a "Deeming" System for Physicians Participating in CVD Registries [TRHCA—SECTION 101(b): PQRI]

Sanofi-aventis applauds CMS for recognizing the value of establishing a simplified data system for sharing of data collected by registries.[34] As we have noted in our past comments on the Hospital Inpatient Prospective Payment System Reporting Hospital Quality Data for Annual

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31 72 Fed. Reg. at 38200.

32 NQF, *NQF-Endorsed™ Definition and Framework for Measuring Care Coordination* (May 2006).

33 *Id.*

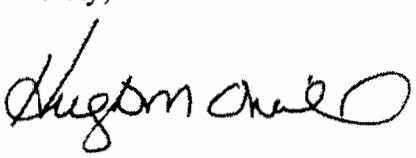
34 72 Fed. Reg. at 38203-04.

Update Payment Program, we believe that a deeming process that would allow for the streamlining of data collection would be beneficial. By accepting documentation from the registries as sufficient to meet reporting and performance requirements for PQRI, CMS could reduce duplicative reporting and receive access to a broader range of measures. Acute Coronary Syndrome (ACS) registries, such as the American College of Cardiology Foundation's National Cardiovascular Data Registry Acute Coronary Treatment and Intervention Outcomes Network (NCDR-ACTION), are voluntary quality improvement initiatives that track a number of outputs, both process and outcome based, and set standards for understanding treatment patterns, clinical outcomes, drug safety, and the overall quality of care provided for ACS patients. At least in the case of hospitals, there is evidence that quality improvements achieved by hospitals voluntarily participating in a heart registry are comparable to those of hospitals participating in the CMS pay-for-performance pilot program.[35] Such evidence suggests participation by providers in registries can be an effective quality improvement mechanism, and we believe CMS should encourage participation by physicians as well as hospitals in the registries. CMS should take advantage of extensive data collection already being carried out by the registries and encourage physician participation through development of a deeming process.

V. Conclusion

We thank you for your consideration of these comments on the Proposed Rule and hope we can continue to work with you to advance Medicare beneficiaries' access to high quality, state-of-the-art care. Again, we believe this goal can best be met by acting promptly on compendia applications that currently are pending such that additions may be made by the end of the year and by continuing to refine the PQRI measure set and program. Please contact me, or Saira Sultan, at 202-360-9985, if you have any questions on these comments. Thank you for your attention to these important issues.

Sincerely,



Hugh O'Neill
Vice President, Market Access and Business Development

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[35] S. Glickman, et al., *Pay for Performance, Quality of Care, and Outcomes in Acute Myocardial Infarction*, JAMA, 297: 21, 2373-2380 (2007).

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

Organization : **jerry miller**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Jerry Miller

Steve D. Israel

Submitter : **Miss. Jessica Shirk** **Date: 08/31/2007**

Organization : **Conestoga Valley School District**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam,

I am an athletic trainer who works in the high school setting. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

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

Sincerely,

Jessica Shirk, ATC

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

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 30, 2007

To Whom It May Concern:

I writing in regards to the current issue that physical therapy should not be apart of the in house ancillary service . I have been a PT for 5 years now and am more and more convinced that having physical therapy in a physician owned clinic is not in the best interest of the patient.

No matter how honest or how much integrity I have if I am running a practice myself and have ownership in a PT clinic more time than not the supervision of the care there will be abdicated to the PT. The PT then is put in a situation where the more patients he sees the more he money he makes. The almighty dollar is very tempting and when put in a busy situation with the potential to earn a lot of money your integrity is challenged every day.

Patients tend to get cookie cutter programs in those settings as well since there are so many patients the PT has to become more efficient so he tends to have the same program for all shoulders, the same program for all backs, and so on. This allows the PT to utilizes techs much easier and the patient therefore does not reccive the care needed or deserved.

So it making the decision to include or not include physical therapy as an in house ancillary service PLEASE DO NOT. For the profession of physical therapy and the improved care of patients physical therapy clinics need to be owned by people who cannot benefit from referring people there to ensure the decision is based on if it is medical necessary or not. Thank you.

Sincerely,

Adam Cope, PT

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

Organization : Associated Orthopedics of Detroit

Category : Other Health Care Professional

Issue Areas/Comments

Ambulance Services

Ambulance Services

Dear Sir or Madam:

I am a certified athletic trainer that has been working for and with hospital based physical therapy programs for the past 16 years. I have seen the benefits of having athletic trainers in the hospital based outpatient physical therapy settings first hand. Working hand in hand with physicians, physical therapists and secondary schools in completing an effective chain of assessment, referral and treatment of active people that become injured. Hospitals and health systems have enjoyed the benefits of having athletic trainers treat patients along side physical therapists and physicians and at the same time providing a valuable service to secondary schools, providing them with qualified health care providers to assess activity related injuries and make appropriate referrals. This team of health care providers working in hospitals has been utilized for many years. Not allowing athletic trainers to continue to provide quality rehabilitation services in the hospital setting would adversely affect the hospitals ability to continue to provide outreach services to secondary schools through injury assessments and appropriate treatment and referral. These service opportunities have been a valuable tool in keeping hospitals in contact with their surrounding communities.

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

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

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

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

Sincerely,

Joseph Cimino, A.T.,C.

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

Organization : **AthletiCo**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a Certified and Licensed Athletic Trainer working for AthletiCo in Chicago, Illinois. I am currently contracted by them to work with the Athletic Training/Sports Medicine Staff at Concordia University, Chicago. I have been nationally certified since early 2001 and received my degree in Athletic Training Education from New Mexico Stated University in December, 2000. My course load during college was consistantly at 15+ credits, including multiple anatomy, physiology, injury prevention/rehabilitation and theraputic modality courses. Since then, I have worked with all three levels of collegiate athletics, as well as in the high school and clinical setting. I also hold a Masters of Education in Applied Kinesiology from the University of Minnesota. Currently, I am completing my Performance Enhancement Specialization Certification through the National Academy of Sports Medicine.

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 proposcd rules will create additional lack of access to quality health care for my patients.

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Sincerely,

Kim Kistler, MEd., ATC, LAT

Submitter : **Ms. Charlene Schreiber** **Date: 08/31/2007**

Organization : **American Association of Nurse Anesthetists**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
Charlene Schreiber, CRNA_____
Name & Credential
_709 Martin Drive,
Address
_West Fargo,ND 58078-7110_____
City, State ZIP

Submitter : **Mrs. Deanna Balvitsch** **Date: 08/31/2007**

Organization : **AANA**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
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ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
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America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,

_____
Name & Credential
__Deanna Balvitsch CRNA_____
Address
__4217 Ashton Ct_____
City, State ZIP Fargo ND

Submitter : **Mr. Marc Sickel** **Date: 08/31/2007**

Organization : **Fitness for Health**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Marc Sickel. I founded a company called Fitness for Health. We work with children with special needs helping them with motor planning and visual spatial issues, and many other areas of motor development, as well as confidence building and self-esteem. By working with these children and young adolescents we give them the tools to help them navigate comfortably at school and outside the home, allowing them to participate in physical movement among others.

I have a B.S. Degree in Kinesiology and am a certified Athletic Trainer with over 20 years of experience in the field.

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

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

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 clients 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 clients. 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,

Marc Sickel, ATC
President, Fitness for Health

Submitter : **Dr. Courtney Burken** **Date: 08/31/2007**

Organization : **University of Mary Hardin Baylor**

Category : **Other Health Care Professional**

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam:

I am a certified athletic trainer who is also program director for an accredited athletic training education program. I have been a certified athletic trainer for 15 years, and have practiced in the college setting. As an athletic trainer, I am an allied health professional who is recognized by the American Medical Association to prevent, evaluate, treat, and rehabilitate the injuries of the physically active. I have obtained all the necessary credentials, including national certification as an athletic trainer and state Licensure in Texas and Kansas, as well as completing my masters and doctoral degrees.

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

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

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

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

Sincerely,

Dr. Courtney Burken, ATC. LAT, PhD

Submitter : **Dr. Bruce Levy** **Date: 08/31/2007**

Organization : **Mayo Clinic**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a sports medicine surgeon working at the Mayo Clinic in Rochester, MN.

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.
Athletic trainers are qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. Their education, clinical experience, and national certification exam ensure that their patients receive quality health care. State law and hospital medical professionals have deemed them 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,

Bruce A. Levy , M.D.

Submitter : **Mr. Kenneth Rude** **Date: 08/31/2007**

Organization : **Pine Plains Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I do not believe that the intention of the Stark exception to the referral-for-profit laws was to countenance the formation of regional health-care monopolies. The exceptions are wisely specified to exist for the convenienee of the patient. However, the exception as it is currently construed not only invites fraud and abuse of the Medicare system, it permits physicians to grab a controlling interest of an independent discipline. This practice weakens the health-care system, and it benefits only physicians, not their patients.

Circumstances in the mid-Hudson Valley well illustrate the consequences: choice of a provider becomes no longer the discretion of the patient, but of the self-interested physician. And rural health care is threatened as services are gobbled up by a centralized vertical monopoly.

I strongly urge that you amend the Stark laws to eliminate the incentive of physicians to refer to clinics which they own, and to restore strength, diversity and integrity to the relationship between physical therapists and prescribing physicians.

I stand squarely with the American Physical Therapy Association and call for the removal of physical therapy as a designated health service permissible under the in-office ancillary exception to the physician self-referral laws. I thank you for your consideration of this letter, and I trust you will always be guided by sound judgment.

Sincerely,
Ken Rude, PT
Pine Plains Physical Therapy

Submitter : **Mr. Matthew Anderson** **Date: 08/31/2007**

Organization : **Minnesota Hospital Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14542-Attach-1.PDF

Minnesota Hospital Association

2550 University Ave. W., Suite 350-S
St. Paul, MN 55114-1900
phone: (651) 641-1121; fax: (651) 659-1477
toll-free: (800) 462-5393; www.mnhospitals.org

August 31, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1385-P, Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; 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 (Vol. 72, No. 133), July 12, 2007.

Dear Mr. Kuhn:

On behalf of our 145 Minnesota hospital members, the Minnesota Hospital Association (MHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed changes to regulations regarding prohibited physician self-referrals.

MHA supports CMS' efforts to modernize how federal laws manage potential physician conflicts of interest. The physician self-referral law's underlying intent to avoid conflicts of interest remains an important goal in today's health care environment. The ultimate regulations must also accommodate certain necessary and beneficial collaborations between hospitals and physicians that serve the public interest. MHA hopes that CMS will not promulgate regulations that have the unintended consequence of impeding hospitals' ability to work together with physicians by using appropriate incentives to improve quality, patient safety and community access to services. **We urge CMS to view the application of physician self-referral prohibitions as a means to appropriately encourage care improvement initiatives that benefit patients, hospitals and physicians, as well as a way to control and prevent abusive behavior.**

PHYSICIAN SELF-REFERRAL PROVISIONS

High-quality hospital care depends upon hospital leaders, physicians, nurses and other care providers working together to best ensure that patients get the right care, at the right time, in the right setting. This need for collaboration is intrinsic in virtually every health care quality improvement or cost reduction initiative.

Federal laws that affect hospital-physician relationships should be applied in a manner that recognizes and facilitates care-improvement initiatives that would benefit patients, hospitals and physicians. They should allow and encourage hospitals and physicians to come together, using incentives where appropriate, to not only reduce costs, but also improve access and the efficiency, quality and safety of hospital care. Therefore, regulations should not impede hospital-physician incentive arrangements designed to improve or maintain community access to services, or to make health care safe, effective and efficient.

Specifically, the MHA believes the self-referral rules should foster hospital-physician incentive arrangements that are designed to:

- Achieve needed improvements in the health care delivery system, even if they do not produce an immediate cost savings.
- Sustain community access to services that are essential. With physicians less dependent on hospitals as a place to practice, new relationships, including financial relationships, should be allowed in order to maintain community access to services (such as trauma and emergency department services), support community outreach efforts, care for the uninsured and other aspects of hospital operations that require physician support.
- Promote the integration of clinical care across providers, across settings and over time. As more purchasers move toward pay-for-performance methods, the need to align hospital and physician payment incentives becomes critical for quality improvement.
- Enhance institutional or practitioner productivity or achieve other efficiencies.

The MHA urges CMS to reconsider its proposed changes to achieve the goals of the self-referral laws while allowing for the further development of evidence-based, patient-centered, and systems-oriented care delivery.

Our specific concerns and comments on this proposed rule follow three over-arching themes:

1. The percentage-based compensation proposal would hinder efforts to achieve clinical integration and coordination.
2. The proposals do not adequately facilitate the coordination and cooperation needed to serve certain communities, especially in rural areas.
3. The proposed expansion of the exception for subsidizing obstetrical (OB) malpractice insurance is too narrow.

1.) THE PERCENTAGE-BASED COMPENSATION PROPOSAL WOULD WORK AGAINST ACHIEVING CLINICAL INTEGRATION AND COORDINATION.

The proposal to limit percentage-based compensation solely to "revenue directly resulting from personally performed physician services" is too limiting and fails to account for the important, legitimate role financial incentives play in efforts to improve health care.

Percentage-based payments should be permitted for certain types of arrangements when (1) they are designed to achieve an acceptable purpose; (2) there are mechanisms in place to protect the quality of care and avoid inappropriate influence on physician referrals; and (3) the incentive arrangements are transparent to patients. Examples of arrangements that should be permitted include:

- sharing of cost savings resulting from efficiencies;
- incentives to meet quality indicators (even when savings may not accrue to the hospital);
- incentives to clinically integrate services and coordinate care across settings;
- sharing of pay-for-performance bonuses from payers;
- service contracts to build new service capacities; and
- management contracts.

These arrangements can improve care and, while they might not yield measurable savings to a hospital, they can yield savings to the health care system overall.

As proposed, the change in regulation is too limiting and out of sync with the relationships that need to evolve to meet the public policy goals for health care delivery. To improve health care delivery and adapt to the use of financial incentives by public and private payers, the integrated care delivery model relies on some level of sharing revenue in appropriate ways as a mechanism to encourage appropriate behavior and best practices. The proposed regulation will frustrate these efforts if the only factor that may be taken into account is physician-performed services.

Because the self-referral law requires strict compliance with limited exceptions, CMS should not limit appropriate innovations designed to achieve safe, effective and efficient care.

2.) THE PROPOSALS DO NOT ADEQUATELY FACILITATE THE COORDINATION AND COOPERATION NEEDED TO SERVE COMMUNITIES, ESPECIALLY IN RURAL AREAS.

MHA supports narrowing the in-office ancillary services exception to cover only those services "necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office." The current expansive use of the exception has led to the duplication of services and technology and, as reported by the Medicare Payment Advisory Commission (MedPAC), to over-utilization, higher expenses and unnecessary procedures for patients. In today's environment, overuse of the in-office ancillary exception is one of the many forces driving hospitals and physicians apart and hindering efforts to improve health care.

Narrowing the in-office exception is a good beginning, but it does not adequately address the access issues created for MHA's members of rural communities. **The rules for the "rural provider" exception also should be revised.** As currently applied, the exception can be used without regard to whether there is an unmet need in the community or if there will be

Submitter : **Mr. fred prendergass ms, crna** **Date: 08/31/2007**

Organization : **anesthesia asoc., jersey city, nj**

Category : **Hospital**

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 Revicw)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has rccognized 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 cnsure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Ms. Mary Patton** **Date: 08/31/2007**

Organization : **Association of American Medical Colleges**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14545-Attach-1.DOC

14545

August 31, 2007

Association of
American Medical Colleges
2450 N Street, N.W., Washington, D.C. 20037-1127
T 202 828 0400 **F** 202 828 1125
www.aamc.org

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue
Washington, DC 20201

Dear Mr. Kuhn:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the proposed rule "Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008". The Association of American Medical Colleges represents all 125 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems and 94 academic and scientific societies. Through these institutions and organizations, the AAMC represents 109,000 faculty members, 67,000 medical students, and 104,000 resident physicians.

Of the 109,000 faculty members, nearly 97,000 are full-time clinical faculty associated with the nation's medical schools and their group practices. These faculty members provide a variety of services, including primary, subspecialty, and tertiary level care, to Medicare and other patients. On a national basis Medicare is nearly one quarter (24.9%) of the total practice plan payer mix and Medicaid represents 16.6% of the total payer mix. Thus, many practice plans have a combined payer mix of greater than 40% for these two public payers and also serve many of the dually eligible Medicare-Medicaid beneficiaries. On behalf of its members, AAMC is keenly interested in the impact of the Medicare program on practicing physicians.

Updates to the Physician Fee Schedule

Several items discussed in the proposed rule will have negative financial consequences for physicians and practice plans. These include the mandated 9.9% decrease to the conversion factor (CF), an increase to the budget neutrality factor (BNF) for work relative value units (RVUs); and changes to the Geographic Price Cost Indices (GPCIs).

Impact (p. 38211)

AAMC and the physician community have long commented on the negative impacts of the Sustainable Growth Rate (SGR) and are concerned that, if not resolved, patient access to care

will deteriorate. The nearly 10% decrease to the conversion factor comes at a time when inflation costs, as measured by the Medicare Economic Index (MEI), are expected to grow by 1.9%. Many academic medical centers (AMCs) and their faculty serve as safety net providers in their communities and are committed to providing the best possible care to Medicare beneficiaries. However, the current proposed payment reduction has the potential to weaken their financial stability.

In 2007, CMS completed the statutorily required comprehensive five-year work RVU review. AAMC applauds CMS for appropriately recognizing and valuing the work effort for services such as anesthesia. However, the AAMC is concerned that under the current Sustainable Growth Rate (SGR) Part B payment methodology, increases in payments for specified services automatically decreases payments for other services. Because CMS is required to maintain budget neutrality, the total increase in work RVUs due to the five-year review led to an overall adjustment in payment. In the 2007 rule, CMS instituted a 10.1% budget neutrality factor to deflate the work RVUs for payment purposes. For 2008, CMS proposes to increase the BNF to 11.8%, an increase of 1.7% from the 2007 rate. The change in the BNF makes it increasingly more difficult for specialties, or practice plans as a whole, to accurately project and budget for future payments.

Geographic Practice Cost Indices (GPCIs) (p. 38137)

Changes to the geographic price cost index will add to the financial stress of some practice plans. The Medicare Improvements and Extension Act of 2006, as part of the Tax Relief and Health Care Act of 2006, extended a floor for work GPCIs to the end of 2007. The floor, set at 1.0, is due to expire in 2008. An analysis of 77 practice plans identified that removal of the work GPCI floor will negatively impact over half of these practice plans (41 practice plans or 53%). One midwestern practice plan estimates that removing the 1.0 floor for work GPCIs will further decrease their Medicare revenues by an additional 0.8%. When the GPCI change is considered with the other proposed changes, this practice plan projects a revenue decrease of $2.8 million compared to payments received for providing the same services in 2007.

The AAMC conducted a preliminary analysis of the impact of the proposed fee schedule on fifty faculty practice plans. Medicare billing data for the most recent twelve months for all departments, excluding anesthesiology were analyzed (complete Anesthesiology data were not available). Forty-seven of the fifty practice plans (94%) are projected to experience decreases greater than the nearly 10% national decrease projected by CMS, and twenty practice plans (40%) are expected to experience decreases greater than 12%.

AAMC appreciates that CMS does not have the authority to change statute; however, we strongly encourage CMS to reconsider all options within its administrative authority to mitigate the effects of the SGR changes on the physicians' practices. We also request that CMS work collaboratively with Congress so that issues such as the SGR and GPCI floor may be addressed legislatively.

Physician Self-Referral Provisions

Obstetrical malpractice insurance subsidies (p. 38182)

In the discussion in the preamble, it is stated that "we are concerned that our exception for obstetrical malpractice insurance subsidies is unnecessarily restrictive." The AAMC agrees, and requests that CMS considers proposing a further change in this exception to allow subsidies for malpractice insurance for other specialties and in broader geographic areas. Given growing concern that the number of physicians will not be adequate in the coming years, it may be particularly important for hospitals to provide assistance with malpractice insurance in a way that will not be subject to abuse. To attain this goal, CMS could expand the exception and impose a new requirement—similar to that involving the donation of electronic health records to physicians—that physicians must pay a certain percentage of the premium to qualify for this exception.

Set in advance (p. 38184)

The AAMC asks CMS to clarify that the proposed revision to the "set in advance" requirement would not affect compensation arrangements that include patient satisfaction survey results, pay for performance (P4P) measures, or that take into account faculty contributions made through teaching and research. AAMC considers that these compensation criteria are based on personally performed services. In addition, the latter two criteria support missions that are recognized in the academic medical center exception. We understand that there can be no link between the compensation paid under these arrangements and the volume or value of referrals. In recent years AAMC has been encouraged by CMS's apparent recognition that in the realm of hospital-physician relationships it is important that there be sufficient flexibility to allow parties to appropriately align incentives without fear of violating fraud and abuse laws. We believe that this further clarification will be helpful in maintaining flexibility without incurring the risk of program abuse.

Thank you in advance for consideration of our comments. Please contact Ms. Denise Dodero at 202-828-0568 or ddodero@aamc.org.

Sincerely,

Robert M. Dickler
Senior Vice President
Division of Health Care Affairs

Cc: Darrell G. Kirch, M.D., President
Richard M. Knapp, Ph.D., Executive Vice President
Denise E. Dodero, Associate Vice President

Submitter : Ms. Mary Jo Carden **Date:** 08/31/2007

Organization : Transplant Pharmacy Coalition

Category : Health Care Professional or Association

Issue Areas/Comments

ASP Issues

ASP Issues

The Transplant Pharmacy Coalition submits comments in regard to the Medicare Part B supplying fee for immunosuppressant agents. This issue is related to the ASP payment for outpatient drugs and biologicals. Please see attached documents for comments and background information.

CMS-1385-P-14546-Attach-1.PDF

CMS-1385-P-14546-Attach-2.DOC

CMS-1385-P-14546-Attach-3.DOC

CMS-1385-P-14546-Attach-4.DOC

CMS-1385-P-14546-Attach-5.PDF

CMS-1385-P-14546-Attach-6.DOC

CMS-1385-P-14546-Attach-7.PDF

CMS-1385-P-14546-Attach-8.DOC

CMS-1385-P-14546-Attach-9.DOC

#14546 - #1

Transplant Pharmacy Coalition

August 31, 2007

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

Re: **CMS-1385-P, Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, *et al.***

I Introduction

The Transplant Pharmacy Coalition (TPC) is pleased to provide comments on 42 CFR Part 409 *et al.* TPC's comments focus on the pharmacy supply fee for Medicare Part B immunosuppressant drugs. TPC understands that the proposed rule does not contain a specific reference to an update to the pharmacy supply fee; however, as described in *Section II* below, we believe that CMS has the regulatory authority to provide this update under a "logical outgrowth" rationale. Despite increases in Medicare administrative burdens, the supply fee has been negatively adjusted to a two-tiered rate, $24 for the first prescription and $16 for each subsequent prescription in a 30-day period, since its inception in 2005.

Recognition of the services of specialty transplant pharmacies through a supply fee increase is consistent with recent efforts by CMS to establish separate service payments for pharmacists under the Medicare Part D program and other initiatives, including pay-for-performance, that encourage payment to providers that improve outcomes. TPC understands that CMS presently has only the supplying fee to compensate pharmacies for the billing services provided to patients with Medicare Part B. Therefore, until such time as other programs are developed, CMS should continue to recognize the services of specialty transplant pharmacies and increase the supplying fee appropriately.

TPC is willing to work with CMS to establish appropriate pay for performance systems for pharmacies that demonstrate positive outcomes for transplant patients. TPC has conducted an adherence and compliance study assessing medication possession rates for patients from five TPC member companies compared to medication possession rates recorded in the general literature. The general literature confirms an adherence rate of approximately 65% compared to TPC members that demonstrated an 84.2% adherence rate. The study then correlated the literature-based findings with potential costs savings and found that the increase in adherence would result in nearly $4,150 in annual costs savings per patient. This study is described further in *Section V* below and is attached as *Appendix 3*. TPC is willing to supplement the literature-based findings a step further by working with CMS to establish a statistical, patient-based study examining the potential for the success of pay for performance initiatives. TPC believes this effort will result in decreased medical and related costs for the government and improved outcomes for individuals who receive transplants.

In these comments, TPC provides an analysis of the cost to supply immunosuppressants to individuals with Medicare Part B coverage. An independent analysis conducted by the Lewin Group finds that the cost to supply *each* Medicare Part B immunosuppressant prescription is $30.73. An analysis of the Lewin Group report findings is found in *Section III* and attached as *Appendix 2* of these comments. The Lewin Group calculation of the supply fee rate is well above the current monthly reimbursement of $24 for the first immunosuppressant and $16 for each subsequent prescription provided in a 30-day period.

The current supply fee produces a financial loss for transplant pharmacies on each prescription supplied. CMS developed the tiered supply fee for immunosuppressants assuming some economies of scale would occur after the patient's initial prescription in a month. TPC's analysis and actual experience with the supply fee show that the economies of scale thought to occur after the initial prescription are insignificant. The cost analysis submitted to CMS by TPC was based on the average costs of prescriptions per month. These costs were analyzed considering all of the billing issues associated with Medicare Part B claims. This means that the costs associated with resubmission of denied claims and the denial rationale must also be considered. Furthermore, a tiered supply fee structure has resulted in an impractical approach to paying for Medicare Part B claims. This tiered fee structure has created additional burdens upon both pharmacy providers and the DME MACs and thus should be eliminated. In *Section IV* of these comments, TPC provides an overview of the unique services provided by specialty transplant pharmacies; the Medicare billing process for immunosuppressants; an analysis of the rationale for multiple claims billed in the same month, and the process associated with claim denials. To illustrate costs associated with Medicare billing and claims rejection, TPC uses publicly available salary information for pharmacists and pharmacy billing personnel and technicians to support this information.

In *Section VI* of these comments, TPC provides an overview of the state of ASP and the continued underpayment to pharmacies using the ASP methodology. TPC is particularly concerned about CMS' efforts to require reimbursement at average manufacturer prices (AMP) or widely available market price (WAMP) plus 3% when ASP is 5% or more above these benchmarks. TPC does not believe that these pricing methodologies can appropriately capture the true costs associated with pharmacy's acquisition prices for Part B pharmaceuticals.

TPC is a coalition of seven specialty transplant pharmacies that are both independently owned and public companies. The members of the coalition are Amber Pharmacy (Omaha, NE); Echo Drugs (Flushing, NY); F&M Specialty Pharmacy (New Orleans, LA); PharmaCare, Inc (Lincoln, RI); Skyemed Pharmacy (Pompano Beach, FL); Transcript Pharmacy (Jackson, MS); and Two Thousand Ten (2010) Pharmacy (Los Angeles, CA). Contact information for each of these pharmacies is found in *Appendix I*. These companies supply immunosuppressant medications and associated, necessary pharmacy services to approximately 35% of all US organ transplant recipients and approximately 40% of Medicare Part B beneficiaries who have received an organ transplant.

TPC would like to thank representatives from the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) for their willingness to address our concerns regarding the pharmacy supply fee and ASP for immunosuppressant medications.

II. Updating the Supply Fee is a Logical Outgrowth of the Proposed Rule

Despite lack of specific language in the proposal, TPC believes that CMS may update the supply fee using a logical outgrowth rationale based on context of the proposal. TPC provides the basis for the logical outgrowth rationale below.

CMS language from proposed rule summary: "We are proposing these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services." [1]

TPC rationale for logical outgrowth: the current tiered supply fee does not reflect changes in medical (pharmacy) practice consistent with the purpose of the rule. CMS first implemented the supply fee in 2005. Since then, despite increases in costs to bill Medicare Part B, the supply fee has not been updated to reflect the current value of services as consistent with the spirit of this rule. Therefore, the fee should be updated to reflect the current costs.

CMS language from summary: "This proposed rule also discusses. . . payment for covered outpatient drugs and biologicals;" [2]

TPC rationale for logical outgrowth: payment for outpatient covered drugs includes the pharmacy supply fee as a critical component of Medicare Part B drug coverage. No current mechanism exists to recognize payment to pharmacists and pharmacies as separate from the drug payment; therefore, it logically follows that the supply fee is included in this provision.

CMS language from preamble: Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations. Information on the regulation's impact appears throughout the preamble and is not exclusively in section VI.[3]

TPC rationale for logical outgrowth: HHS has the discretion to modify the supplying fee as indicated in the MMA.[4] The preamble indicates that the proposed rule includes information regarding payment for outpatient drugs and biologicals. As suggested above, the supply fee is included in this discussion.

CMS language from Section VI. Regulatory Impact Analysis; T. Impact on Beneficiaries We do not believe that beneficiaries will experience drug access issues as a result of the proposed changes with respect to Part B drugs and CAP.[5]

TPC rationale for logical outgrowth: While CMS has not proposed any changes to the supplying fee, TPC and others can rationally conclude that without an increase in the supply fee, some pharmacies, particularly those considered small businesses might not be able to continue to provide some Medicare Part B beneficiaries with immunosuppressant agents. While the transplant market is relatively small compared to other markets, the need for pharmacies to serve individuals with transplants is necessary to ensure access to vial medications that necessary to sustain transplanted organs. Therefore, CMS should increase the supply fee for 2008. TPC believes that this can be achieved in a manner that has no little impact on other provisions in this rule.

In summary, TPC believes that CMS has the authority to increase the supply fee based upon its intent to ensure that its payment rate reflects current market practices, including payments for drugs and biologicals to which the supply fee is inextricably intertwined. As these comments and TPC's data demonstrate, the current tiered supplying fee does not adequately reflect the current practice rates for supplying Medicare Part B immunosuppressants.

III. ANALYSIS OF THE FINDINGS OF THE 2007 LEWIN GROUP REPORT

With the encouragement of CMS staff, in early 2007 TPC commissioned the Lewin Group to update a 2004 study examining the cost of supplying Medicare Part B immunosuppressant agents. A full copy of the study, *Assessing the cost of Dispensing Immunosuppressive Drugs to Medicare Transplant Recipients-An Update*, is attached in *Appendix 2*. The Lewin Group is a national health care and human services consulting firm with extensive experience in providing data verification and information to the federal government. The 2007 Lewin Group report finds that an appropriate supply fee for Part B immunosuppressant billing is $30.73. CMS staff has acknowledged that the Lewin Group report and other information provided by TPC represent the primary source of data submitted in regard to the supply fee. Therefore, CMS should use the Lewin Group report and the further analysis of supply fee costs provided in these comments as a basis of an increase for 2008.

A. Lewin Group Report: Results and Findings in Brief

The Lewin Group surveyed TPC members using a "top down" perspective to identify costs associated with providing immunosuppressant pharmacy services. Based on this survey, The Lewin Group report offers the following findings:

- Billing and administrative costs for Medicare Part B claims are significantly greater and more labor intensive than for adjudicated claims under Medicare Part D and other private third party payers.
- Specialty transplant pharmacies also provide assistance to Medicare beneficiaries in finding programs to reduce the economic burden associated with transplant medication costs.
- Specialty transplant pharmacies routinely stock immunosuppressant medications. Immunosuppressants are costly for pharmacies to acquire and maintain in inventory. TPC member pharmacies fill more than 30,000 prescriptions per month for immunosuppressants alone. Given the volume of dispensing, specialty transplant pharmacies must maintain regular stock of immunosuppressant medications. In contrast, retail chain pharmacies and large mail-order PBMs often do not supply immunosuppressants at the same level as specialty transplant pharmacies. Considering costs to maintain an inventory of these medications and the low dispensing volume, patients cannot be assured that retail community pharmacies or large mail-order PBMs will have medications in stock to suit their needs.

B. The Lewin Group Report: Process and Survey Instrument

To conduct its survey, the Lewin Group collected individual cost accounting data from each TPC member pharmacy. These data were allocated to each pharmacy's Medicare Part B transplant business figures using a "top down" approach. The cost categories defined in the survey instrument included the number of Medicare and non-Medicare prescriptions filled by pharmacies; the cost of goods sold; pharmacy supply costs; inventory and overhead costs; cost of processing Medicare claims; and Medicare bad debt and collection costs.

The analysis divided certain costs into further component parts including cost of including pharmacy personnel, shipping, rent, administrative overhead, and rent. The analysis also included Medicare bad debt that included co-payments never paid and collection costs. While individual cost categories might not be Medicare-billable expenses, collectively these components are unavoidable costs of doing business with the program and represent the reality confronted by the supplier community.

This analysis by the Lewin Group represents the traditional methodology for capturing costs and transactions associated with pharmacy billing. In most cases, pharmacy dispensing surveys use this data set to quantify costs associated with dispensing on a per prescription basis. However, to similarly quantify the supply fee, all of the costs associated with pharmacy billing and providing Part B medications must be considered. The Lewin Group report, described in *Section IV* below accounted for all the billing issues based on the average of supply costs associated with all prescriptions—new and refills.

IV. Overview of Specialty Transplant Pharmacy Services, Medicare Part B Billing for Immunosuppressant Agents and TPC Recommendations for the 2008 Supplying Fee

A. Services of Specialty Transplant Pharmacies

TPC members provide services to individuals who have received solid organ transplants. These services are in addition to those provided by traditional large, PBM based mail-order pharmacies and community pharmacies. Specialty transplant pharmacies ship transplant medications, provide patient educational services, but also provide Medicare Part B billing services to individuals. In 2006, the National Association of Chain Drug Stores (NACDS) conducted an analysis that defined the characteristics of specialty pharmacy services.[6] Some of these characteristics and the relationship to transplant patients and pharmacy services provided are defined below:

- **Compliance management:** TPC members provide these patient-specific services on a regular basis. Pharmacists employed by a specialty transplant pharmacy regularly communicate through phone calls to individual patients. In some cases, patients have direct access to pharmacists through store front locations owned by TPC members. Whether patients receive information from a central pharmacy via telephone or in person, TPC members have shown that the services that they provide through call centers and compliance management programs improve outcomes for transplant patients. *Section V* below describes in greater detail the relationship of these services to patient outcomes.
- **Frequent dosage adjustments**: transplant patients often require adjustments to immunosuppressant regimens over several months prior to reaching the appropriate dosage. TPC members monitor these adjustments and the need for these adjustments in conjunction with the individual's care team including the physician, transplant coordinator, transplant nurse and social worker.
- **More severe side effects than traditional drugs**: immunosuppressant medications given in too large doses can cause systemic infections requiring hospitalizations and weeks or months of infused antibiotic agents or other treatments. Inadequate dosing may cause a person to experience acute or permanent rejection with the need for retransplantation or other more costly interventions such as dialysis in the case of kidney transplant patients.
- **Special storage, handling, or administration**: While these medications are generally oral solids, most are very costly medications that are not regularly stocked by all pharmacies. In many cases traditional pharmacies require patients to call in advance for a new or refill prescription. TPC members regularly stock these medications and manage inventory based on patient's renewal dates. The value of ensuring a supply of medications from a pharmacy cannot be underestimated for these patients. Many of these individuals take

multiple dosages many times a day. This is unnecessarily complicated if they are unable to obtain an entire supply of the immunosuppressant medications from the pharmacy.

In addition to the services described above, TPC members also bill Medicare Part B on behalf of transplant patients. This service is invaluable to individuals with Medicare and cannot be underestimated. Even if a traditional large mail-order pharmacy were to focus on transplant patients, Medicare Part B billing would add to the cost of the transaction. These billing services are described below.

B. Description of Medicare Part B Billing Services

Transplant patients receive their initial monthly supply of 3-5 medications and then in nearly 75%- 85% of cases the orders are changed at least once during the first month and beyond. Many are changed several times within the first few months and therefore, multiple filling dates exist for each patient. As a result, many patients may have 3-4 claims in a month. To improve administrative efficiencies for both the Medicare Part B program and to attempt to receive appropriate payment in a timely manner, pharmacies typically bill several claims in a one-month time frame for each patient. These billing processes are costly and in many cases require re-verification of information for patients experiencing changes to their Medicare billing status. In many cases, a patient's Medicare billing status might be questionable for a period of time and therefore, re-verification is necessary on multiple occasions. This often occurs if a patient who is not yet eligible for the full Medicare benefit but is eligible for Medicare Part B as a primary for a 36-month period because of a kidney transplant after a diagnosis of ESRD. After the 36-month period, Medicare Part B pays as a secondary payer unless a patient subsequently becomes permanently disabled or turns 65 making them eligible for the full Medicare Part B benefit. Other changes in status include interim hospitalizations or admissions to nursing homes.

Unlike claims submitted to Medicare Part D and other third party payers, Medicare Part B claims do not rely solely on computer systems to process claims. These claims often require 1-3 of a pharmacy's billing personnel or perhaps even pharmacists to process a claim. The billing process alone may take between 15 minutes for a claim with no change to 1 hour for a patient who with changes to their Medicare Part B billing status. The reasons for the lengthy billing processes include the need to re-submit paperwork and other questions that often arise from a DME MAC. These costs are in addition to the pharmacist's and technician time to fill a prescription.

According to a recent cost to dispense study commissioned by the National Community Pharmacists Association and NACDS, pharmacists reported that it takes approximately 12.5 minutes to fill a single Medicare Part D prescription.[7] According to TPC members, the time to fill a single new Part B prescription often takes an additional 25 minutes because of the specificity required by the Medicare Part B program, including physician signature. While refills take less time, many

Part B prescriptions are not refilled in the manner traditionally considered a refill by third parties and other payers. This is because any change to a prescription requires a new prescription and the pharmacists must complete the process of obtaining a new prescription again. Even if a refill is processed with no changes to the prescription order, the medication must be filled (either directly by a pharmacist or assisted by a technician) and then checked directly by a pharmacist.

Publicly available data from the Bureau of Labor Statistics (BLS) website provides information regarding pharmacists and technicians salaries from 2004 and 2005.[8] This information, along with averages from TPC members, provides another calculation for the costs associated with filling and billing for a Medicare Part B claim. According to BLS, in 2005, the median pharmacist hourly wage was $44.23. This is consistent with TPC member reports. According to the BLS website, in 2004, technicians earned a median of $11.37 per hour. TPC members report that technicians earn a slightly higher rate in their pharmacies because they often have a greater knowledge and understanding of transplant patients. TPC members pay technicians approximately $12-$20 per hour (average of $16). Furthermore, TPC members also must employ billing personnel who must understand the complexities of Medicare Part B billing. These billing personnel are paid between $12-$30 (average of $21 per hour.)

Using these numbers alone, the cost to supply a Medicare Part B medication is as follows:

Pharmacist time: $22
Technician time: $8
Billing personnel time (based on a ½ hour claims processing time):$11

Total projected cost using this methodology is $41, greater than the Lewin Group number because as described above, these costs were averaged across all prescriptions. The figures above represents averages rather than the actual costs that the Lewin Group collected from TPC member companies. In both analyses, the current supply fee structure does not accurately compensate pharmacies for supplying Part B medications.

The primary reason for the costs associated with the expense of Medicare Part B billing is that it continues to be a manual process requiring human interaction by both the pharmacy and the DME MACs. This system is much different than other prescription billing systems that are highly automated and process claims electronically. The Part B system also creates issues related to rejections and the need for resubmissions. Pharmacy billing personnel often find it difficult to communicate directly with DME MACs and claims are often left unresolved for weeks or months—even after a patient has received their medications. These issues place additional costs on the system.

Furthermore, the ASP reimbursement rate is much lower than payments from other third party payers. Therefore, if billing issues arise under these other programs, the staff time labor costs associated with resolution can be partially subsidized with the margins on the drug product reimbursement.

Problems and rejections often occur in 30-50% of cases and must be fully resolved. These problems are described in "C" and then quantified in a similar manner as those above in "D" below.

C. Common Medicare Part B Billing Problems that Add Costs to Medicare Part B

Over the past three years, CMS eliminated several billing procedures, including the assignment of benefits form (AoB) and DMERC information form (DIF). CMS intended for these changes to reduce some of the Medicare claims processing costs identified by the Lewin Group studies in 2004 and 2007, *Assessing the Cost of Dispensing Immunosuppressive Drugs to Medicare Transplant Recipients*. In 2006, CMS then negatively adjusted the supplying fee from $24 per prescription supplied to $24 for the first prescription to $16 for each subsequent prescription. However, TPC members have not experienced a proportional decrease in billing costs. Medicare Part B billing continues to be a labor-intensive process requiring a great amount of specialized staff within pharmacies. The reasons for this are described below.

DME MAC regions often interpret Medicare Part B payment policies inconsistently. Education and insight by pharmacy personnel is necessary on a regular basis to communicate the information to representatives at the DME MACs. Turnover of personnel and recent changes to contractors also contribute to billing problems attributed to DME MACs. This communication and education process consumes much pharmacy staff time on a regular basis.

Nearly three years after implementation of the Medicare supply fee, many DME MACs reject initial claims for the supply fee. Immunosuppressant claims are often rejected because of administrative errors caused by the DME MACs during processing. These claims must then be reconciled between pharmacy billing personnel and the DME MACs. The pharmacies must employ additional personnel to handle the extra burden of preparing Part B claims for submission to the DME MACs. Pharmacies must also contract with outside billing entities that facilitate computer communications between the pharmacy and DME MAC and convert the pharmacy claim into the acceptable transaction standard, the X12N 837. In comparison to the amount paid for an adjudicated claim, the costs to transmit Medicare Part B claims are approximately 10 times greater.

A traditional adjudicated third party prescription or Medicare Part D claim will have significantly less administrative tasks regarding its submission for payment. For third party claims, a pharmacy's billing department is not involved in the transmission of each claim submitted. Rather, the billing department functions to reconcile claims from each plan on a regular basis. However, because of the need to submit "clean claims" for Medicare Part B prescriptions, the billing representatives in each company must examine the prescription as written by the physician, verify that it meets the Medicare requirements and then complete the necessary paperwork and verification information prior to submission.

In comparison to other payers, orders for Medicare Part B immunosuppressant medications also require a high level of additional information that must be submitted to DME MACs with each claim. It would seem logical that the DME MAC record the date of transplant and the name of the transplant center properly and not request this information on a regular basis. However, DME MACs often question this information sent by the pharmacy and the prescribing physician months into a patient's therapy. Pharmacy personnel must then seek the appropriate documentation. Unfortunately, this information is not easily verifiable because it must be obtained through the Social Security Administration that often does not have the appropriate information. The number of claims resubmitted for additional verification has increased since the implementation of the Medicare Part D program and the elimination of certain paperwork reduction requirements. The rationale for this increase is unknown by both pharmacies and DME MACs, however, it creates an even greater administrative burden on pharmacies when billing claims.

If a pharmacy submits a clean claim to the DME MAC, there is no guarantee that payment will be submitted to the pharmacy in a timely manner. As described above, DME MACs often make administrative errors upon receipt of the paper claim or do not recognize HCPCS or supply fee codes for certain medications. When this occurs, the entire claim is rejected but the pharmacy must then re-create the billing process and re-submit the claim. This process is not recognized through additional payments in the supply fee despite the additional staff time associated with this process. Furthermore, the pharmacy does not receive payment for the medication or the supply fee until the claim is properly submitted. Even a properly submitted Part B claim is subject to a significant lag in payment time--often as long as six weeks. The burden of resubmitting the claim doubles this payment lag time. This means that a pharmacy might wait up to three months--an entire business quarter-- to receive any payment for a claim.

D. Quantifying the Costs of Resubmissions and Claim Denials

The analysis below provides examples of the costs associated with resubmissions and claim denials. Again, these examples are illustrative of certain cases and do not reflect every possible situation. Some cases might be more extreme than others.

i. "Patient not identified as our insured" or "coverage expired"

These denials account for approximately 10% of cases after an initial evaluation of the individual's Medicare status. This generally requires a phone call by a pharmacist to either the DME MAC or a claims processing company contracted by the pharmacy. This requires a live discussion and therefore with hold times, the interaction might be between 30 minutes to 1 hour. Based on estimated labor costs, this transaction costs between $22-$44.

ii. Coordination of benefit (CoB) denials

These denials account for approximately 40% of cases and can typically be resolved with one level of appeal through direct contact to the Medicare CoB coordinator and/or the patient. The DME MAC databases must then be updated to verify payment status and the claim cannot be processed until the system update occurs. A billing representative must contact the Medicare interactive voice response system (IVRS) regularly to verify status. When the IVRS verifies payment status, the claim can then be processed through a redetermination process. A billing representative then must prepare redetermination forms and locate and copy primary insurance for the CoB information.

Initial approval based on communication with the IVRS and the CoB determination consumes approximately 1-1½ hours of a billing representative's. The redetermination form requires approximately another ½ hour more for a total of 2 hours time invested. Based on average labor costs, this equates to approximately $42.

If the initial rejection is not resolved at the first appeal, the second level of appeal then requires an additional 1 hour to resolve subsequent issues at a cost of $21. The third level of appeal requires another 1½ hours at a cost of $31.50, and potentially more if a direct phone call to the IVRS or DME MAC is required.

iii. "No transplant on file"

Generally requires two or three levels of appeal. During the extensive process, the patient must receive their medications to prevent organ rejection. However, neither Medicare Part B nor the secondary payers will reimburse the pharmacy until there is complete resolution.

These denials usually take longer because billing personnel must directly contact physician offices for a letter of medical necessity indicating that the transplant occurred. Furthermore, the patient must provide his or her Medicare status through receipt of a copy of a Medicare card by the pharmacy. This preparation time may take days or weeks to resolve with all of the paperwork that must be received and processed. Approximately 5-5 ½ hours of staff time, or $105-$115.50, are required for this first level of appeal.

In most cases a second level of appeal will be necessary and the paperwork requirements are lengthy and detailed. On this level, all documentation previously submitted and prior Medicare determinations must be copied and provided to the Qualified Independent Contractor responsible for reviewing these claims. This requires an additional 2 hours of staff time at a cost of about $42. About 50% of claims submitted at the second level will require advancement to a third level of appeal requiring an additional 1 hour of time at a cost of $21.

iv. "Wrong payer", "expired coverage" or "duplicate services"

These denials are less frequent than others, and typically involve a first level of appeal, including a phone call to the patient and a redetermination form, about 1 hour of time for a total of $21.

E. TPC Recommendations for 2008 Supply Fee

The administrative burdens associated with Medicare Part B billing are immense for pharmacies. This rationale is described above and the costs are estimated and quantified by the Lewin Group report. Since its inception in 2005, the supply fee has been negatively adjusted from $24 for each immunosuppressant prescription to $24 for the first prescription and $16 for each subsequent prescription provided in a 30-day period. The tiered supply fee has proven difficult for both pharmacies and DME MACs to administer and this type of approach to pharmacy payment has neither been efficient nor effective. The Lewin Group quantified costs across all prescriptions filled by TPC member pharmacies. This analysis averages the time to dispense and bill prescriptions as well as file appeals. All of these factors must be included when calculating the supply fee and are not currently considered by CMS. TPC believes that the current supply fee uses an inflation factor to traditional dispensing fees to determine the supply fee. This is improper because of the additional labor costs and resubmissions associated with Medicare Part B billing.

CMS should consider an update for 2008 that accurately and adequately reflects the costs associated with actually supplying a Part B immunosuppressant prescription. CMS should reconsider policies and reimbursement rates that force pharmacies to supply immunosuppressants at a loss. The Lewin Group analysis finds that the appropriate cost to supply a Part B claim is $30.73. TPC recommends that the supply fee be appropriately adjusted from its current tiered structure to a single fee reflects actual costs associated with supplying Part B immunosuppressants.

V. Analysis of TPC's Adherence and Compliance Study

A. Participation by Pharmacies and Patients and Data Collection

Five of the seven TPC members recently participated in a study to analyze outcomes associated with adherence and compliance. Participating TPC members are Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and Transcript Pharmacy. The remaining TPC members did not participate primarily because of time constraints for data collection. TPC may expand the adherence study in the future to be more comprehensive. However, the other members concur that the findings are generally indicative of the adherence rates of all TPC member companies and demonstrate the value of the patient care services provided by specialty pharmacies.

Researchers at VCU examined medication possession rates (MPRs), a commonly accepted measure to determine adherence, in 1,590 renal transplant

patients of the five specialty pharmacies. The study examined MPRs for the following immunosuppressants: Imuran® (azathioprine), CellCept® (mycophenolate mofetil), Myfortic® (mycophenolic acid), and Rapamune® (sirolimus). Two commonly used immunosuppressants; Neoral® (cyclosporine A) and Prograf® (tacrolimus) were excluded because of frequent dosage adjustments that made calculation of MPRs difficult.[9] Renal transplants were used as a basis for the study because they are the most commonly covered Medicare transplants.

Information for individuals identified as only Medicare primary coverage was submitted by each of the pharmacies to ensure that all identifiers and other patient identifiers were masked. Prescription fill data were obtained between January 1 and June 1, 2005. To be eligible, patients must have had one prescription filled in the first month, January 2005 and the last month, June 2005. The patients were identified as compliant if the MPR was greater than or equal to 80%.[10] The study calculated MPRs defined as: . . .the total number of days supply available during the investigation period (that is, the sum of all the days supply dispensed minus the days supply of the last fill) divided by the length of time between the first fill and the last fill.[11]

As the commentary in the study explains, MPR is a fairly accurate determination of medication compliance and is actually favorable to self-reporting that tends to overestimate compliance.[12] The study acknowledges, however, that it cannot determine whether an individual takes the medications in the manner prescribed. This would involve a more invasive and extensive study requiring monitoring of laboratory levels and direct medication administration monitoring. However, the participating pharmacies often identify non-compliance and intervene immediately to manage the signs of rejection. Estimates for medical cost avoidance associated with improved adherence were based upon the 2005 Annual Data Report published by the United States Renal Data System USR (2005). This report contains information compiled through 2003.[13]

B. Study Methodology and Results in Brief

Overall adherence ranged from 81.5% on Rapamune (sirolimus) to a high of 89.1% on Imuran (azathioprine). The average across all age groups totaled 84.2% compared with 65% recorded in the literature.[14] Upon determining the adherence rates and drawing the comparisons, the researchers then assessed any potential cost avoidance and savings using expert clinical opinions and literature reviews. Cost estimates were based upon probability of death, probability of survival with a functioning graft, and probability of survival with a failed graft. Using data from USRDS in 2002, the researchers estimated that the annual medical costs for patients in the five specialty pharmacies totaled approximately $27,853 compared to $32,003 for patients in other pharmacies. The total annual medical savings for each patient in the specialty pharmacy group is estimated at $4,150 based on greater adherence rate alone.

This information was extrapolated to determine the potential for annual savings and cost avoidance to the health care system. Researchers projected cost

estimates based on costs associated with the 15,136 renal transplants documented in 2003 by the Organ Procurement and Transplantation Network. Using this estimate, if each patient were to use a specialty transplant pharmacy that participated in the study, the total cost to the health care system would be $421.6 million rather than $484.4 million for other pharmacies. This produces an average savings of $63 million when using the specialty pharmacies.

C. Impact to the Medicare Program: Specialty Transplant Pharmacy Services and Billing Services Improve Adherence

The positive adherence and cost avoidance findings in the study are attributed to the services often provided by specialty pharmacies. The 2004 and 2007 Lewin Group reports identified the coordination of billing services by specialty pharmacies as a significant factor in improving patient compliance. Specialty pharmacies help to lower patient costs by working to eliminate paperwork burdens. Coordination services include ensuring proper billing and payment of benefits among private insurers, Medicare Part D, Medicaid, and Medicare Part B. Specialty pharmacies often seek additional financial assistance to help beneficiaries pay for medications.[15] Billing services are shown to improve adherence by ensuring access to medications. These services are often not provided by community pharmacies and patients often struggle to understand the billing processes and pay for expensive medications. This often leads to non- adherence. The positive outcomes associated with billing are only one piece of the services regularly provided by specialty pharmacies that improve outcomes.

Specialty pharmacies engage in other proactive patient follow-up and medication management that contribute significantly to improved adherence. All of the specialty pharmacies in the study engage in patient care activities including proactive refill reminders, education regarding the patient's disease state and medication interactions, and call centers dedicated to providing patients with information and education. The study concludes that a combination of the billing services and proactive patient interactions results in improved compliance for these specialty pharmacies in comparison to the general population.

Transplants are costly to Medicare and to the overall health care system. However, the lifetime savings for individuals who receive transplants compared to those who continue on dialysis is approximately $200,000.[16] After a transplant, patients generally require a lifetime of immunosuppressant medications to protect against organ rejection. Medicare costs for these immunosuppressant medications might be as high as $13,000 annually.[17] However, given the significant cost associated with the organ transplant and even greater costs associated with organ graft failure, return to dialysis, and re-transplantation,[18] Medicare should invest in protecting transplanted organs. As the literature suggests, lack of interventions by pharmacies could significantly reduce adherence with immunosuppressant regimens.

A Health Affairs article from 2006 considered the value of ensuring access to specialty medications.[19] This study examined the impact of cost sharing

requirements by privately insured patients and the economic impact of limiting coverage to expensive specialty medications for patients who require them.[20] The study suggests that despite the cost of the specialty medications, patients properly identified as requiring them should be ensured access to these medications. The study further suggests that the insurers should find ways to manage utilization to ensure continued access.[21] The Medicare program faces the same economic challenges as the private sector and should also work to ensure appropriate access to specialty medications for those who require them.

Transplant patients are clearly proper candidates for life-long immunosuppressant therapy. Medicare Part B and the Medicare Part D programs have made a concerted effort to cover these medications. Like privately insured patients, Medicare patients also face significant co-payments for these medications and as the literature suggests, nearly 40% of transplant patients are non-adherent. However, the management techniques used by specialty pharmacies can and do improve adherence and thus promote access to these medications. Medicare Part B should continue to recognize the services that specialty pharmacies provide and ensure that an appropriate supplying fee is paid to pharmacies for these medications.

VI. Overview of Issues Related to ASP Data Collection and Response to CMS' Request for Comments

A. Current WAC for Most Immunosuppressant Agents Below ASP

Appendix 4 shows that the most current WAC rates for 7 of the 10 most commonly used immunosuppressant agents are substantially below July 2007 ASP rates. Approximately 60% of community pharmacies pay WAC for acquisition of immunosuppressant agents. This figure represents the most current ASP data for July 2007. This is especially disturbing considering the extensive billing services associated with Medicare Part B and the inadequate supply fee. Coupled together, these factors result in a financial loss for many pharmacies. If this situation were to continue, contraction in the marketplace might occur. CMS' suggested use of the lower of AMP or WAMP plus 3% if ASP is found to be 5% or more above these figures could make the current situation even worse. This situation is considered in "B" below.

B. AMP and WAMP +3% Pricing Will Result in Greater Reductions in Payment to Pharmacies for Immunosuppressant Agents

Based on TPC's experience with ASP since 2005, we do not believe that a survey of pharmacy providers would yield a WAMP that is lower than ASP. TPC's trend analysis suggests that on balance ASP prices have been consistently lower than pharmacy acquisition over time.

AMP is untested in the market for pharmacy providers but will potentially be implemented in 2008 as a payment methodology for generic medications paid by the Medicaid program. Even government agencies such as the General Accountability Office question the ability of AMP to serve as an appropriate

benchmark for pharmacy payment. Use of AMP as a benchmark will potentially further lower payments to pharmacies and serve as a further deterrent for some pharmacies to continue serving the transplant market.

VII. SUMMARY

Once again, TPC thanks CMS for the opportunity to provide comments on this proposed rule. TPC encourages CMS to increase the 2008 supplying fee to properly compensate pharmacies for the billing and clinical services associated with improved outcomes for transplant patients and potentially lower Medicare costs. For questions regarding these comments, please contact Mary Jo Carden, TPC's Washington representative, at 202-744-2773 or MCarden@CardenAssociates.net.

Sincerely,

Mary Jo Carden, RPh, JD
On behalf of the Transplant Pharmacy Coalition

[1] 72 FR 38122.
[2] *Ibid.*
[3] 72 FR 38123.
[4] 42 USC §1842(o)(6) as amended by *Medicare Modernization Act* §302(e).
[5] 72 FR 38220.
[6] *Ibid.*
[7] Cost of Dispensing Study. An Independent Comparative Analysis of U.S. Prescription Drug Dispensing Costs. Grant Thorton, LLP. January 2007
[8] Bureau of Labor Statistics. Available at www.bls.gov. Accessed August 27, 2007.
[9] Matzke GR, Harpe SE. (2006). Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence. Virginia Commonwealth University College of Pharmacy.
[10] *Ibid.*
[11] *Ibid.*
[12] *Ibid.*
[13] Matzke *ibid.*
[14] *Ibid.*
[15] Pharmaceutical Care Mgment. Assn. (2005). An introduction to specialty pharmacy. Washington, DC.
[16] Davis T. Organ donations falling short waiting lists grow more patients dying as donors run short. Ann Arbor News. Jul. 8, 2004.
[17] Yen EF, Hardinger K, et al. (2004). Cost-effectiveness of extending Medicare coverage of immunosuppressive medications to the life of a kidney transplant. Am. J. of Transplantation, 4, 1703 – 1708.
[18] Schnitzler M. Implications of transplant policy. Presented before a Congressional briefing. Oct. 17, 2005.
[19] Goldman DP, Joyce GF, et al. (2006). Benefit design and specialty drug use. Health Affairs, 25 no. 5, 1319 – 1331.
[20] *Ibid.*
[21] *See* Goldman 1330.

#14546 Attachment #2

The Transplant Pharmacy Coalition
Comments Medicare Part B Supply Fee

Appendix 1
Membership & Contact Information

#14546 Attachment #3

Transplant Pharmacy Coalition

Members and Contact Information
As of August 2007

Amber Pharmacy
Tim Kaplan
President & Chief Executive Officer
10004 S. 152nd Street
Omaha, NE 68138
888-370-1724

Echo Drugs
Boris Mantell
Chief Executive Officer
7035 Parsons Boulevard
Flushing, NY 11365
718-591-1040

F&M Specialty Pharmacy
Henry Skelton
President & Chief Executive Officer
631 Lakeland East Drive
Flowood, MS 39232
601-939-9353

PharmaCare, Inc.
Greg Weishar
President & Chief Executive Officer
695 George Washington Highway
Lincoln, RI 02865
610-783-0242

Gregory S. Kaupp, Attorney
Consultant to PharmaCare
761 Gulph Road
Wayne, PA 19087
610-783-0242

#14546 - #5

The LEWIN GROUP

Assessing the Cost of Dispensing Immunosuppressive Drugs to Medicare Transplant Recipients – An Update

Report Prepared for:

Transplant Pharmacy Coalition

Prepared by:

The Lewin Group, Inc.

April 15, 2007

authors estimated a potential cost savings of $4,150 per patient per year associated with increased adherence. Since transplant patient non-adherence with immunosuppressive medications can result in organ rejection, graft loss, and death, there is a compelling need for public policy to support providers' efforts to help these patients adhere to their medication regimens.

The Transplant Pharmacy Coalition commissioned The Lewin Group to update its 2004 analysis of the pharmacy costs associated with providing immunosuppressive drugs under Part B. Eight specialty pharmacies comprise the Transplant Pharmacy Coalition, whose members collectively fill more than 28,000 immunosuppressive prescriptions monthly and hold about 40% of the Medicare Part B market share in immunosuppressive drug dispensing.

As in 2004, The Lewin Group surveyed Coalition members for costs associated with providing immunosuppressive drugs and related pharmacy services in general and also to Medicare beneficiaries. The purpose of this report is to present our findings, comparing them to our 2004 findings where appropriate. We found that:

- Transplant pharmacies' average supply cost per immunosuppressive drug prescription has remained relatively stable between 2004 and 2007. In 2007, it is $30.73, down slightly from $32.62 in 2004. (These results are for those six pharmacies that participated both in 2004 and 2007.) The stability of our results suggests that our surveys have been working as intended and show a high level of reliability.

- Unlike retail chain pharmacies, transplant pharmacies routinely provide immunosuppressive drugs covered under Medicare Part B, as well as other direct services to encourage patient adherence to their drug regimen. Together with additional labor-intensive Medicare Part B requirements for documentation, pharmacies' personnel requirements are sizeable. We found that personnel costs have risen from 21.6% to 28.1% of supply costs (excluding the cost of goods sold) between 2004 and 2007. Personnel costs rose from $7.04 in 2004 to $8.65 in 2007.

- Although Centers for Medicare and Medicaid Services (CMS) eliminated the requirement for the submission of the Durable Medical Equipment Regional Centers Information Forms (DIFs) to receive reimbursement for immunosuppressive drugs, administrative costs for filing Medicare claims still account for a sizeable amount of the pharmacies' supply cost. We found these administrative costs to be approximately 23.2%, up from 19.7% in 2004, from $6.43 to $7.13. This is contrary to CMS' expectation.

- Unlike other prescription drug payers, Medicare does not provide real-time online adjudication of claims, making coordination of benefits with secondary insurers costly and sometimes impossible. Several pharmacies noted that Medicare denials have increased since 2004, resulting in additional work and expense for the pharmacy to resubmit the claim and file an appeal. This observation was confirmed by the survey which found that administrative overhead has increased to 13.4% from 9.0% in 2004. Administrative overhead increased from $2.93 in 2004 to $4.13 in 2007.

- In contrast, other non-labor costs declined from 6.4% in 2004 to 1.2% in 2007, or from $2.08 to $0.37. Shipping declined from 14.8% in 2004 to 11.5% in 2007, or from $4.82 to $3.55. Inventory cost declined from 11.8% in 2004 to 1.7% in 2007, or from $3.84 to $0.52.

Assessing the Cost of Dispensing Immunosuppressive Drugs to Medicare Transplant Recipients – An Update

Report Prepared for:

Transplant Pharmacy Coalition

Prepared by:

Joan E. DaVanzo, Ph.D., M.S.W.
Allen Dobson, Ph.D.
Ted Kirby

April 15, 2007

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EXECUTIVE SUMMARY

The Medicare Prescription Drug, Improvement and Modernization Act (MMA) was implemented in January 2005. The MMA requires CMS to pay specialty pharmacy providers a "pharmacy supply fee" to cover the administrative and other costs associated with dispensing immunosuppressive drugs and providing associated professional services to Medicare transplant patients. Professional services include focused therapeutic management, patient counseling, and assistance with the paperwork associated with insurance reimbursement. MMA also mandated a change to an average sales price (ASP) based payment system for Medicare Part B drugs.

Successful immunosuppressant therapy has two requirements: first, that the treatment be fine-tuned to each individual patient in terms of drugs selected, dosages, and side effects. Doctors use different combinations of medications, and work to maintain a delicate balance in each patient, to try to reduce the chances that an organ will be rejected. The second requirement is that transplant recipients take their medications as prescribed, and promptly report any complications or adverse reactions to their doctors in order that dosages can be corrected over time. These two aspects make immunosuppressant therapy a challenge, especially in the initial months after the transplant, and require sustained and careful attention from the specialty pharmacy staff.

The literature contains numerous studies of medication non-adherence by patients with chronic diseases, including studies of transplant patients who are non-adherent with their immunosuppressant therapies and its effect on graft survival. We conducted a focused review of the literature on the effects of patient adherence, and found that as many as one-third of transplant patients do not adhere to their drug regimens. [1,2,3] Furthermore, patients are more adherent in the early post-transplant period, and less adherent as time goes by.[4]

This finding underscores the importance of the specialty pharmacy service model in which pharmacists and other staff work with patients to educate them, and help them with the paperwork and other requirements for obtaining insurance reimbursement, which have both been shown to improve patient adherence.[5] A recent study of Transplant Pharmacy Coalition members found an overall adherence rate of 84.2% across all immunosuppressive agents and ages vs. a 65% adherence rate found in the literature.[6] Using decision analysis methods, the

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[1] Rovelli M, Palmeri D, Vossler E., et al. (1989). Non-compliance in renal transplant patients: evaluation by socioeconomic groups. *Transplant Proc* 21: 3979-3981.

[2] Butler J, Roderick P, Mullee M, et al. (2004). Frequency and impact of non-adherence to immunosuppressants after renal transplantation: A systematic review. *Transplantation* 77: 769-789.

[3] Denhaerynck K, Dobbells F, Fluri C, et al. (2005). Prevalence, consequences, and determinants of non-adherence in adult renal transplant patients: A literature review. Transplant International 18: 1121-1133.

[4] Vlaminck H, Maes B, Evers G, et al. (2004). Prospective study on late consequences of subclinical non-compliance with immunosuppressive therapy in renal transplant patients. *Am J Transplant* 4(9): 1509-1513.

[5] Newton S. (1999). Promoting adherence to transplant medication regimens: a review of behavioral analysis. Jour Transplant Coordination 9(1): 13-16.

[6] Harpe S, Matzke G. (2006). *Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence.* Virginia Commonwealth University School of Pharmacy. Report submitted to Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and Transcript Pharmacy.

Exhibit 1 below presents a summary of the 2007 survey results, as compared to the results from 2004. The ratio of average pharmacy supply costs to average total costs decreased from 8.0% to 7.0%, reflecting both a higher cost of goods and somewhat lower supply costs. The average per prescription cost declined from $32.62 in 2004 to $30.73 in 2007. The amount of the supply costs devoted to filing Medicare claims rose from $8.86 in 2004 to $9.40 in 2007.

Exhibit 1
Summary Results

	2004 Survey [a/]	2007 Survey
Ratio of Average Supply Costs to Average Total Costs	8.0%	7.0%
Average per-Prescription Supply Cost	$32.62	$30.73
Amount Attributable to Additional Cost for Filing Medicare Claims	$8.86	$9.40

a/ Reanalysis of 2004 survey using data from the six pharmacies that responded to the 2007 survey and 2007 data categories. The 2007 survey collected FY 2006 data.

Source: Lewin Group analysis of survey data.

INTRODUCTION

The Transplant Pharmacy Coalition is comprised of eight specialty pharmacies who serve approximately 40% of the Medicare immunosuppressive market. The remainder of the market is served by retail pharmacy chains, hospital outpatient pharmacies at transplant centers, and Pharmacy Benefit Managers (PBMs) [which do not typically serve Medicare patients due to the high cost of filing Medicare claims].

The Transplant Pharmacy Coalition commissioned the Lewin Group to update its 2004 study of transplant pharmacy costs for providing immunosuppressive drugs to Medicare beneficiaries. We collected FY 2006 cost data from coalition members, and also conducted a focused review of the research literature on transplant patient adherence to immunosuppressive therapy. Because transplantation is the preferred treatment for end-stage renal disease (ESRD) and is less expensive than dialysis, the preservation of functioning kidney transplants has been considered to be a national priority. [7] Medication non-adherence is a leading barrier to continued transplant function, so we conducted a focused review of what is currently known about the topic.

In this introduction, we present the study purpose, study rationale, and a discussion of the services provided by specialty transplant pharmacies.

Study Purpose

The study purpose was threefold:

- To identify the supply costs associated with providing pharmacy services to Medicare Part B transplant recipients;
- To approximate average total and component clinical administrative costs of providing these services; and
- To develop average per prescription pharmacy supply cost estimates under the payment methodology outlined by the *Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).*

Study Rationale

Transplantation represents a solution to many kinds of end-stage disease. However, without immunosuppressive drug therapy, transplant recipients experience organ rejection, meaning that the body's immune system attacks the donor organ's cells, reacting to them as if they were harmful.[8] Medications that curb the immune system (called immunosuppressant drugs) are

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[7] Dobson A, DaVanzo J, Kerns J. (2000). Appendix E. Cost estimates for expanded Medicare benefits: skin cancer screening, Medically necessary dental services, and immunosuppressive therapy for transplant recipients. In: Field MJ, Lawrence RL, Zwanziger L (eds). *Extending Medicare Coverage for Preventive and Other Services.* Institute of Medicine. Washington D.C.: National Academy Press:347-362.

[8] Kreis HA, Ponticelli C. (2001). Causes of late renal allograft loss: chronic allograft dysfunction, death, and other factors. Transplantation 71: SS5.

essential for transplant recipients. The discovery of immunosuppressant drugs – and the advances still being made – allow many transplant recipients to live longer, healthier lives.[9]

Nevertheless, immunosuppression creates a new set of problems. People with suppressed immune systems are less likely to reject their transplanted organs, but also less able to fight off harmful "invaders." This leaves them vulnerable to infections and some types of cancer. Immunosuppressive drugs (also called "anti-rejection drugs") can also cause other side effects. Doctors use different combinations of medications, and work to maintain a delicate balance in each patient, to try to reduce the chances that an organ will be rejected. Finally, immunosuppressant medications can be costly.[10]

The rapidly increasing growth of organ transplantation has resulted in a dramatic increase in the number of immunosuppressive agents and other medications used in transplantation, resulting in more complex medication regimens and greater potential for interactions, adverse effects and increased costs. However, despite advances in immunosuppressive therapy, a major weakness in the "therapeutic chain" remains the patient's behavior.[11]

Pharmacists and other staff at specialty transplant pharmacies often work closely with each patient to provide specialized therapeutic management, medication distribution, and counseling. An early study demonstrated that patients' knowledge about anti-rejection medications increased from 53% to 75% after counseling by pharmacists. Their knowledge level about other drugs such as antimicrobial and antihypertensive agents was 15% before pharmacist counseling and increased to 50% to 60% following counseling.[12]

Transplant centers typically have outpatient pharmacies that provide many of these services to patients. However, a large percentage of patients live too far from transplant centers to use them on a regular basis.

Retail chain pharmacies typically do not supply immunosuppressive drugs due to:

- The small number of transplant patients relative to population;
- The high cost of inventory and high risk of waste from drug expiration (due to the high cost of drugs and small number of patients); and
- Lack of business desire to deal with complex Medicare claims procedures.

Mail-order PBM pharmacies typically do not serve Medicare Part B transplant patients, as most mail-order pharmacies do not have processes in place to file Medicare claims.
Therefore, specialty transplant pharmacies are the only practical option for many patients, especially Medicare Part B patients.

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[9] Pascual M, Theruvath T, Kawai T et al. (2002). Strategies to improve long term outcomes after renal transplantation. *N Eng J Med* 346:580.

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Transplant Pharmacy Practices that Increase Supply Costs of Dispensing

Transplant pharmacy practice differs from that of retail pharmacies in several ways, all of which increase costs. The transplant pharmacy service model involves the provision of many specialized services. For example, the initial prescriptions are often hand-delivered to the hospital on the day of discharge. Until the correct dosage for the patient is determined (approximately four months), the pharmacist works closely with the prescribing doctor to determine the correct dosage, and with the patient to monitor for symptoms of incorrect dosage or side effects.

Transplant pharmacies not only accept Medicare patients, they file Medicare claims. The filing of Medicare claims is more difficult and more costly than filing other types of claims.

Non-Medicare payers - both private insurers and Medicaid - offer and require instant online adjudication of claims at the time a prescription is filled. Pharmacies know before delivering the product how much they will be paid and how much of a co-payment to collect. Medicare Part B does not utilize the online adjudication system. This increases billing errors and makes coordination of benefits with secondary insurers difficult and sometimes impossible. Medicare often errs in identifying patients as having "primary" or "secondary" Medicare coverage. Prior to filing a claim, pharmacies can call Medicare to determine this status, but the answers are often incorrect.

Medicare claims add substantial costs due to a complicated filing process and the increased cost of coordinating benefits without the presence of an instant adjudication process. In addition, Medicare often provides inaccurate information about patient coverage status (primary vs. secondary), and secondary reimbursement is often lost due to Medicare errors discovered after date of service.

Successful immunosuppressant therapy has two requirements: first, that the treatment be fine-tuned to each individual patient in terms of drugs selected, dosages, and side effects. Doctors use different combinations of medications, and work to maintain a delicate balance in each patient, to try to reduce the chances that an organ will be rejected. The second requirement is that transplant recipients take their medications as prescribed, and promptly report any complications or adverse reactions to their doctors. These two aspects make immunosuppressant therapy a challenge, especially in the initial months after the transplant, and require sustained and careful attention from the specialty pharmacy staff.

The literature contains numerous studies of medication non-adherence by patients with chronic diseases, including studies of transplant patients who are non-adherent with their immunosuppressant therapies and its effect on graft survival. We conducted a focused review of the literature on the effects of patient adherence, and found that as many as one-third of transplant patients do not adhere to their drug regimens. [13,14,15] Furthermore, patients are more adherent in the early post-transplant period, and less adherent as time goes by.[16]

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[13] Rovelli M, Palmeri D, Vossler E., et al. (1989). Non-compliance in renal transplant patients: evaluation by socioeconomic groups. *Transplant Proc* 21: 3979-3981.

This finding underscores the importance of the transplant pharmacy service model in which pharmacists and other staff work with patients to educate them, and help them with the paperwork and other requirements for obtaining insurance reimbursement, which have both been shown to improve patient adherence.[17]

A recent study of Transplant Pharmacy Coalition members found an overall adherence rate of 84.2% across all immunosuppressive agents and ages, vs. a 65% adherence rate obtained from the literature. [18] Using decision analysis methods, the authors estimated a potential cost savings of $4,150 per patient per year associated with increased adherence. The study also presented the annual cost of functioning grafts of $15,537 vs. $70,930 for failed grafts.[19] Since transplant patient non-adherence with immunosuppressive medications can result in organ rejection, graft loss, and death, it seems sensible for public policy to support providers' efforts to help these patients adhere to their medication regimens.

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[14] Butler J, Roderick P, Mullee M, et al. (2004). Frequency and impact of non-adherence to immunosuppressants after renal transplantation: A systematic review. *Transplantation* 77: 769-789.

[15] Denhaerynck K, Dobbells F, Fluri C, et al. (2005). Prevalence, consequences, and determinants of non-adherence in adult renal transplant patients: A literature review. Transplant International 18: 1121-1133.

[16] Vlaminck H, Maes B, Evers G, et al. (2004). Prospective study on late consequences of subclinical non-compliance with immunosuppressive therapy in renal transplant patients. *Am J Transplant* 4(9): 1509-1513.

[17] Newton S. (1999). Promoting adherence to transplant medication regimens: a review of behavioral analysis. Jour Transplant Coordination 9(1): 13-16.

[18] Harpe S, Matzke G. (2006). *Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence.* Virginia Commonwealth University School of Pharmacy. Report submitted to Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and Transcript Pharmacy.

[19] USRDS, 2005.

METHODOLOGY

In this section, we present an overview of our study process, and a discussion of our data analytic methods.

In 2004, Lewin developed a study process that was comprised of the following five steps. In this update study, we followed the same five steps, and performed a targeted review of the literature on non-adherence with immunosuppressive medications. As in 2004, we worked closely with the Transplant Pharmacy Coalition to verify study objectives.

1. In the earlier study, we worked with the Transplant Pharmacy Coalition to identify pharmacy supply cost categories and to develop a survey instrument. In this study, we verified the 2004 cost categories with the pharmacies, updating our instrument where needed.

2. We collected cost accounting data from participating transplant pharmacies using the updated instrument. Cost data were allocated to the Medicare Part B transplant line of business using the same top-down approach that was used in 2004.

3. We reviewed data with each participant to ensure their accuracy.

4. We analyzed the survey data, and presented draft study results for review.

5. We then drafted and finalized the report.

Data Collection

Data were collected from six of the eight specialty pharmacies of various sizes providing wide geographic coverage. As part of the earlier survey development, The Lewin Group and the Transplant Pharmacy Coalition identified and defined cost categories. The prior survey was used for this update study. For this study, we verified that the cost categories were still being created in the same way as in 2004. Where categories had changed for one company, we asked that costs in the new category be allocated to the original 2004 categories. Six transplant pharmacies completed the survey, providing FY2006 cost information. As before, to ensure consistency of reporting and accuracy of cost data, we worked individually with each company.

The current survey collected cost data on:

- Number of Medicare and non-Medicare prescriptions filled
- Cost of goods sold
- Clinical and administrative costs
- Inventory and overhead costs
- Cost of processing Medicare claims
- Medicare bad debt and collection costs

The 2007 survey instrument can be found in **Appendix A.**

Analytic Methods

Cost estimates were made with the intent of accurately representing the transplant pharmacy industry as a whole, given our sample of six specialty pharmacies. **Average cost per prescription** was calculated for each company and then a weighted average was calculated according to the number of prescriptions (not by dollar volume).

Data were used to analyze the major cost components associated with providing immunosuppressive drugs to patients. The **percent of total cost** for each component was also calculated. Cost components include:

- Cost of Goods Sold
- Pharmacy Supply Costs
  - Pharmacy personnel
  - Medicare Part B claims processing
  - Inventory cost and inventory shrinkage*
  - Shipping
  - Rent
  - Sales and marketing
  - Administrative overhead
- Medicare Bad Debt
  - Co-payments never made
  - Collection costs

Exhibit 2 contains the key summary variables and how they were calculated.

Exhibit 2
Key Summary Variables

Statistic	Numerator	Denominator
Ratio of Average Supply Costs to Average Total Costs	Aggregate pharmacy costs, except cost of goods sold (COGS)	Aggregate pharmacy total costs (includes COGS)
Average per-Prescription Supply Cost	Aggregate pharmacy costs, except cost of goods sold (COGS)	Number of prescriptions supplied to Medicare patients
Amount Attributable to Additional Cost for Filing Medicare Claims	Aggregate cost of submitting Medicare claims plus Medicare bad debt and collection costs	Number of prescriptions supplied to Medicare patients

(Provider data reflect CY 2006)

RESULTS

In this section, we present the key summary variables for both 2007 and 2004. This is followed by a presentation of the component cost structures, also from both 2007 and 2004.

Exhibit 3 contains the results of our analyses, as well as a comparison to our 2004 results, which have been adjusted to include the same six pharmacies that participated in the study in 2007. The ratio of average pharmacy supply costs to average total costs decreased from 8.0% to 7.0%, reflecting a higher cost of goods and somewhat lower supply costs. The average per prescription cost declined from $32.62 in 2004 to $30.73 in 2007. The amount of the supply costs devoted to filing Medicare claims rose from $8.86 in 2004 to $9.40 in 2007.

Exhibit 3
Summary Results

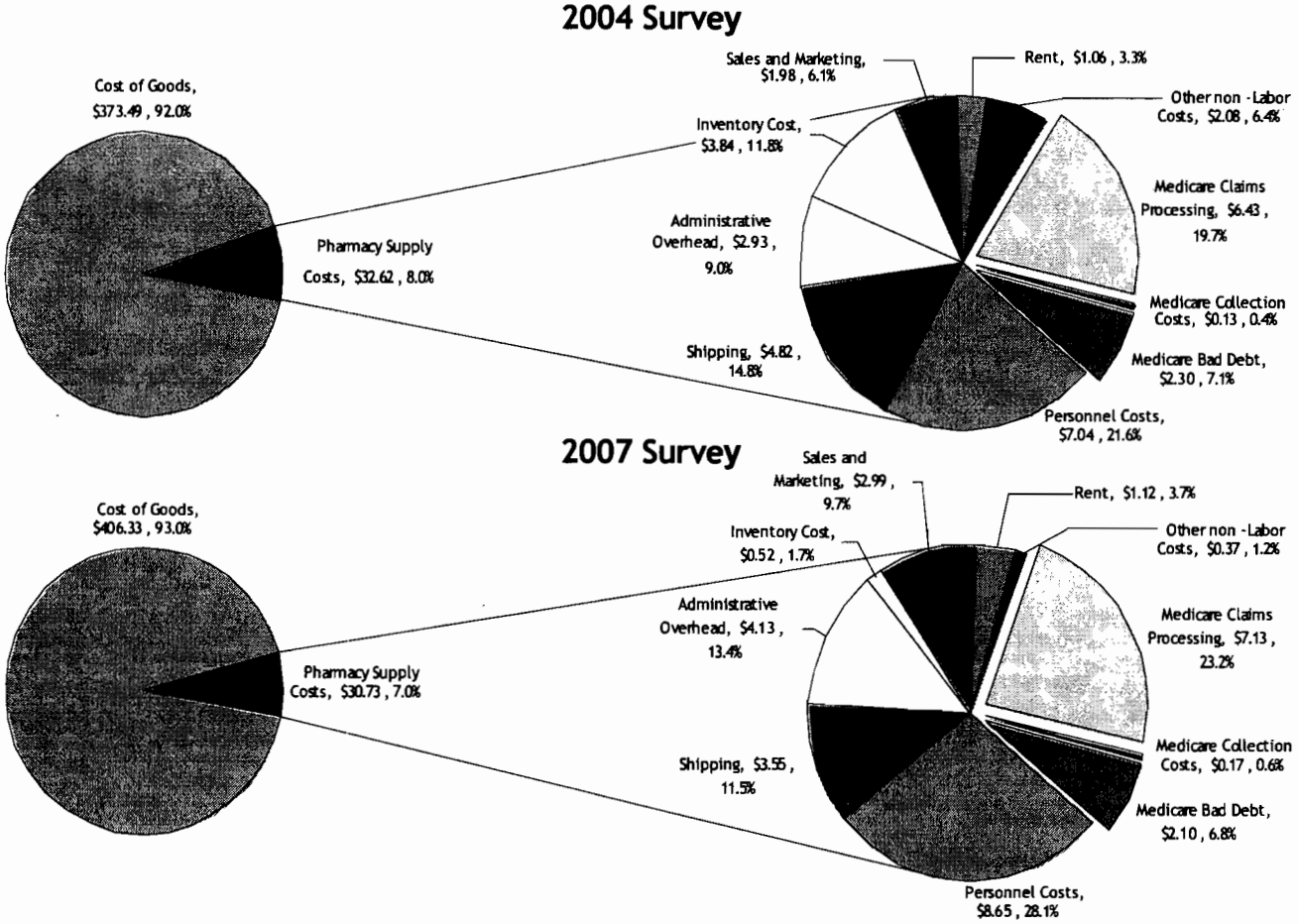
	2004 Survey [a/]	2007 Survey
Ratio of Average Supply Costs to Average Total Costs	8.0%	7.0%
Average per-Prescription Supply Cost	$32.62	$30.73
Amount Attributable to Additional Cost for Filing Medicare Claims	$8.86	$9.40

a/ Reanalysis of 2004 survey using data from the six pharmacies that responded to the 2007 survey and 2007 data categories. The 2007 survey collected 2006 data.
Source: Lewin Group analysis of survey data.

Exhibit 4 below contains a side by side comparison of the components of the supply cost for both 2007 and 2004.

- Transplant pharmacies' average supply cost per immunosuppressive drug prescription has remained relatively stable between 2004 and 2007. In 2007, it is $30.73, down slightly from $32.62 in 2004. (These results are for those six pharmacies that participated both in 2004 and 2007.) The stability of our results suggests that our surveys have been working as intended and show a high level of reliability.
- Unlike retail chain pharmacies, transplant pharmacies routinely provide immunosuppressive drugs covered under Medicare Part B, as well as other direct services to encourage patient adherence to their drug regimen. Together with additional labor-intensive Medicare Part B requirements for documentation, pharmacies' personnel requirements are sizeable. We found that personnel costs have risen from 21.6% to 28.1% of supply costs (excluding the cost of goods sold) between 2004 and 2007. Personnel costs rose from $7.04 in 2004 to $8.65 in 2007.
- Although Centers for Medicare and Medicaid Services (CMS) eliminated the requirement for the submission of the Durable Medical Equipment Regional Centers Information Forms (DIFs) to receive reimbursement for immunosuppressive drugs, administrative costs for filing Medicare claims still account for a sizeable amount of the pharmacies' supply cost. We found these administrative costs for Medicare claims processing to be approximately 23.2%, up from 19.7% in 2004, from $6.43 to $7.13. This is contrary to CMS' expectation.

Exhibit 4
Comparison of 2004 and 2007 Surveys
Using 2007 Cost Category Data from Respondents to Both Surveys



- Unlike other prescription drug payers, Medicare does not provide real-time online adjudication of claims, making coordination of benefits with secondary insurers costly and sometimes impossible. Several pharmacies noted that Medicare denials have increased since 2004, resulting in additional work and expense for the pharmacy to resubmit the claim and file an appeal. This observation was confirmed by the survey which found that administrative overhead has increased to 13.4% from 9.0% in 2004. Administrative overhead increased from $2.93 in 2004 to $4.13 in 2007.
- In contrast, other non-labor costs declined from 6.4% in 2004 to 1.2% in 2007 or from $2.08 to $0.37. Shipping declined from 14.8% in 2004 to 11.5% in 2007 or from $4.82 to $3.55. Inventory cost declined from 11.8% in 2004 to 1.7% in 2007 or from $3.84 to $0.52.
- We found that the literature contains numerous studies of medication non-adherence by patients with chronic diseases, including studies of transplant patients who are non-adherent with their immunosuppressant therapies and its effect on graft survival. We conducted a focused review of the literature on the effects of patient adherence, and found that as many as one-third of transplant patients do not adhere to their drug

regimens. [20,21,22] Furthermore, patients are more adherent in the early post-transplant period, and less adherent as time goes by.[23]

- A recent study of Transplant Pharmacy Coalition members found an overall adherence rate of 84.2% across all immunosuppressive agents and ages vs. a 65% adherence rate found in the literature.[24] Using decision analysis methods, the authors estimated a potential cost savings of $4,150 per patient per year associated with increased adherence.

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[20] Rovelli M, Palmeri D, Vossler E., et al. (1989). Non-compliance in renal transplant patients: evaluation by socioeconomic groups. *Transplant Proc* 21: 3979-3981.

[21] Butler J, Roderick P, Mullee M, et al. (2004). Frequency and impact of non-adherence to immunosuppressants after renal transplantation: A systematic review. *Transplantation* 77: 769-789.

[22] Denhaerynck K, Dobbells F, Fluri C, et al. (2005). Prevalence, consequences, and determinants of non-adherence in adult renal transplant patients: A literature review. Transplant International 18: 1121-1133.

[23] Vlaminck H, Maes B, Evers G, et al. (2004). Prospective study on late consequences of subclinical non-compliance with immunosuppressive therapy in renal transplant patients. *Am J Transplant* 4(9): 1509-1513.

[24] Harpe S, Matzke G. (2006). *Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence.* Virginia Commonwealth University School of Pharmacy. Report submitted to Amber Pharmacy, Echo Drugs, F&M Specialty Pharmacy, Skyemed Pharmacy, and Transcript Pharmacy.

CONCLUSIONS

Organ transplant is the most effective, and sometimes the only, treatment for patients with a non-functioning heart, lung, kidney, liver, pancreas, or intestine. The most common organ transplanted is the kidney (61%) for treatment of End Stage Renal Disease (ESRD). Transplanted organs are rarely an exact match for the patient, and are therefore "rejected" by the patients immune system.

Lifetime treatment with immunosuppressive drugs is required to suppress the patient's immune system to prevent organ rejection. Without immunosuppressive drugs supplied at the proper dosage, the patient will reject the organ and require a return to dialysis, re-transplantation or die. Successful transplantation has become inseparably linked to pharmacological immunosuppression that must be maintained for the life of the graft.[25]

Specialty pharmacies are a dominant supplier of immunosuppressive drugs to Medicare Part B transplant patients. Together they serve about 40% of Medicare transplant patients. The Coalition's average cost of supplying a prescription to a Medicare Part B transplant patient is $30.73, down from $32.62 in 2004, exclusive of the cost of the drug itself (when comparing pharmacies that completed both surveys). The supply cost attributable to filing Medicare claims rose to $9.40 from $8.86 in 2004.

Many patients do not have reasonable access to alternative sources for these essential drugs. Continued assurance that Medicare transplant patients have access to quality service and life-sustaining drugs is an important policy objective as payment changes are considered for Medicare Part B drugs. As the cost of goods increases and supply cost pressures mount, Medicare payment policies will become ever more important to ensuring access to transplant recipients.

Our findings underscore the importance of the specialty pharmacy service model in which pharmacists and other staff work with patients to educate them, and help them with the paperwork and other requirements for obtaining insurance reimbursement, which have both been shown to improve patient adherence.[26] Since transplant patient non-adherence with immunosuppressive medications can result in organ rejection, graft loss, and death, there is a compelling need for public policy to support providers' efforts to help these patients adhere to their medication regimens.

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[25] Gaston RS. (2000). Immunosuppressive Therapy: The Scientific Basis and Clinical Practice of Immunosuppressive Therapy in the Management of Transplant Recipients. In Extending Medicare Coverage for Preventive and Other Services (2000). National Academy of Science, Institute of Medicine.

[26] Newton S. (1999). Promoting adherence to transplant medication regimens: a review of behavioral analysis. Jour Transplant Coordination 9(1): 13-16.

Appendix A: Survey Instrument

The Lewin Group
Transplant Pharmacy Coalition survey

Company Name: _____

Is your business exclusively for transplant patients?
? Yes ? No
(If Yes, columns A and B should be the same.)

Data for:
? Calendar year 2006
? Calendar year 2005
? Other period _____

	Total Pharmacy (A)	Transplant Patients (B)	Medicare Transplant Patients (C)
Number of Prescriptions			
New Presciptions			
Refills			
Cost of Goods Sold			
Clinical Administration Costs (Personnel)			
Personnel costs, including benefits, payroll taxes, etc.			
Total cost of receiving and processing prescription orders			
Toal cost of preparing orders for shipping			
Total cost of maintaining inventory (ordering, stocking, etc.)			
Total cost of processing claims			
Total cost of patient education & counseling			
Sub-total: Direct labor costs			
Clinical Administration Costs (Other)			
Total cost of shipping (UPS/FedEx/USPS/etc. bill)			
Inventory cost (Average inventory times cost of capital)			
Sub-total: Non-labor clinical administrative costs			
Administrative Overhead			
Accreditation, licensing, and permits			
Supervision			
Office supplies and other administrative expenses.			
Sales and Marketing			
Rent			
Utilities (electric, gas, heating oil, etc.)			
Insurance			
Computer hardware/software			
Telephone/Internet			
Bank charges, legal and accounting expenses			
Sub-total: Unallocated Overhead			
Medicare Bad Debt			
Include ***only*** Medicare copayments that were never paid. ***Do not*** include denied claims or non-Medicare bad debt.			
Collections costs			
TOTAL COSTS:			

If you have any questions, please contact Joan DaVanzo, (703) 269-5724.

Please return survey by e-mail or fax to:
Joan DaVanzo, E-mail: joan.davanzo@lewin.com, Fax: (703) 269-5501

#14546 Attachment #6

The Transplant Pharmacy Coalition
Comments Medicare Part B Supply Fee

Appendix 3
2006 Transplant Pharmacy Adherence Report

#14546-#7

Assessment of Adherence with Immunosuppressant Medications in Transplant Patients and the Potential Cost Savings Associated with Increased Adherence

September 25, 2006

Prepared by:

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Commissioned by:

Amber Pharmacy
Omaha, Nebraska

Echo Drugs
New York, New York

F & M Specialty Pharmacy
Jackson, Mississippi

Skyemed Pharmacy
Pompano Beach, Florida

Transcript Pharmacy
Jackson, Mississippi

The sponsoring pharmacies are members of both the Transplant Pharmacy Coalition (TPC) and Specialty Pharmacies of America (SPofA). The TPC is a group of eight specialty pharmacies who collectively provide immunosuppressants for about 1 in every 3 Americans who have had an organ transplant. SPofA is a group of specialty pharmacies servicing patients with chronic medical conditions that include organ transplant, hepatitis, HIV, arthritis, and many other conditions.

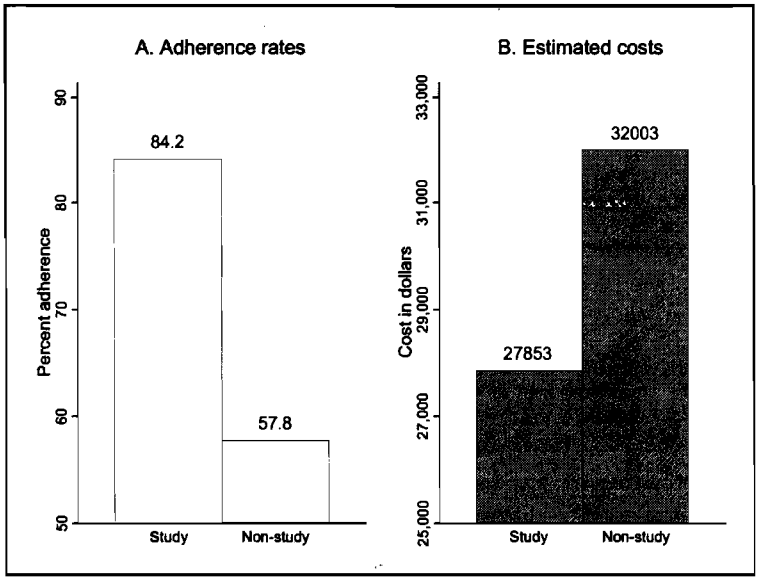
ASSESSMENT OF ADHERENCE WITH IMMUNOSUPPRESSANT MEDICATIONS IN TRANSPLANT PATIENTS AND THE POTENTIAL COST SAVINGS ASSOCIATED WITH INCREASED ADHERENCE

PROJECT SUMMARY

Objective:
The primary goal of the study was to examine the rate of adherence with immunosuppressant medications in transplant patients served by a group of five specialty pharmacies. The adherence estimates were then compared to literature-based adherence estimates for the purposes of determining whether potential cost savings were associated with increases in adherence.

Findings:
Adherence was estimated for 1,590 patients receiving four immunosuppressant agents: azathioprine, mycophenolate mofetil, mycophenolic acid, and sirolimus. Medication possession ratios (MPRs) were calculated for each drug taken by each patient. Patients were identified as "adherent" if the MPR was ≥ 0.8 for all prescribed immunosuppressant agents. The estimated adherence rate among the five study pharmacies was 84.2%, which was significantly higher than the literature-based estimate of 65% (Panel A below). The adherence estimates were applied to current Medicare cost estimates for functioning renal grafts and failed renal grafts to determine whether the differences in adherence were associated with potential cost savings. With the increased adherence rate from the group of study pharmacies, the estimated yearly cost was $27,853. The cost associated with the literature-based estimate was $32,003 resulting in a potential cost savings of $4,150 per patient per year linked to an increase in adherence with immunosuppressant regimens (Panel B below). With a total of 15,136 renal transplants in 2003, this cost difference translates to a potential savings of almost $63 million per year.

Conclusions:
These findings suggest that the reduced risk of rejection associated with increased adherence with immunosuppressant agents translates into avoidance of significant costs associated with a failed renal graft. The service model used by the group of study pharmacies involves a high level of patient contact to promote adherence, which is enhanced from the services provided by traditional mail-order and retail pharmacies. The higher level of service attributed to the specialty pharmacy service model is likely responsible for the increased adherence rates. Instituting policies to ensure appropriate reimbursement, such as CMS's proposed pay-for-performance framework, would be an important step to support and promote patient care.



Introduction

Lack of adherence with medication regimens is a well-established problem in many patients with chronic disease states. Despite marked advances in the safety and efficacy of medications, no agent will work if the patient fails to take their prescribed regimen. Non-adherence may include failure to take medication doses as directed (with respect to dose and frequency), failure to finish a prescribed course of therapy, taking medications that were not prescribed for the condition, and even failing to pick up the prescription once filled (Wainwright & Gould, 1997).

Adherence in transplant patients represents a unique situation given the potentially serious consequences of non-adherence (Chisholm, 2002). More importantly, the consequences of on-adherence may be realized sooner than in other conditions, such as hypertension or hyperlipidemia. Immunosuppressant agents are quite effective at preventing rejection of a transplanted organ; however, lack of adherence to the course of therapy can significantly reduce positive transplant outcomes. In fact, lack of adherence can significantly increase the risk of rejection of the transplanted organ (Butler et al., 2004; Denhaerynck et al., 2005). Non-adherence and its consequences in the transplant population have been the focus of some investigators since the mid-1970s (Owens, Maxwell, Goodnight, and Wolcott, 1975). In addition to rejection, other adverse consequences of non-adherence may include increased hospitalizations and health care costs and decreased quality of life. Despite the potential for rejection and other untoward consequences, non-adherence to immunosuppressant regimens is surprisingly high with some estimates as high as 68% (Chisholm, 2005; De Geest et al., 2005; Dew et al., 1996). A 2004 meta-analysis of adherence in the renal transplant population reported an estimated median non-adherence rate of 22% with an interquartile range of 18% to 26% (Butler et al., 2004). Interestingly, non-adherence is an increasingly important problem in the pediatric population. Literature reports of non-adherence among pediatric renal transplant recipients range from 8% to 70% with a mean value of around 40% (Wolff et al., 1998). Research suggests that determinants of adherence in the pediatric population are somewhat different that their adult counterparts and tend to focus on the psychosocial development of the adolescent patient, level of family-functioning, and parent/caregiver stress levels (Wolff et al., 1998; Griffin & Elkin, 2001; Gerson, Furth, Neu, and Fivush, 2004).

Non-adherence may be the result of numerous factors, including the provision of poor instructions to the patient, apathy on the patient's part, lack of established patient-pharmacist relationship, patient confusion, and adverse effects associated with the agents. One major factor that is repeatedly mentioned in the literature is the potential financial barrier associated with immunosuppressant agents (Paris et al., 1999; Chisholm, 2004). Unfortunately, the number of non-elderly adults in the US without any health insurance is estimated to be between 16% and 18% (Hoffman & Schwartz, 2006). Medicare does provide coverage for kidney transplants in ESRD patients and some costs for other transplants depending on whether eligibility requirements are met. State Medicaid plans and third party insurers also provide some coverage for transplants (Chisholm, 2004; Yen, 2004; Woodward, 2001). The cost of immunosuppressant therapy is significant with annual estimated costs as high as $13,000 (Yen et al., 2004). Research findings suggest that access to prescription drugs continues to be a problem in the US. A 2003 survey by the Center for Studying Health System Change (CSHSC) reported that the percentage of adults who reported trouble filling a prescription for financial reasons was 12.8%. This figure was even higher at 18.3% among adults with at least one chronic

condition. Moreover, some 15% of adults with chronic health conditions reported not filling all of their prescriptions due to financial reasons. All of these figures represent significant increases over findings from a similar study in 2000 (CSHSC, 2005).

In a perfect world, the measurement of adherence would involve objective, practical, and unobtrusive processes (Rudd, 1979). Current measurement methods can generally be broken down into two categories: direct and indirect methods. Direct methods involve the assessment of whether the medication was actually taken and may include detection of the parent drug compound or metabolite in blood or urine. Personal observation of medication ingestion is another method of direct assessment. Indirect methods tend to be less intrusive but may also be less accurate. Methods such as patient self-reporting, pill counts, and electronic monitoring devices are all indirect methods with varying degrees of accuracy (Chisholm, 2002). One frequently used indirect method of assessing adherence involves using administrative claim data from prescription refills. Administrative claims can provide information on the number of doses dispensed (i.e., the days supply) and the days on which refills were processed. The medication possession ratio (MPR) is a frequently used measure of prescription adherence when using administrative claim data. It is defined as the sum of the days supply during the investigation period divided by the number of days during the same period (Sclar et al., 1991). The resulting value represents the percentage of time during the investigation period that the patient would have been in possession of a dose of the medication, hence the name of the measure. A patient is defined as "adherent" by selecting some cut-off value for the MPR. Although there are other methods for calculating adherence, the MPR has a long track record in the literature (Sikka, Xia, and Aubert, 2005; Steinger & Prochazka, 1997). As with most administrative claim-based measures, the MPR assumes that the patient actually took the medication as directed after the prescription was filled and in the patients' possession (Fairman & Motheral, 2000).

The current study sought to determine the adherence of transplant patients from the participating study pharmacies and then compared these estimates of adherence with literature-based adherence estimates. Using these estimates, the potential cost differences associated with varying adherence rates were examined, specifically the potential costs which would be incurred if patient's kidney graft failed.

Methods

Prescription fill data on transplant patients were obtained from each of the five participating study pharmacies. All patient identifiers, including names and dates, were masked so that patient confidentiality was maintained. Prescription fill data were obtained from January 1, 2005, to June 30, 2005, for patients with Medicare listed as the primary payer. In order to be eligible for analysis, patients had to have at least one prescription filled in the first month (January) and the last month (June) of the evaluation period. This criterion provided an equal follow-up period for each patient. The MPR was calculated for each immunosuppressant agent for each patient. As mentioned previously, MPR is defined as the total number of days supply available during the investigation period (that is, the sum of all the days supply dispensed minus the days supply of the last fill) divided by the length of time between the first fill and the last fill. Adherence was then defined as an MPR $\geq$ 0.8 (or 80%). The estimate of adherence in patients from the study pharmacies was used in a decision analysis to determine the potential

cost savings associated with increased compliance. For the purposes of this investigation, four immunosuppressant agents were included in the sample: azathioprine (Imuran®, Prometheus Laboratories), mycophenolate mofetil (CellCept®, Roche), mycophenolic acid (Myfortic®, Novartis), and sirolimus (Rapamune®, Wyeth). Cyclosporine A and tacrolimus, two commonly used immunosuppressant agents, were excluded since patients receiving these agents often undergo frequent dosage adjustments. With these frequent changes in dosages, great difficulty can arise in estimating the appropriate days supply value. Without an accurate estimation of days supply, significant discrepancies could arise between the estimated refill date and the actual refill date resulting in biased estimates of adherence for these agents. Estimates for overall compliance were obtained from the literature, and clinical and economic outcome estimates were obtained from the 2005 Annual Data Report published by the United States Renal Data System, or USRDS (2005). This report contains information compiled through 2003. Economic data were provided from Medicare's perspective since it is the primary payer for most renal transplant patients. Sensitivity analyses were conducted to examine the effects of changing the adherence and outcome estimates along clinically plausible ranges. Given that information on the type of organ transplanted was not available, all patients were assumed to have received kidney transplants to simplify the analysis. Statistical analyses were conducted in Stata/SE version 9 (StataCorp LP; College Station, TX). The decision analysis was performed using TreeAge Pro 2006 (TreeAge Software; Williamstown, MA).

Results

Assessment of adherence

A total of 16,537 individual prescriptions representing 3,362 patients were identified from the pharmacies. After applying the eligibility criteria, 1,599 patients were identified. In nine patients, age could not be determined so these patients were excused from the analysis resulting in a final sample size of 1,590. The mean ($\pm$ standard deviation) age of patients was 52.3 ($\pm$ 15.0) years. Age was divided into four categories for the analysis (Table 1). The two most frequently used products were mycophenolate mofetil (73.0% of patients) and sirolimus (19.3% of patients). The other two agents were used in less than 10% of the study sample. Most patients received only one immunosuppressant agent; however, two received both sirolimus and mycophenolate mofetil. The distribution of immunosuppressant usage by agent and age category is provided in Table 2.

To assess adherence with medication therapy, the MPR for each immunosuppressant agent for each patient was calculated. The mean MPR values for each agent across age categories are presented in Table 3. Overall, adherence was relatively high with most MPRs being greater than 0.8. Using the aforementioned adherence cutoff of an MPR $\geq$ 0.8, overall adherence ranged from 81.5% for sirolimus to 89.0% for azathioprine (Table 4). For patients receiving more than one agent, overall adherence was established if the MPR was greater than 0.8 for each prescribed immunosuppressant agent. Adherence was not significantly different across age categories. The adherence rate over all immunosuppressant agents and age was 84.2% for the study pharmacies.

Decision analysis

The second portion of the study involved assessing whether there were any potential cost savings associated with increased adherence. The adherence estimates generated above were

compared to adherence estimates from the literature. An expected adherence of 65% was used for the general transplant population (i.e., those other than the participating study pharmacies) (Chisholm, Mulloy, and DiPiro, 2005). Given the wide range of reported non-adherence rates, this "non-study" group adherence rate was varied from 40% to 95% in the sensitivity analysis. Clinical outcome probabilities and cost estimates were obtained from the literature and expert opinion. These estimates represented the probability of death, probability of survival with a functioning graft, and probability of survival with a failed graft. Using the most recent estimates from the USRDS, estimated annual costs for functioning grafts were $15,537 and $70,930 for failed grafts. The estimates are notably higher for failed grafts since they represent a return to chronic dialysis and associated dialysis maintenance services. The base probabilities and sensitivity analysis ranges are provided in Table 6. The decision tree was constructed using the outcome estimates. After rolling back the decision tree, the expected annual cost within the group of study pharmacies was $27,853 and $32,003 for other pharmacies (Figure 1). This represents a potential savings of $4,150 per patient over the course of a year associated with increases in adherence (Figure 2). In 2003, there were 15,136 kidney transplants according to the Organ Procurement and Transplantation Network (2006). Applying the cost estimates generated in this study to those kidney transplants, the study pharmacy adherence rate would result in projected costs of just over $421.6 million compared to $484.4 million for the non-study pharmacies resulting in a potential cost savings of almost $63 million due to increased adherence.

Discussion

Overall, the group of five study pharmacies exhibited a significantly higher adherence rates than literature-based estimates. These differences in adherence were associated with a significant cost avoidance per person. Still, it is important to note the assumptions made during the analysis. The decision analysis did not take into account any demographic information such as race or gender as it was unavailable for analysis. To simplify the analysis, overall probabilities and costs irrespective of age were used. Also, all transplanted organs were assumed to be kidneys. While it is unlikely that there are significant differences in adherence associated with other organ types (Schweizer et al., 1990; Dew et al., 1996; Wainwright & Gould, 1997; De Geest, 2005), it is possible that differences in adherence among those patients receiving other transplanted organs (ex., heart, liver, lung, etc.) could change the results. Renal transplantation was chosen for the current study because of the well-documented costs associated with functioning and failing grafts.

Another important potential limitation is the selection of literature-based estimates for cost and probabilities. Estimates for costs and graft survival probabilities were obtained from various literature reports as described above and in Table 6. Furthermore, all costs were provided with the assumption that the full costs would be incurred over the course of the following year, that is the individual would survive for an entire year and not die during that time period. When conducting a decision analysis, it is common to perform sensitivity analysis to determine whether changing any particular estimates might change the conclusions. Aside from changing the rates of adherence in the two study groups, the study pharmacies resulted in the lowest cost in almost all situations unless the probability of graft survival was extremely low (< 40%) in which case increased adherence would not be sufficient to overcome the low graft survival rate.

In the absence of drawing blood levels, there are various methods for estimating adherence using non-invasive means such as pill counts, patient surveys, and pharmacy refill data (Steiner & Prochazka, 1997; Chisholm, 2002; Chisholm, Lance, Williamson, and Mulloy, 2005). In this study, adherence was estimated using pharmacy claims by the medication possession ratio. Unfortunately, every method has certain limitations. The MPR method has been used extensively in the literature. Although the MPR does provide fairly accurate information about the percentage of time that medication is available for consumption, it does not provide information about the appropriate usage of medications with respect to time that the dose is taken (Sikka, Xia, and Aubert, 2005). It is possible that non-adherent patients were misclassified as adherent based solely on their refill history; however, these effects should be minimal. Actually, using administrative data theoretically avoids biases such as the "Hawthorne effect" associated with allowing patients to self-report adherence or directly inquiring about adherence through questionnaires (Fairman & Motheral, 2000).

One likely explanation for the difference in adherence rates is the service model that the study pharmacies employ in providing care to their patients. The five participating organizations all represent specialty pharmacies. These specialty pharmacies provide focused therapeutic management, medication distribution, and patient counseling to patients affected by high-cost, chronic disease states, such as multiple sclerosis, rheumatoid arthritis, hemophilia, and solid organ transplantation. The specialty pharmacy practice model provides unique benefits to the patient. Among these benefits are consolidated and controlled distribution of medications and financial support (ex., paperwork necessary for insurance reimbursement, patient assistance program applications, etc.). Specialty pharmacies may use such methods as proactive refill reminders, disease-focused education, and pharmacist-staffed patient call-centers to improve adherence and maximize patient outcomes (Pharmaceutical Care Management Association, 2005).

In addition to the financial barriers associated with adherence, there are strong behavioral and educational components to adherence that must be addressed (Newton, 1999). Through their proactive efforts, specialty pharmacies can address the important educational and behavioral barriers to adherence through direct and frequent patient-contact. Indeed, the dedicated support staff available at most specialty pharmacies provide an outlet for patients to seek information concerning their condition and potential effects of their medications, as well as a mechanism for reinforcement of concepts important for adherence. The increased level of contact could be of added benefit in the pediatric population where families and caregivers may encounter a variety of behavioral and psychological issues that adversely affect adherence (Griffin & Elkin, 2001; Gerson, Furth, Neu, and Fivush, 2004). Frequent contact with a pharmacist might provide increased awareness of the potential psychosocial barriers to adherence and promote dialogue between the pediatric patient, parent/caregiver, and pharmacist in order to promote adherence with the therapeutic regimen.

Medicare does provide payment to specialty pharmacies serving transplant patients. However, increases in drug acquisition costs and decreases in reimbursement may result in discontinuation of extra services for financial reasons. The results of this analysis support CMS's goal of using a "pay-for-performance" reimbursement framework to improve outcomes and reduce medical costs. In the new age of medication therapy management and the potential for increased reimbursement, it is important for actions to be taken by policymakers to ensure

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Table 1. Distribution of age categories

	Number	Percent
≤18	32	2.01%
19 – 40	344	21.64%
41 – 65	848	53.33%
> 65	366	23.02%
Total	1,599	100.00%

Table 2. Drug utilization across age categories*

	Azathioprine	Mycophenolate mofetil	Mycophenolic Acid	Sirolimus
≤18	3.13% (1)	78.13% (25)	0% (0)	21.88% (7)
19 – 40	4.65% (16)	73.55% (253)	2.62% (9)	19.19% (66)
41 – 65	6.25% (53)	73.47% (623)	1.53% (13)	18.87% (160)
> 65	7.92% (29)	71.04% (260)	2.19% (8)	18.85% (69)
Total	6.23% (99)	73.02% (1,161)	1.89% (30)	19.31% (302)

Values in parentheses indicate cell frequency.
*Percentages are within each age category. Each row may not sum to 100% as patients may have received multiple agents.

Table 3. Mean medication possession ratio (MPR) by drug and age category

	Azathioprine (n = 99)	Mycophenolate mofetil (n = 1,165)	Mycophenolic Acid (n = 30)	Sirolimus (n = 307)
≤18	0.97 (n/a[b])	0.96 (0.22)	—[c]	0.98 (0.19)
19 – 40	0.90 (0.23)	0.94 (0.18)	0.96 (0.13)	0.96 (0.22)
40 – 65	0.98 (0.15)	0.95 (0.18)	0.95 (0.13)	0.93 (0.18)
> 65	0.96 (0.14)	0.94 (0.20)	0.99 (0.12)	0.96 (0.27)
Overall[a]	0.96 (0.16)	0.95 (0.18)	0.96 (0.12)	0.94 (0.21)

Values in parentheses represent standard deviations.
[a]Overall values calculated on total sample within each drug (represented as "n" in the column headings).
[b]Standard deviations not calculated because there was only 1 person in that category.
[c]No patients were in this category.

Table 4. Adherence by drug and age category (defined as MPR ≥ 0.8)[a]

	Azathioprine (n = 99)	Mycophenolate mofetil (n = 1,165)	Mycophenolic Acid (n = 30)	Sirolimus (n = 307)
≤18	100.0% (1)	84.0% (21)	—[b]	85.7% (6)
19 – 40	81.3% (13)	82.6% (209)	77.8% (7)	83.4% (57)
40 – 65	90.6% (48)	85.7% (534)	84.6% (11)	81.3% (130)
> 65	89.7% (26)	83.5% (217)	87.5% (7)	76.8% (53)
Overall	89.0% (88)	84.5% (981)	83.3% (25)	81.5% (246)

Values in parentheses indicate cell frequency.
[a]Percentages represent the percent of patient within that age group who had an MPR ≥ 0.8.
[b]No patients were in this category.

Table 5. Total adherence by age category

	Percent adherent (Number)
≤18	84.4% (27)
19 – 40	83.1% (286)
40 – 65	85.1% (722)
> 65	82.8% (303)
Overall	84.2% (1,338)

Table 6. Decision analysis probability and cost estimates

	Initial estimate	Sensitivity analysis range
Adherence in group of study pharmacies	0.842	0.60 – 0.95
Adherence in other pharmacies	0.65[a]	0.40 – 0.95
Probability of death (regardless of graft survival status)	0.03[b]	0.02 – 0.10
Probability of functioning graft in adherent patients	0.894[c]	0.80 – 0.99
Probability of graft failure in non-adherent patients	0.578[d]	0.15 – 0.99
Cost of functioning graft per patient per year	$15,357[c]	$8,000 – $30,000
Cost of failed graft per patient per year	$70,930[c]	$30,000 – $140,000

[a]Chisholm, Mulloy, and DiPiro, 2005
[b]Yen et al., 2004
[c]USRDS, 2005
[d]Gaston et al., 1999

Figure 1. Decision tree with expected values

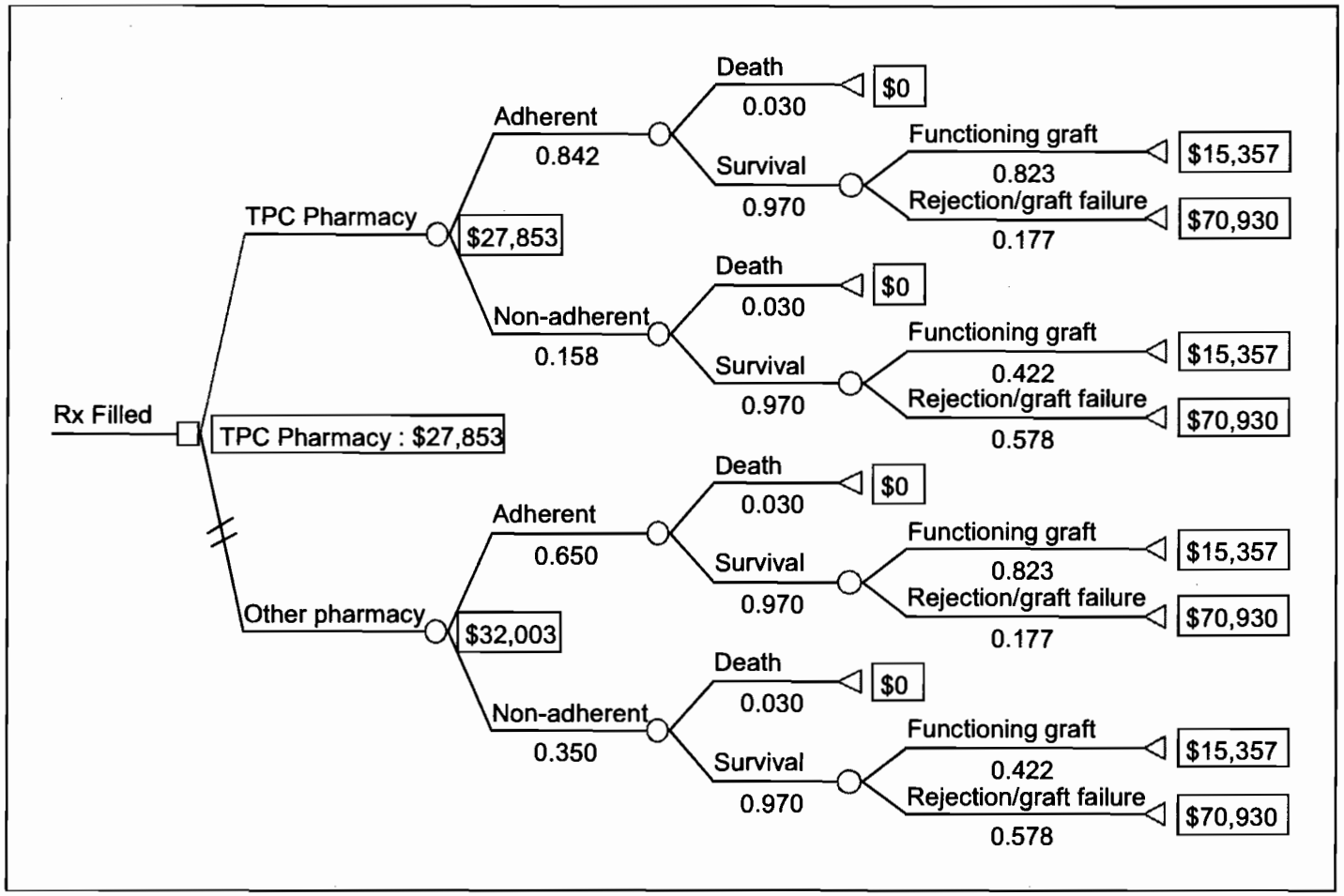
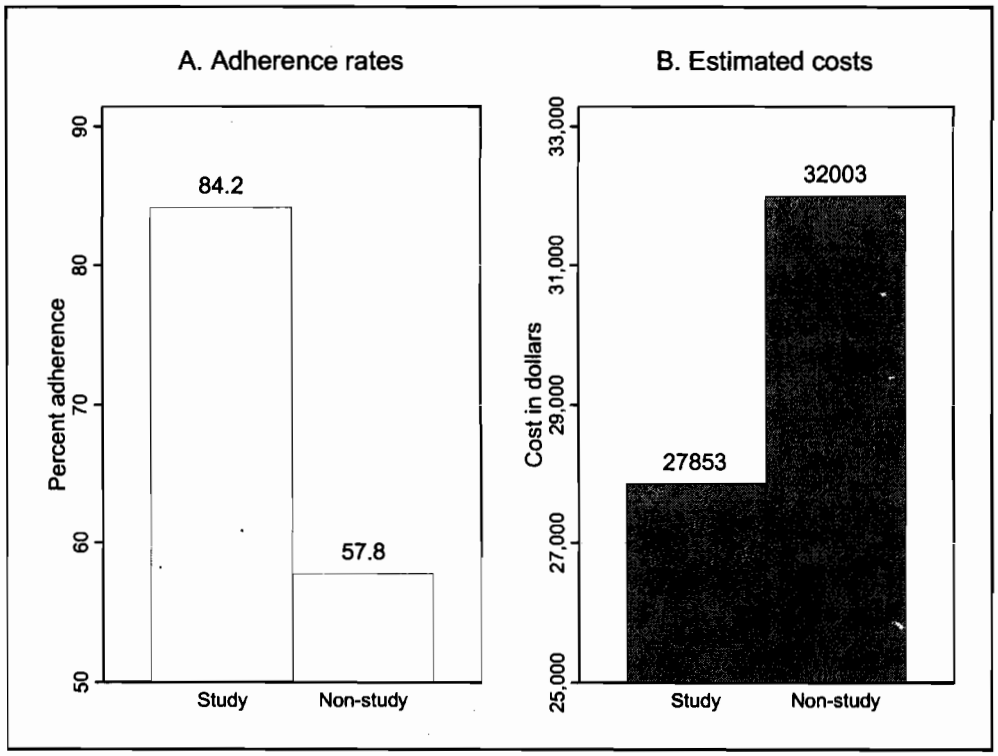


Figure 2. Comparison of adherence rates and estimated annual costs per person associated with type of pharmacy



#14546 Attachment #8

The Transplant Pharmacy Coalition
Comments Medicare Part B Supply Fee

Appendix 4
WAC Pricing Versus July 2007 ASP Rates

#14546 Attachment #9
CURRENT ASP REIMBURSEMENT SCHEDULE

NOTE: There are currently 10 Jcodes that are billed to CMS for immunosuppression. Seven of these ten are currently reimbursed at or below the acquisition cost of the pharmacy.

Jcode	Item	ASP	WAC	#Units	Loss
J7502	Cyclosporine 100 mg*	3.536	5.089	180	279.54
J7507	Tacrolimus 1 mg	3.738	3.812	240	17.76
J7509	Methylprednisolone 4 mg	0.086	0.287	60	12.06
J7510	Prednisolone 5 mg	0.029	0.079	60	3.00
J7515	Cyclosporine 25 mg*	0.916	1.274	180	64.44
J9517	Mycophenolate 250 mg	2.629	2.909	240	67.20
J7518	Mycophenolic 180 mg	2.269	2.452	240	43.92

* If brand name Neoral is dispensed. Currently about 50% of cyclosporine prescriptions are designated "DAW" (dispense as written).

WAC = Wholesale Acquisition Cost. This is the price that approximately 60% of retail pharmacies pay for their drugs.

Submitter : **Ms. Lori Bartenfeld** **Date: 08/31/2007**

Organization : **Dosher Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Physician Self-Referral Issues

I am a Physical Therapist in an outpatient setting and have concerns regarding Physician-owned therapy. As a PT, I have received numerous comments from current and previous patients that point to patient confusion in regards to choosing a facility for their rehabilitaion. It seems that many do not realize they have a choice and assume they must be seen by their doctor, despite the fact that the Physician office may be less convenient. There also seems to be quite a bit of evidence that points to overutilization by Physician -owned therapy services. Thank you for your consideration of these comments.

Submitter : **Ms. Sharmila Sandhu** **Date: 08/31/2007**

Organization : **American Occupational Therapy Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment for full comments.

CMS-1385-P-14548-Attach-1.DOC

#14548

The American Occupational Therapy Association, Inc.

Occupational Therapy: Skills for the Job of Living

Via online submission

August 31, 2007

The Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1282-P
P.O. Box 8016
Baltimore, MD 21244-8016

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)**

Dear Sir or Madam:

The American Occupational Therapy Association (AOTA) represents over 36,000 occupational therapy professionals, many of whom are reimbursed under the Medicare Physician Fee Schedule (MPFS) and are affected by Medicare Part B payment policies. We appreciate the opportunity to comment on the rule containing revisions to payment policies under the MPFS and other Part B payment policies for calendar year 2008, as published in the Federal Register on July 12, 2007 at 72 Fed. Reg. 38122. AOTA presents the following comments on the MPFS proposed rule:

I. THERAPY STANDARDS AND REQUIREMENTS

A. *Revisions to Personnel Qualification Standards for Therapy Services* (72 Fed. Reg. 38230)

AOTA is pleased to see that the Centers for Medicare and Medicaid Services (CMS) has proposed updated qualification standards for occupational therapists (OTs) and occupational therapy assistants (OTAs). For years, AOTA has been advocating for CMS to revise the regulations at 42 C.F.R.§ 484.4 since these regulations have been outdated for decades. AOTA recognizes the thoughtful consideration that went into the development of the proposed personnel qualifications, but we would like to suggest that CMS consider simplifying the requirements. ***We believe that the personnel qualifications should be simple and straightforward. We suggest that the personnel qualifications should first and foremost be tied to state regulation. In the case of states without state regulation or when services are being provided "incident to" a physician's service, we respectfully request that the education and exam requirements for the occupational therapy profession apply to those individuals wishing to provide occupational therapy services.***

The American Occupational Therapy Association, Inc. 4720 Montgomery Lane Bethesda, MD 20814-3425 301-652-2682 301-652-7711 Fax 800-377-8555 TDD www.aota.org

1. *AOTA Requests That Personnel Qualifications Be Tied to State Regulation First and Foremost*

For more than 25 years, AOTA has worked with state occupational therapy associations to enact state regulatory laws for the occupational therapy profession. As of August 2007, 47 states, the District of Columbia, Guam and Puerto Rico license occupational therapists; 2 states (Hawaii and Michigan) have registration laws and 1 state (Colorado) has a title protection law.

The form of regulation for occupational therapy assistants is often, but not always, the same for occupational therapists in a given jurisdiction. The District of Columbia, Guam, Puerto Rico and 43 states license occupational therapy assistants; 3 states (California, Indiana and New York) have certification laws; 1 state (Michigan) has a registration law and 1 state (Virginia) has a title protection law. Colorado and Hawaii do not regulate occupational therapy assistants.

State licensure, certification, registration and trademark laws establish education, training and exam requirements to practice as occupational therapists and occupational therapy assistants. These education, training and exam requirements are consistent across the states. AOTA closely monitors proposed changes in state occupational therapy practice acts and regulations and we advocate for state laws that are consistent with the Association's *Standards of Practice, Policy on Licensure* and the *AOTA Model Practice Act.*

AOTA has a long standing policy of supporting the role and authority of state regulatory boards. State occupational therapy regulatory boards have the legal authority to discipline practitioners who violate the law and have the authority to prevent someone from practicing that does not meet the licensure requirements. Furthermore, most state occupational therapy practice acts include a continuing education requirement for licensure renewal, which we believe reinforces the continuing competence of occupational therapists and occupational therapy assistants. To date we have heard no complaints from members or other stakeholders to suggest that the state practice acts are inadequate at protecting the public from unqualified or unscrupulous practitioners.

AOTA holds full confidence in state regulatory boards. In fact, nationally recognized accreditation organizations such as the Joint Commission (JCAHO) and the Commission on Accreditation of Rehabilitation Facilities (CARF) demonstrate similar confidence in state licensure boards by requiring verification of state licensure or related requirements for personnel employed by the facilities they accredit. For example, the Joint Commission (JCAHO) has a similar standard for many facility settings (including but not limited to hospitals; home care; long term care; and critical access hospitals), which requires that the organization have a process in place to ensure that organization staff qualifications are consistent with job responsibilities. An organization can meet this JCAHO standard by verifying the staff's current state licensure, certification, or registration at the time of hire or upon expiration of the credentials.

State legislatures have historically regulated the health professions. ***We request that CMS rely on these state laws to determine who is qualified to provide services under Medicare. To ensure that there are standards in place for states without regulation, we request that 42 C.F.R. § 484.4 include the education and exam requirements that personnel must meet to practice as occupational therapists or occupational therapy assistants.*** While most states license or otherwise regulate the occupational therapy profession, there have been attempts to deregulate health professions in the name of regulatory reform and cost savings. By including the education and exam requirements in 42 C.F.R. §484.4, there will still be standards in place should a state or states unwisely decide to deregulate the occupational therapy profession.

2. *AOTA's Recommended Language Maintains the Integrity of Incident to Services*

AOTA asserts that our interpretation of AOTA's recommended language does not create a problem for the occupational therapy profession by permitting unqualified personnel to perform incident to occupational therapy services under 42 C.F.R. § 410.59. The incident to provision at 42 C.F.R. § 410.59(a)(3)(iii), requires that an individual must meet the qualifications in 42 C.F.R.§ 484.4 for an occupational therapist or appropriately supervised occupational therapy assistant, except that a license to practice occupational therapy in the state is not required. As set forth in greater detail below, AOTA's recommended language for § 484.4 states that a qualified occupational therapist must meet one of two requirements: 1) be licensed or otherwise regulated as an occupational therapist by the state of practice or 2) graduate from an occupational therapist education program accredited by ACOTE and successfully complete or be eligible to take the entry-level certification examination for occupational therapists.

AOTA's recommended language then, read together with the incident to provision at § 410.59(a)(3)(iii), would permit an individual to provide incident to occupational therapy services without a license to practice occupational therapy in the state **only if** the remaining AOTA recommended requirement for § 484.4 is satisfied (since licensure is not required under the incident to provision)—that the individual graduate from an occupational therapist education program accredited by ACOTE and successfully complete or be eligible to take the entry-level certification examination for occupational therapists. AOTA asserts that an individual who has completed an accredited occupational therapy education program is qualified to provide incident to therapy services. This supports an underlying principle in AOTA's recommended language that any personnel providing occupational therapy services much be officially recognized (through formal education in OT school or licensure) as an occupational therapist. ***We do not believe that these two regulatory provisions could be read together to eliminate the occupational therapist education/exam requirement and it is AOTA's intent that this education/exam requirement remain in place for individuals providing incident to services.***

AOTA RECOMMENDED LANGUAGE

42 C.F.R. § 484.4 Personnel Qualifications

Occupational Therapist.
(1) For an occupational therapist trained in the United States, a person who meets either of the following requirements:
(i) Licensed or otherwise regulated as an occupational therapist by the state in which he or she is practicing; or
(ii)(A) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or predecessor organizations; and (B) Successfully completed or is eligible to take the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT) or another credentialing body recognized by the American Occupational Therapy Association.

(2) For an occupational therapist trained outside the United States, a person who meets either of the following requirements:
(i) Licensed or otherwise regulated as an occupational therapist by the state in which he or she is practicing; or
(ii)(A) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or predecessor organizations; or graduated after successful completion of an occupational therapist education program approved by the World Federation of Occupational Therapists; and (B) Successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT) or another credentialing body recognized by the American Occupational Therapy Association.

Occupational Therapy Assistant.
(1) For an occupational therapy assistant trained in the United States, a person who meets either of the following requirements:
(i) Licensed or otherwise regulated as an occupational therapy assistant by the State in which he or she is practicing;
or
(ii) (A) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or predecessor organizations; and (B) Successfully completed or is eligible to take the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT) or another credentialing body recognized by the American Occupational Therapy Association.

(2) For an occupational therapy assistant trained outside the United States, a person who meets either of the following requirements:
(i) Licensed or otherwise regulated as an occupational therapy assistant by the State in which he or she is practicing;
or
(ii)(A) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA); and (B) Successfully completed the entry-level certification examination for occupational therapy assistants developed by a credentialing body recognized by the American Occupational Therapy Association.

AOTA Comments Regarding CMS Proposed Personnel Qualifications

Again, AOTA recognizes the thoughtful consideration that went into the development of the proposed personnel qualifications. With this in mind, we would like to address some of the specific concerns we have with language proposed by CMS for occupational therapists and occupational therapy assistants.

CMS Proposal:

Occupational therapist. A person who meets one of the one of the following requirements:
(1) *Requirements for individuals beginning their practice on or after January 1, 2008.* Meets all practice requirements set forth by the State in which occupational therapy services are furnished and meets one of the following educational/training requirements on or after January 1, 2008:

(i)(A) Graduated after successful completion of an occupational therapist curriculum accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA); and

(B) Successfully completed the National Registration Examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

AOTA Comments:

- This provision establishes standards based on when an individual begins their practice after January 1, 2008. CMS should clarify how this requirement will be applied. Does this mean when someone starts to provide services under Medicare or when an individual starts to practice occupational therapy in general?
- ACOTE accredits education programs rather than curriculum.
- Language regarding ACOTE should also address predecessor organizations.
- Language regarding the exam should allow for another professionally recognized credentialing body besides NBCOT to develop or administer the entry-level examination in the event that NBCOT leaves the market or another body enters into the market to offer the entry level exam.
- This provision requires occupational therapists to pass the exam. Many states offer temporary licenses/permits to occupational therapists that have graduated from school and are eligible to take the exam. The CMS proposal would be more restrictive and have a profound negative impact on new graduates entering the workforce. We believe that the standard should be that the individual has passed the exam or is eligible to take the exam.

CMS Proposal:

(ii) If educated outside the United States, or trained by the United States military—

(A) Graduated after successful completion of an occupational therapist curriculum accredited by the World Federation of Occupational Therapists, (WFOT));

(B) Is deemed eligible to test as a result of completing the NBCOT International Occupational Therapy Eligibility Determination (IOTED) review; and

(C) Successfully completed the National Registration Examination developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT)).

AOTA Comments:

- The United States Military does not offer education programs for occupational therapist at this time. Any future military program would need to meet ACOTE standards for occupational therapy programs in the United States. The United States Department of Education recognizes ACOTE accreditation standards.
- NBCOT determines the education requirements to sit for the examination. We do not believe it is necessary to include information about the IOTED process in the regulations.
- ACOTE should be mentioned along with WFOT as a body that may accredit foreign education programs.
- Language regarding the exam should allow for another professionally recognized credentialing body besides NBCOT to develop or administer the entry-level examination in the event that NBCOT leaves the market or another body enters into the market to offer the entry level exam.
- Consistent with regulations from the Department of Homeland Security (8 CFR Part 212.15(f)(1)(iv)), foreign trained occupational therapists should be required to pass the entry-level certification exam.

CMS Proposal:

(2) *Requirements for individuals beginning their practice after December 31, 1977 and before January 1, 2008.*

Meets the one following requirements after December 31, 1977 and before January 1, 2008:

(i) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association. (ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association.

(3) *Requirements for individuals beginning their practice on or before December 31, 1977.* (i) Has 2 years of appropriate experience as an occupational therapist; and (ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service on or before December 31, 1977.

AOTA Comments:

- These provisions reference archaic standards for the exam and occupational therapy education programs. AOTA and AMA collaborated on standards for occupational therapy education programs from 1935-1993; ACOTE became operational as an accrediting agency independent of CAHEA/AMA on January 1, 1994. The national registration exam for occupational therapists was initially offered by AOTA, then the American Occupational Therapy Certification Board (AOTCB) which is now known as the National Board for Certification in Occupational Therapy. NBCOT was formed in 1986 as AOTCB and retains the historical record for anyone that has taken the entry-level exam. AOTA has urged CMS to update these standards for many years.
- State laws define education, training and exam requirements. State regulatory bodies have already "grandfathered in" occupational therapists that met the old standards.
- If CMS retains this provision, the language should be amended to recognize the appropriate education and examination entities for both US trained and internationally trained occupational therapists.

CMS Proposal:
Occupational therapy assistant. A person who meets one of the following requirements:

(1) *Requirements for individuals beginning their practice on or after January 1, 2008.* Provides certain occupational therapy services under the supervision of a qualified occupational therapist, continues to meet all practice requirements set forth by the State in which occupational therapy services are furnished, and meets one of the educational/training requirements if his or her professional practice begins on or after January 1, 2008:
(i)(A) Graduated after successful completion of coursework and clinical field work from an occupational therapy assistant curriculum accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA); and (B) Successfully completed the certification examination for Certified Occupational Therapy Assistant developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

AOTA Comments:

- The proposed standards for occupational therapy assistants include provisions regarding supervision. While we agree that occupational therapy assistants must practice under the supervision of an occupational therapist, that issue might be best addressed in separate regulations or in CMS Medicare Manuals, as is done under the current 42 CFR §484.4. Currently the qualification standards for occupational therapy assistants do not reference supervision. AOTA also supports the role of state occupational therapy practice acts and regulations to address supervision of issues. In fact, many state laws are based upon AOTA professional standards regarding supervision and role delineation.
- This provision establishes standards based on when an individual begins their practice after January 1, 2008. CMS should clarify how this requirement will be applied. Does this mean when someone starts to provide services under Medicare or when the starts to practice occupational therapy in general?
- ACOTE accredits education programs rather than curriculum.
- This provision includes a requirement that occupational therapy assistants complete coursework and clinical fieldwork. Fieldwork is part of the education program, so this provision could be simplified to require that the person complete an accredited education program.
- Language regarding ACOTE should also address predecessor organizations.
- Language regarding the exam should allow for another professionally recognized credentialing body besides NBCOT to develop or administer the entry-level examination in the event that NBCOT leaves the market or another body enters into the market to offer the entry-level exam.
- This provision requires occupational therapy assistants to pass the exam. Many states offer temporary licenses/permits to occupational therapists that have graduated from school and are eligible to take the exam. The CMS proposal would be more restrictive and have a profound negative impact on new graduates entering the workforce. We believe that the standard should be that the individual has passed the exam or is eligible to take the exam.

Department of Education (USDE) for recognition as the accrediting body for occupational therapy assistant education. In 1991, occupational therapy assistant programs with approval status from the AOTA Accreditation Committee became accredited by CAHEA/AMA in collaboration with the AOTA Accreditation Committee. ACOTE became operational as an accrediting agency for OT and OTA programs independent of CAHEA/AMA on January 1, 1994. The national certification exam for occupational therapy assistants was initially offered by AOTA in 1977, then the American Occupational Therapy Certification Board which is now known as the National Board for Certification in Occupational Therapy. NBCOT was formed in 1986 as AOTCB and retains the historical record for anyone that has taken the entry-level exam. AOTA has urged CMS to update these standards for many years.

- State laws define education, training and exam requirements. State regulatory bodies have already "grandfathered in" occupational therapy assistants that met the old standards.
- If CMS retains this provision, the language should be amended to recognize the appropriate education and examination entities for both US trained and internationally trained occupational therapy assistants.

B. Cross-References to Personnel Qualifications (72 Fed. Reg. 38231)

AOTA concurs with CMS that therapy personnel qualifications should be required according to the same standards and policies in all settings to the extent possible, consistent with statute. AOTA supports revised regulations which cross-reference the personnel qualifications for occupational therapists and occupational therapy assistants in 42 C.F.R. §484.4 in these settings:

- Inpatient Hospital Services and Inpatient Critical Access Hospital Services
- Posthospital SNF Care
- Partial hospitalization services
- Outpatient occupational therapy services
- Hospice
- Rehabilitation Services
- Comprehensive Outpatient Rehabilitation Facilities
- Clinics, Rehabilitation Agencies, and Public Health Agencies

C. Application of Consistent Therapy Standards (72 Fed. Reg. 38193)

1. Standards Must Not Impede Access to Occupational Therapy

While AOTA supports the general intent of consistent standards and appreciates the helpful recognition that occupational therapy services can only be furnished by qualified occupational therapists (OTs) and occupational therapy assistants (OTAs), AOTA is gravely concerned that the same standards can not be applied across all therapy settings without negative impact in some settings. The MPFS proposed rule would require that inpatient hospital therapy services require a treatment plan consistent with that

established in a Medicare outpatient setting through new proposed regulation 42 C.F.R.§ 409.17. Specifically, the new regulation would require establishment of a treatment plan before treatment begins and that any changes in the plan be incorporated immediately in writing and signed by a treating practitioner. Hospital inpatient practice is often done quickly and the timing of physician approval of the treatment plan may take 24 hours, delaying provision of ordered care. A physician order in the chart should be sufficient to begin treatment. Any changes to the inpatient hospital requirements should enhance patient care and expedite the delivery of medically necessary therapy services. ***AOTA asserts that changes to inpatient hospital documentation requirements should not impede or delay access to therapy unnecessarily in an inpatient setting.***

2. *Service Delivery Distinctions Exist Across Settings*

The manner in which occupational therapy services are furnished to acutely ill beneficiaries in an inpatient setting differs significantly from how the same services are furnished and paid for in the typical Part B outpatient setting. In the typical Part B setting, beneficiaries are seen by scheduled appointment, with both the payment and scheduling taking into account the therapists' time spent providing services as well as documenting every minute of treatment and evaluation in the record. However, in the inpatient hospital, beneficiaries often are furnished occupational therapy services at the bedside, with their availability subject to a myriad of procedures and tests performed by other hospital personnel related to their acute condition. A therapist may only have an hour with a patient on one day and the same patient may be suddenly discharged by the physician only days later.

While both inpatient and outpatient settings require an occupational therapy plan of treatment, in the inpatient hospital setting, the patient's acuity and a number of other factors significantly impact the feasibility of implementing that plan of care and how far into the future a plan goes. A hospital inpatient plan of treatment may only go to the point of discharge and not toward regaining pre-morbid levels of function—those are likely to be addressed in subsequent or outpatient care. ***AOTA asserts that time frames are more limited and unpredictable in inpatient hospitals than in Part B outpatient settings, and new proposed regulation 42 C.F.R. § 409.17 should allow for such differences, while still assuring proper documentation.***

AOTA is also concerned that the proposed rule brings back part of CMS' Transmittal 65 that was issued earlier this year, but then rescinded. Transmittal 65 would have required that local Medicare contractors apply Part B outpatient payment policies to acute care hospitals, inpatient rehabilitation facilities, psychiatric hospitals and units, long term acute care hospitals, and critical access hospitals. ***AOTA urges CMS to avoid requiring Medicare Part B outpatient therapy policies in Part A inpatient settings if they result in undue burden to therapists in those facilities.***

3. *Changes to Plan of Treatment Cannot Always be Incorporated Immediately in Inpatient Hospital Settings*

One problem in requiring a plan of treatment where any changes to the plan must be "made in writing, incorporated immediately, and signed" by the treating practitioner in all inpatient hospital settings will be that often hospital inpatients are discharged from the hospital prior to the completion of the therapy plan of care, which often precludes incorporating all relevant changes in the treatment plan or the completion of a therapy discharge plan. Another example is the use of dictation in smaller hospitals; sometimes a dictation backlog occurs making it more difficult to meet the requirement in the proposed rule to immediately incorporate in writing and sign any changes to the treatment plan. The "incorporated immediately" requirement is unclear. ***AOTA respectfully request that CMS revise proposed 42 C.F.R. § 409.17(d) "content of plan" to require that any change to the plan be incorporated into the medical record "as soon as possible" and to eliminate the requirement that changes be "incorporated immediately" in light of the unpredictable circumstances in which hospital inpatient occupational therapists practice.***

4. *Proposed Rule Increases Therapy Documentation Burden*

In depth documentation in the acute inpatient hospital setting would be quite time consuming and costly, with limited benefit in terms of assuring appropriate payment. Proper documentation under Part B is critical to determine if the therapy is necessary and appropriate, and thus reimbursable. Inpatient care is part of an overall treatment protocol paid for in toto; necessary and appropriate payment for therapy services is determined within the scope of the larger treatment plan. In addition, such an increased requirement may have the unintended consequence of hospitals electing to forgo identifying therapy services as skilled and not reporting them as therapy in order to avoid the time and cost of meeting these enhanced documentation requirements. We see this as a particular problem in acute hospitals. AOTA also questions the relation of these new requirements to the Paperwork Reduction Act (44 U.S.C. §3501). ***AOTA respectfully requests that CMS reconsider requiring increased documentation in the inpatient hospital setting, particularly in acute care hospitals.***

5. *Clarify "Content of Plan" requirement in Proposed 42 C.F.R. § 409.17(c)*

Another issue involves goal setting. Not all services provided in acute care involve interventions intended to change a person's functional status. Some services are purely diagnostic/evaluative (e.g., bedside swallow evaluation), case management (e.g., discharge planning, procurement of equipment, referrals), or preventative (e.g., splinting to prevent decubiti, ROM to prevent contractures). These are occupational therapy services that are medically necessary, but goal setting and treatment planning may not fit the mold of what's typically required by CMS in outpatient settings -- i.e., functional restoration. ***Thus, AOTA asserts that the section for "content of plan" needs further clarification to reflect OT services that are skilled and medically necessary in a manner appropriate for inpatient settings.***

6. *AOTA Agrees that Recertification Requirements Need Not Apply in Inpatient Hospitals and Requests Deletion of Reference to Certification*

AOTA agrees with CMS' rationale regarding the decision not to apply recertification requirements to inpatient hospitals because the physician's review and certification of the treatment plan is implied by the review and approval of a facility plan that includes therapy services. The decision appears to appropriately consider occupational therapy practice needs and patterns in facility settings. CMS clarifies in the preamble language that certification requirements will not apply in inpatient hospitals and that review of the plan of treatment should occur as the patient's condition requires in inpatient hospitals. AOTA agrees with this rationale, but finds the reference to certification in the last phrase of 42 C.F.R. § 409.17(e) to be inconsistent with the CMS preamble rationale. ***Thus, AOTA requests that CMS delete the last phase of proposed regulation 42 C.F.R. § 409.17(e), which states, "but at least prior to certification."***

D. Outpatient Therapy Certification Requirements (72 Fed. Reg. 38193)

AOTA has previously advocated for and strongly supports the MPFS rule proposal, in proposed regulation 42 C.F.R. § 424.24, to permit a plan of care to cover therapy services for up to 90 days and that recertification would be required for therapy services provided beyond 90 days. This positive change to the certification and recertification timing allows for variation among patients' needs and puts decision-making back in the hands of treating practitioners.

While AOTA agrees that there may be public policy reasons to ensure that physicians (or other appropriate practitioners) review the therapy plan of care and attest to a continuing medical need for therapy services, the length of time for recertification at 30 days was arbitrary and not based upon any data about the need for recertification. AOTA also strongly supports CMS' rationale for changing the certification requirement because many other means of ensuring appropriate utilization exist, including CCI edits, recent edits required by the Deficit Reduction Act, local coverage determination policies and related local contractor and CMS claims review mechanisms, to name a few.

Physicians rely on close communication with the therapist to track the progress and effectiveness of therapy and will choose to see the beneficiary again based on their consultation with the therapist. The proposed 90 day recertification requirement puts medical decision making squarely where it belongs, back into the hands of the treating physician, in coordination with the occupational therapy practitioner. ***AOTA strongly supports CMS' action in the MPFS proposed rule to leave it up to the physician's discretion to determine when and how often it is necessary for each beneficiary under his or her care who is receiving occupational therapy services to be reassessed.***

II. <u>TRHCA—SECTION 201: THERAPY CAPS</u> (72 Fed. Reg. 38205)

AOTA continues to oppose the underlying policy to apply a financial cap on therapy services. AOTA asserts the therapy cap is an arbitrary and inappropriate solution to assure correct utilization of therapy services. As CMS stated itself in the preamble of the proposed rule with respect to changes in therapy certification timing, **CMS has**

instituted many other means of ensuring appropriate utilization of therapy services. Some of these means include: CCI edits, edits required by the Deficit Reduction Act, local coverage determination policies and related local contractor claims review mechanisms, and Transmittal 63 setting forth greater documentation and evaluation requirements, among others.

Although AOTA recognizes that current law allowing for the exceptions process will expire on December 31, 2007, AOTA continues to advocate that Congress take action to extend the exceptions process. AOTA asserts that the exceptions process is effectively achieving its original objective to assure appropriate therapy service utilization and create savings for the Medicare program. The feedback that AOTA has heard from occupational therapists regarding the cap exceptions process has been overwhelmingly positive with regard to the diagnoses (ICD-9 codes) that are acceptable for automatic exceptions. At the same time, Preliminary Part B carrier data suggests a large decrease in Medicare expenditures for outpatient therapy services. The exceptions process has only been in effect for two years, and there is certainly room for improvement and further tightening of the system. AOTA is happy to assist with any endeavors to improve the cap exceptions process. In addition, AOTA has been working closely with CMS and Congress on appropriate alternatives to the therapy cap and will continue to offer feedback needed by CMS. ***In conclusion, AOTA asserts that the therapy cap is arbitrary CMS policy and AOTA continues to strenuously advocate to Congress to extend the cap exceptions process because it is effectively achieving its objective to assure appropriate utilization.***

III. COMPREHENSIVE OUTPATIENT REHABILITATION FACILITY (CORF) ISSUES

A. *Social and Psychological Services* (72 Fed. Reg. 38174)

With regard to the change in the definition of social and psychological services in CORFs, AOTA is concerned with the underlying premise that mental illness falls outside of the purpose of CORFs stated as "rehabilitation of injured, disabled or sick patients." While AOTA appreciates CMS' intent to interpret the underlying purpose of CORFs and prevent inappropriate use of CORFs, we urge caution in using the arguments CMS presents that mental illnesses do not make patients "disabled or sick" and that rehabilitation cannot or should not be provided to those with mental illnesses. AOTA recognizes that there are other Medicare benefits that specifically meet the needs of individuals with mental illnesses; for example, partial hospitalization, which includes occupational therapy, is available for patients with specific mental illness diagnoses. However, we urge CMS to be cautious about separating mental illness rehabilitation from physical illness rehabilitation. While CMS may choose to limit the diagnoses that are reimbursable in a CORF rehabilitation plan, AOTA wants to emphasize that care should be taken in making these distinctions overall. CMS states that social and psychological services should "include only those services that address the patient's response and adjustment to the treatment plan" and other items related to the "rehabilitation goals." AOTA notes that "rehabilitation goals" can in some contexts be related only to a mental illness rehabilitation plan that contains occupational therapy. While AOTA is not aware

of any CORFs providing occupational therapy services solely to provide rehabilitation for mental illness, occupational therapy provided in other contexts does address mental illness.

Furthermore, in CORFs, occupational therapy may be provided for an individual who has had a stroke but who also has mental illness such as schizophrenia. Attention to the schizophrenia related to rehabilitation for the stroke would be central to an occupational therapist's approach to the treatment plan. AOTA does not want to see the CMS proposed change to the definitions of social services and psychological services to be too broadly interpreted as meaning that mental illness would be a valid reason for denial of CORF eligibility. Nor does AOTA want to have the proposal implemented in ways that have a chilling effect on or limit the full and appropriate scope of occupational therapy. It is intrinsic to the profession of occupational therapy to consider the functioning of the whole person in occupational therapy evaluations—and this includes social and psychological aspects of performance. The Occupational Therapy Framework, the profession's guiding practice document, describes social participation as an area of occupation including activities associated with organized patterns of behavior that are characteristic and expected of an individual or an individual interacting with others within a given social system. Social and psychological issues are critical constructs to address in any rehabilitation plan of occupational therapy.

Thus, while we see the intent of CMS, we urge caution in separating mental and physical illnesses and their rehabilitation. ***AOTA urges CMS to further refine its arguments about the appropriate use of CORFs to provide rehabilitation for mental illnesses and to assure that any interpretation of policy does not restrict the provision of needed occupational therapy to address the psychosocial aspects of a beneficiary's function.***

B. *Clarification and Payment Updates for Other CORF Services* (72 Fed. Reg. 38175)

1. AOTA Supports CMS Clarification Regarding Therapy Provided in the Beneficiary's Home

The MPFS proposes to clarify at § 410.105(b)(3) that no fixed location requirement exists, permitting CORF therapy services, including occupational therapy, to be furnished in a beneficiary's home when payment for those services are not otherwise covered under the Medicare home health benefit. ***AOTA supports the CMS clarification regarding therapy provided in the beneficiary's home.***

2. Home Environment Evaluation Presence Requirement Needs Clarification

In addition, the proposed rule would clarify that the beneficiary must be present in their home, *as appropriate*, for coverage of the home environment evaluation described in proposed § 410.100(k). CMS believes beneficiary presence is necessary to fully evaluate the potential impact of the home situation on the rehabilitation goals. AOTA asserts that

requiring the beneficiary to be present in the home following discharge from certain settings, such as skilled nursing facilities (SNFs), is not always beneficial for an occupational therapist to perform her work. It is the occupational therapist's role to evaluate the entire environment to assess whether it is most conducive to current beneficiary function upon discharge from a setting like a SNF; sometimes a therapist determines that this evaluation is best performed without the beneficiary present. ***AOTA respectfully requests that CMS clarify the meaning of the language "as appropriate" in the context of proposed § 410.100(k)(2) to permit therapists to use their clinical judgment in situations where it may be inappropriate to have the patient present during the home environment evaluation.***

IV. TRHCA – SECTION 101(B): PHYSICIAN QUALITY REPORTING INITIATIVE (PQRI)

A. *Requirements for Measures Included in the 2008 PQRI* (72 Fed. Reg. 38196)

AOTA supports CMS in requiring that a consensus based process must be used for developing measures. AOTA also supports the process of requiring National Quality Forum (NQF) or AQA Alliance (AQA) endorsement of measures. AOTA would also support CMS considering other valid national endorsement bodies for purposes of reviewing and adopting PQRI quality measures. Furthermore, CMS should assure that initial development of measures is done in an open process emphasizing participation by all appropriate professional associations.

B. Categories of Proposed 2008 PQRI Quality Measures (72 Fed. Reg. 38199)

1. Table 16- 2007 PQRI Measures

AOTA requests that CMS consider expanding the possible eligible providers for certain current 2007 measures to include occupational therapists beginning on January 1, 2008. Previously, AOTA prepared detailed specifications and submitted a formal request to CMS and the American Medical Association that occupational therapists be deemed eligible to apply the following measures in the 2007 PQRI[1]:

- Screening for Future Fall Risk
- Plan of Care for Urinary Incontinence in Woman Aged 65 Years and Older
- Osteoporosis: Communication with the Physician Managing Ongoing Care Post Fracture
- Stroke and Stroke Rehabilitation: Screening for Dysphagia
- Cataracts: Assessment of Visual Functional Status

AOTA was granted only one of the above measures for 2007, Screening for Future Fall Risk. While AOTA understands that the statute does not allow refinements or modifications to the detailed specifications for 2007 PQRI quality measures, there does

[1] AOTA will provide a copy of its proposed 2007 specifications for CMS review upon request.

not appear to be a restriction on revising the 2007 quality measure specifications for use in the 2008 PQRI. ***AOTA respectfully requests that CMS create a process to give consideration to including occupational therapists as eligible to apply the 2007 measures cited above in the 2008 PQRI.***

2. Table 18- Non-Physician Measures Currently Under Development

AOTA greatly appreciates the opportunity to be involved with the PQRI and to help identify occupational therapists to assist Quality Insights of Pennsylvania (QIP) to develop relevant non-physician measures. AOTA has been working closely with QIP since measure development was initiated in 2007. Occupational therapists are eligible professionals for and continue to be closely involved with QIP's 2008 measure development and beta testing for the following measures:

- Documentation Of Current Medications In The Medical Record
- Patient Co-Development Of Plan Of Care
- Pain Assessment Prior To Initiation Of Patient Treatment

AOTA supports CMS inclusion of the above measures because development will be completed in a timely manner for the 2008 PQRI, the measures consider critical policy goals, these measures act to augment the recognition of services provided by occupational therapists beyond the one measure currently available, and these measures fill a need in the Medicare program for consistency in documenting the current medications taken by a patient, assessing the level of pain and considering the patient's objectives in developing the plan of care. ***Since occupational therapists were directly involved in developing these measures, AOTA also asserts that occupational therapists should be deemed eligible providers for the three measures cited above.***

However, under Table 18, QIP non-physician measures on Federal Register pages 38201-38202, there are several listed measures that we understand currently do not apply to occupational therapists. AOTA asserts that the following additional Table 18 measures should apply to occupational therapists as eligible professionals because these measures fit squarely within the occupational therapy scope of practice and meet the important policy goals set forth by CMS in the proposed rule:

- *Universal Weight Screening (BMI)*
- *Screening for Clinical Depression*
- *Screening for Cognitive Impairment*
- *Patient Co-Development of Treatment Plan*

Universal Weight Screening (BMI) fits within the scope of occupational therapy practice. AOTA believes that inquiry into a patient's weight should be a quality consideration asked by every health care professional upon initial Medicare evaluation. A number of studies have demonstrated that obesity appears correlated with increased risk of both acute and chronic diseases, including type II diabetes, sleep apnea, chronic low back pain, hypertension, breast cancer, prostate cancer, colon cancer, cardiovascular

disease, stroke, gall bladder disease, joint problems, activity limitations, reduced generalized health ratings, psychological issues, discrimination, and an increased mortality rate. Occupational therapy is a health care profession that is qualified to provide interventions with individuals, groups, and society to effect change to promote optimum health

Occupational therapy services are often used directly and indirectly to influence weight management and related health concerns through attention to lifestyle and engagement in fulfilling activities. According to AOTA's Obesity and Occupational Therapy Position Paper, occupational therapy interventions in the area of obesity may include, but are not limited to: community programs of health promotion through lifestyle change; education programs; facilitating the development of new habits and routines; recommendation of home modifications; adaptations/equipment; compensatory training in ADL and IADL; wellness programs for adults; patient handling programs in hospitals and skilled nursing facilities; and post-surgical acute care interventions. Occupational therapy practitioners apply their knowledge about engagement in occupation—that is, "everyday life activity"—to help clients who may be experiencing disease, impairment, disability, dissatisfaction, or adverse circumstances to participate in their daily life in a manner that supports their health and well-being.

Screening for Clinical Depression fits within the scope of occupational therapy practice. AOTA believes that inquiry into a patient's mental health should be a quality consideration asked by occupational therapists upon initial Medicare evaluation. Occupational therapy practitioners are skilled in helping people deal with stress, depression, and other emotional issues. Practitioners also offer clients wellness techniques that may prevent injury and disease. People with clinical depression may have difficulty completing tasks at work, managing a household, participating in leisure activities, and maintaining healthy relationships with family and friends. Occupational therapists can help people with clinical depression to regain their ability to function in their daily lives at work and at home through the following skills: evaluating a person's ability to take care of himself or herself; identifying treatment goals that are meaningful to the person such as establishing a personal care routine, managing money, communicating effectively with family/caregivers, and setting realistic short-term and long-term goals; adapting activities and the environment so that the person can participate in tasks that are meaningful to them; monitoring a person's response to medication used for treating clinical depression; and educating family members and caregivers about clinical depression, and collaborating with them on treatment goals.

With regard to ***Screening for Cognitive Impairment***, we understand that QIP supports including occupational therapists as eligible professionals able to apply this measure. AOTA believes that inquiry into a patient's cognitive abilities should be a quality consideration asked by occupational therapists upon initial Medicare evaluation. During AOTA's recent collaboration with QIP, occupational therapists serving on an expert work group for QIP mentioned that they were interested in developing a measure related to screening for cognitive impairment because it is a relevant quality issue that most therapists consider in the initial evaluation of a Medicare beneficiary. AOTA was

informed by QIP that, even though this measure was developed for use by social workers and psychologists, QIP would make a request for occupational therapists to be added to the eligible professional listing. QIP also has provided AOTA with the opportunity to comment on potential changes to the measure language to assure it is written in a way that is conducive to application by an occupational therapist. AOTA appreciates and supports QIP's consideration of the applicability of measures to the scope of practice of additional professionals.

With regard to the measure ***Patient Co-Development of Treatment Plan***, AOTA requests clarification regarding the difference between this measure and Patient Co-Development of the Plan of Care, both listed in Table 18. For a practicing occupational therapist, the treatment plan and plan of care are referred to synonymously and interchangeably. For this reason, we are interested in knowing how CMS defines both treatment plan and plan or care. AOTA also seeks clarification as to which professionals the Patient Co-Development of the Treatment Plan applies and how these professionals differ from those to which Patient Co-Development of the Plan of Care applies. In recent AOTA discussions with QIP, we were informed that it is QIP's understanding that CMS plans to merge these two separate measures into one measure for 2008 as a result of similar confusion voiced from other stakeholders. AOTA supports the merging of these two measures by CMS because no clear difference is apparent.

3. Table 19- QIP Structural Measures

AOTA believes that these structural measures provide a valuable opportunity to enhance the efficiency and quality of patient recordkeeping and data recording through electronic means. Occupational therapists are watching many of their colleagues move in the direction of electronic health records and e-prescribing. AOTA supports CMS approval of the QIP structural quality measures to assure quality care continues to be provided to patients. AOTA also supports CMS moving forward in the arena of electronic health records (EHR). AOTA requests further clarification, however, of how the structural measures might work in practice. For example, could an occupational therapist be rewarded under the PQRI program for having the electronic infrastructure in place to receive some form of an electronic referral from a physician for therapy services? Further clarification of these measures in the final rule will assist AOTA to understand how therapists may participate in PQRI using these measures.

4. Table 20- Additional AQA Starter Set Measures

AOTA asserts that occupational therapists should be provided the opportunity to review with QIP the additional measures from AQA that were not included in the 2007 PQRI quality measures, but that remain relevant to Medicare beneficiaries. Occupational therapists were not given the opportunity to review and consider the applicability of these measures for 2007 and we are requesting that opportunity for review and potential use in the 2008 PQRI. Particularly relevant to the scope of practice of occupational therapy is the quality measure for Advising Smokers to Quit. AOTA supports the practice of all health care professionals inquiring into a patient's tobacco usage. Occupational therapy

practitioners are in a unique position to assist patients to quit smoking successfully due to the profession's focus on all aspects of a patient's function, including psychosocial, cognitive, behavioral, and physical function. AOTA has been involved with a number of projects to expand this area of practice in connection with health promotion, wellness, and prevention initiatives.[2]

C. *Submission of Data via Medical Registry or Electronic Health Record* (72 Fed. Reg. 38202)

In general, AOTA supports the concept of a clinical data registry in which uniform information about a defined population can be collected and reviewed in a systematic manner. AOTA's primary concern continues to be ensuring that Medicare beneficiaries obtain necessary therapy and rehabilitation care without restriction and that the physician's and therapist's clinical judgments remain central to decision-making. AOTA also has an interest in protecting therapy patients' personal identifiable information; therefore, AOTA supports CMS' requirement that any registry developed by the agency be in compliance with HIPAA and the Consolidated Health Informatics Initiative (CHI) standards. Presently, there is no known clinical data registry for occupational therapy services. AOTA will be following CMS's movement in this area closely with regard to how the registries function and in what way such a mechanism can be designed to be most useful for collecting occupational therapy clinical data.

V. PHYSICIAN SELF-REFERRAL PROVISIONS

A. *In-Office Ancillary Services Exception* (72 Fed. Reg. 38181)

1. Referral Relationships between Occupational Therapists and Physicians

In the proposed rule, CMS announced that it is seeking comments on the referral relationships between physicians and occupational therapists (as well as other providers of designated health services). CMS noted its concerns that the in-office ancillary services exception to the physician anti-referral law (Stark): (1) encourages physicians to create physical and occupational therapy practices and (2) enables physicians to order and then subsequently perform ancillary services instead of making a referral to a specialist such as an occupational therapist.

Under the laws of most states, occupational therapists are not obligated to obtain a referral from a physician before evaluating and treating a client. However, authorities other than state law impact the referral relationship between occupational therapists and physicians. For example, Medicare Part B requires occupational therapists to obtain a physician signature on the therapy plan of care as prerequisite for payment. Requirements like this force the therapist to rely on the physician for a referral. Referral requirements are but one of the reasons why a number of occupational therapists forge

[2] American Journal of Occupational Therapy, Wellness Works: Community Service Health Promotion (Nov/Dec 1999); OT Practice, Agency for Health Care Research and Quality (AHCPR) Guidelines Support Smoking Cessation (Nov. 1999).

strong working relationships with physicians. Occupational therapists also are compelled to collaborate with physicians and other members of the care team in order to assure quality care. The Institute on Medicine has highlighted in their report "Health Professions Education: A Bridge to Quality" how collaborations among clinicians is essential to ensure patient safety and quality of care. AOTA believes individuals' rights to direct their own health care can be enhanced by the collaborative approach to rehabilitation that occupational therapists embody. Collaboration, including consultation with physicians, is critical to meet the needs of the Medicare population.

There is a broad spectrum of ways in which occupational therapists collaborate with physicians. Many occupational therapists choose to be employed by a physician practice and extol the benefits of the teamwork that such close collaboration brings. At the same time, many other occupational therapists have chosen to establish therapist owned practices and cherish their independence while maintaining strong working relationships with referring physicians. AOTA strongly supports billing for occupational therapy services under an occupational therapy private practice (OTPP) number. It is crucial that the Medicare program can assure that occupational therapy services are provided by qualified individuals, which the Medicare program can monitor when such services are billed under an OTPP number (whether reassigned or not). The same oversight over whether qualified individuals provide occupational therapy services does not exist when such services are billed as incident to the physician.

Whether CMS should make changes to the in-office ancillary services exception to the Stark law is a significant question, the answer to which would greatly impact occupational therapists. Given the diversity among occupational therapists' practice arrangements with physicians (e.g., employed by a physician and billing under their OTPP number, employed by a physician and billing incident to a physicians services, and employed by a therapist owned OTPP and independently billing Medicare Part B), there are a number of professionals whose livelihood would be impacted either way by a change. For these reasons, AOTA has encouraged its members to directly respond to CMS on this issue. ***AOTA supports CMS' policy objective in the Stark law to ensure appropriate utilization and billing of Medicare outpatient services consistent with the Medicare coverage guidelines and free of improper physician self-referral.***

VI. BUDGET NEUTRALITY/FIVE-YEAR REVIEW WORK ADJUSTER (72 Fed. Reg. 38125)

As stated in earlier comments, ***AOTA continues to request that CMS revise the MPFS formula to eliminate the work value adjuster in favor of an adjustment to the conversion factor (CF).*** The work adjuster has created a number of problems when the RBRVS formula is used by other payers, as it affects the relativity of services. Although this adjustment is solely for Medicare budget-neutrality purposes, it has been used to inappropriately reduce payments by non-Medicare payers. It also is inconsistent with CMS' historical methodology for making budget-neutrality adjustments.

* * * * *

AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on the MPFS proposed rule. AOTA looks forward to a continuing dialogue with CMS on coverage and payment policies that affect the ability of occupational therapists to provide quality care to Medicare beneficiaries.

Sincerely,

Sharmila Sandhu

Sharmila Sandhu, Esq.
Regulatory Counsel

Submitter : **Mr. Kenneth Rude** **Date: 08/31/2007**

Organization : **Pine Plains Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Attachcd is a letter encouraging revision of the Stark exceptions to the physician self-referral laws.

Submitter : **Dr. Danine Fruge** **Date: 08/31/2007**

Organization : **Dr. Danine Fruge**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14550-Attach-1.PDF

14550

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August 30, 2007

BY ELECTRONIC DELIVERY

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services, Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1385-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008)

Dear Acting Deputy Administrator Kuhn:

I appreciate the opportunity to comment on a proposal related to the reporting of cardiac rehabilitation services contained in the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding revisions to payment policies under the physician fee schedule and other Part B payment policies for calendar year 2008 (the "Proposed Rule").[1] I am a physician specializing in Family Practice who practices at the Seaside Medical Group at the Pritikin Longevity Center in Aventura, FL. In 7 years of experience, I have treated a large number of patients who are need of cardiac rehabilitation services, and I have seen first-hand the benefits of the Pritikin Program. My patients have successfully used the Pritikin Program to help prevent and reverse heart disease and other health concerns, dramatically reduce total and LDL cholesterol, lower blood pressure to the point where medication is no longer necessary, eliminate the need for bypass surgery and angioplasty, and substantially reduce the risk of heart disease, hypertension, obesity, diabetes, and risk factors for cancers of the breast, colon, and prostate. The results I have witnessed are supported by more than 110 studies of the Pritikin Program in prestigious medical journals like *The New England Journal of Medicine, Archives of Internal Medicine* and *Circulation.*

I am writing to thank CMS for proposing new coding for cardiac rehabilitation services under the physician fee schedule and to recommend additional changes that would help to further protect beneficiary access to these services. I was delighted that CMS revised its National Coverage Determination (NCD) for cardiac rehabilitation services in 2006 to extend Medicare coverage beyond exercise to include other critical services that, together with exercise, help patients prevent and reverse heart disease. Under the revised NCD, Medicare requires cardiac rehabilitation programs to provide a medical evaluation, a program to modify cardiac risk factors

1 72 Fed. Reg. 38,122 (July 12, 2007).

(e.g., nutritional counseling), prescribed exercise, education, and counseling.[2] As a physician who works with patients throughout the Pritikin Program, I firmly believe that exercise alone is not sufficient to achieve significant cardiac rehabilitation results, and I am glad that Medicare now covers the other services that are essential to cardiac rehabilitation. I also support the discretion granted to Medicare's contractors by the revised NCD to extend coverage, on a case-by-case, to 72 sessions, instead of the 36 sessions that were usually covered under the former NCD.

In the Proposed Rule, CMS explains that it will "clarify the coding and payment" for cardiac rehabilitation services by creating two new Level II Healthcare Common Procedure Coding System (HCPCS) G-Codes for these services when billed under the physician fee schedule.[3] I believe that the G-codes would describe the services provided more accurately because, unlike the current codes (93797 and 93798), they would describe one hour of service rather than an undefined "session." In my practice, patients undergo several modalities of cardiac rehabilitation in a single day. The new codes would clearly instruct physicians to report each hour of the program separately, rather than grouping different services together into a "session." This will help ensure that all providers of cardiac rehabilitation report their services consistently and will help Medicare to set accurate rates for all of the services now covered under the NCD. I strongly recommend that CMS implement the new codes in the final rule.

I am concerned, however, that the abbreviated descriptions of the new G-codes in Addendum B of the Proposed Rule could cause confusion among Medicare's contractors about the services. Although the G-codes and the Current Procedural Terminology (CPT) codes have the same descriptions, with the substitution of "per hour" for "per session," CMS has used different abbreviations for the G-codes in Addendum B. The proposed abbreviations are, "MD serv cardiac rehab wo ECG" and "MD serv cardiac rehab w ECG"[4] instead of, "Cardiac rehab" and "Cardiac rehab/monitor." Medicare's contractors could interpret these descriptions as requiring the physician to be present in the room during these services when they are furnished by auxiliary personnel, even though CMS has not changed the supervision requirements for these services. Like other services furnished by auxiliary personnel incident to a physician's service, Medicare requires the physician to be present in the office suite and immediately available to provide assistance and direction during cardiac rehabilitation, but not necessarily to be in the same room as the auxiliary personnel.[5] I ask CMS to modify the descriptions of the new codes in Addendum B of the Proposed Rule to match the abbreviated descriptions used for 93797 and 93798, respectively: "Cardiac rehab" and "Cardiac rehab/monitor." This change would help to prevent confusion about the level of physician supervision required for cardiac rehabilitation services that are provided incident to a physician's services.

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[2] NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10.

[3] 72 Fed. Reg. at 38,149. The new codes would be: Gxxx1, Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour), and Gxxx2, Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour)

[4] Id. at 38,361.

[5] See Medicare Benefit Policy Manual, ch. 15, § 60.1.

The proposed G-codes are an important first step toward protecting and promoting access to these life-changing services, but the NCD's potential to expand access to these services and prevent future hospitalizations could be frustrated if CMS does not take these additional steps. I make the following recommendations to further support Medicare beneficiaries' use of effective cardiac rehabilitation programs, such as the Pritikin Program. First, I ask CMS to clarify in the final rule that multiple sessions of cardiac rehabilitation can be covered on the same day. As explained above, my patients participate in several modalities of cardiac rehabilitation, such as a medical evaluation, prescribed exercise, education, and counseling, in a single day. In order to be reimbursed appropriately for each modality, we need to be able to bill multiple units of the G-codes on one day. Including a statement in the final rule that modifier 59 may be used with the G-codes would allow us to bill for each "distinct and independent" procedure performed on the same day.[6] I ask CMS to provide this instruction in the final rule.

Second, CMS must set payment for the G-codes at a level that will allow physicians to provide all of the services required for an effective cardiac rehabilitation program. CMS proposes to set payment for the Gxxx1 and Gxxx2 equal to payment for 93797 and 93798, respectively. I am concerned that the current rates for 93797 are not adequate for all of the cardiac rehabilitation services we provide in the Pritikin Program, and I recommend that both G-codes be paid at the rate for 93798. When CMS set the current payment rates for 93797 and 93798, it considered only the resources necessary to provide supervised exercise. Now that medical evaluation, education, and counseling also are covered, CMS will need to calculate new rates that include the resources involved in providing those services. While CMS collects data using the new G-codes, it should set the payment for both new G-codes equal to the current rate for 93798 to protect beneficiary access to these services in the physician office setting.

Third, to ensure that beneficiaries can receive a sufficient number of sessions of cardiac rehabilitation, CMS should explain in the final rule that it is likely to be reasonable and necessary to cover 72 cardiac rehabilitation sessions when multiple sessions are provided in one day. Under the old NCD, which covered only exercise, a cardiac rehabilitation program consisted of 36 sessions of supervised exercise, typically provided in two to three sessions per week. The new NCD recognizes not only that medical evaluation, education, and counseling are necessary, but also that up to 72 sessions of cardiac rehabilitation may be necessary to achieve the full benefits of cardiac rehabilitation, and it gives contractors the discretion to cover the additional 36 sessions.[7] These additional sessions are necessary for my patients because they typically participate in multiple sessions per day, and for each session of exercise, they participate in at least one session of another modality. In this kind of program, patients are likely to need the full 72 sessions to provide enough hours of each modality for the patient to receive the full benefit of the program. I ask CMS to advise its contractors that 72 sessions are likely to be reasonable and necessary for programs providing multiple sessions per day. CMS should remind contractors of their discretion to cover up to 72 sessions and to explain that 72 sessions are likely to be reasonable and necessary where beneficiaries receive cardiac rehabilitation from programs that provide several one-hour sessions per day of the various modalities that are included in the cardiac rehabilitation NCD.

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6 American Medical Association, CPT 2007, at 438.

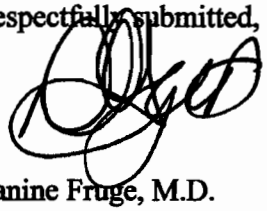
7 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(D).

Finally, CMS should encourage contractors to consider a program's proven results when they make their coverage decisions. My patients participate in the Pritikin Program, which has peer-reviewed and published research showing that it achieves quantifiable results on important metrics, such as reductions in LDL-cholesterol, triglycerides, blood pressure, blood glucose, and weight, or that it affects the progression of coronary heart disease and/or reduce the need for bypass surgery, angioplasty, or stents and/or reduce the need for medication. Contractors should consider 72 sessions to be presumptively covered when they are provided by a program, such as Pritikin, with this kind of published support. Factoring proven results into coverage decisions is consistent with CMS's goals of furthering evidence-based medicine and improving actual health outcomes and will help ensure that Medicare's resources are used appropriately for programs that have demonstrated positive results.

* * *

I greatly appreciate the opportunity to comment on the proposed changes to coding for cardiac rehabilitation services and to recommend additional changes that will help Medicare beneficiaries to receive the benefits of successful cardiac rehabilitation programs, such as the Pritikin Program. Please feel free to contact me at 305-935-7131 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Danine Fruge, M.D.

DF:pc

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

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

What is of most interest to me is the standard to which we establish practice of care. When research reports are conducted to determine efficacy of treatment, whether it be regarding physical therapy treatments, surgical equipment, or pharmaceuticals, it is considered of a higher standard when the company that conducts the research is not the same as the company that created the form of treatment. This is because we like the results to be of an unbiased nature, and know that it will truly benefit the patients. In similar standings, why do we not place this deduction of reasoning to providing care to patients? When I graduated as a Physical Therapist, I began working for a Physician owned facility. I soon learned, that I could not ethically continue to work for such a facility. First of all, the autonomy to which a PT should be able to practice with is completely stripped away from their care in a Physician owned practice.
On an average, 25% of patients discharged from PT, the physician would send them back for more. It was later that I discovered that the physicians were reaping the benefits of such prescriptions, as in turn-around, they received more money for keeping people in physical therapy, even if it meant that it would not benefit the patient and their insurance would not cover it. Putting an end to such an ethical dilemma, I began working for a PT-owned outpatient facility. By treating patients under a PT-owned facility, ethical, autonomous practice is ensured. Patient care is our number one priority. We keep in constant contact with the Physicians, and in this manner, we are able to continue to provide the utmost quality of care, without the bias of working directly for the Physicians. It is in my opinion that for the best treatment,physical therapy should be offered purely under the direction of physical-therapist owned facilities.

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

Organization : **jessele miller**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter
Jessele

Submitter : Dr. Sam Sugar **Date:** 08/31/2007

Organization : Dr. Sam Sugar

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14553-Attach-1.PDF

14553

SEASIDE MEDICAL GROUP, P.A.

AT THE

PRITIKIN LONGEVITY CENTER® & SPA

DAVID LEHR, M.D
(1929-1996)

Robert E. Bauer, M.D.
Michelle Bauer, M.D.
Norman Blum, M.D.
Danine Fruge, M.D.

Maurice Laszlo, M.D.
Ronald J. Scheib, M.D.
William Sherman, M.D.
Sam J. Sugar, M.D.
Susan E. Grober, Ph.D.

August 30, 2007

BY ELECTRONIC DELIVERY

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services, Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1385-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008)

Dear Acting Deputy Administrator Kuhn:

I appreciate the opportunity to comment on a proposal related to the reporting of cardiac rehabilitation services contained in the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding revisions to payment policies under the physician fee schedule and other Part B payment policies for calendar year 2008 (the "Proposed Rule").[1] I am a physician specializing in Internal Medicine who practices at the Seaside Medical Group at the Pritikin Longevity Center in Aventura, FL. In 34 years of experience, I have treated a large number of patients who are need of cardiac rehabilitation services, and I have seen first-hand the benefits of the Pritikin Program. My patients have successfully used the Pritikin Program to help prevent and reverse heart disease and other health concerns, dramatically reduce total and LDL cholesterol, lower blood pressure to the point where medication is no longer necessary, eliminate the need for bypass surgery and angioplasty, and substantially reduce the risk of heart disease, hypertension, obesity, diabetes, and risk factors for cancers of the breast, colon, and prostate. The results I have witnessed are supported by more than 110 studies of the Pritikin Program in prestigious medical journals like *The New England Journal of Medicine, Archives of Internal Medicine* and *Circulation.*

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[1] 72 Fed. Reg. 38,122 (July 12, 2007).

(e.g., nutritional counseling), prescribed exercise, education, and counseling.[2] As a physician who works with patients throughout the Pritikin Program, I firmly believe that exercise alone is not sufficient to achieve significant cardiac rehabilitation results, and I am glad that Medicare now covers the other services that are essential to cardiac rehabilitation. I also support the discretion granted to Medicare's contractors by the revised NCD to extend coverage, on a case-by-case, to 72 sessions, instead of the 36 sessions that were usually covered under the former NCD.

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4 Id. at 38,361.

5 See Medicare Benefit Policy Manual, ch. 15, § 60.1.

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7 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(D).

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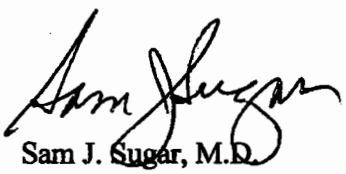
* * *

I greatly appreciate the opportunity to comment on the proposed changes to coding for cardiac rehabilitation services and to recommend additional changes that will help Medicare beneficiaries to receive the benefits of successful cardiac rehabilitation programs, such as the Pritikin Program. Please feel free to contact me at 305-935-7131 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Sam J. Sugar, M.D.

SJS:pc

Submitter : **Dr. Bo Headlam** **Date: 08/31/2007**

Organization : **Dr. Bo Headlam**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14554-Attach-1.DOC

14654

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,

Bo T. Headlam, M.D.
1284 Winans Ave, #3
Bourbonnais, IL 60914

Submitter : **Mrs. Leanne Parks** **Date: 08/31/2007**

Organization : **Comprehensive Physical Therapy Centers**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Mr. Kerry Weems,
Hello, my name is Leanne Parks. I am a student physical therapist from the College of Mount St. Jospeh and will be sitting for my board exam next month. I am writting to comment on the July 12th proposed 2008 physician fee schedule rule. As a future licensed physical therapist I am concerned with the lack of reimbursment for private owned facilities. I have accepted a job at a small, privately owned clinic on the East side of Cincinnati. This clinic provides exceptional, one-on-one patient care. They don't use technicians or aides therefore they are not billing for services provided for by any one else. The in-office ancillary services hurts not only the "small" businesses but hurts the profession of physical therapy as a whole. I urge you to deny the proposed physician fee schedule rule and allow physical therapist's to be paid for services provided.

Thank you,

Leanne Parks

Submitter : **Dr. William Ball** **Date: 08/31/2007**

Organization : **Ball Chiropractic Health Center**

Category : **Chiropractor**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

"MEI"
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Technical Corrections

The proposed rule dated July 12th contained an item under the technical corrections selections calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an xray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.
By limiting a Doctor of Chiropractic from referring fro an X-ray study, the costs for patient care will go up significantly doe to the necessity of a referral to another provider(orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referrel to the radiologist. With fixed incomes and limited resources, seniors may choose to forgo X-rays and thus, needed treatment. If treatment is delayed, illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal. I strongly urge you to table this proposal.

Submitter : **Mrs. Rebecca Janzen** **Date: 08/31/2007**

Organization : **Registered Physical Therapist, Inc**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:
I am a certified athletic trainer in Salt Lake City, Utah. I work at Registered Physical Therapists, Inc. and I am in charge of the rehabilitation of our patients. I also cover the practices and games of athletes at a local high school in the area and I make sure that they are kept safe and recieve the proper medical attention and rehabilitation. I have a bachelor's degree from Brigham Young University in Athletic Training. I have passed the national certification exam and I have a professional liscence here in Utah.

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

While I am concerned that these proposed ehanges to the hospital Conditions of 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 Janzen ATC, LAT

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

Organization : RICK MESHEW

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
RICK MESHEW

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : Dr. Ronald Scheib **Date:** 08/31/2007

Organization : Seaside Medical Group

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

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

Organization : **University of Kentucky Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

As a Professor of Anesthesiology at the University of Kentucky Medical Center, I care for a great many Medicare patients. It has been very difficult for major university medical centers like ours to maintain the level and quality of services because of revenue shortfalls, deficits, and budget cuts. Thus, 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, which dates back to an overt mistake in the original RBRVS calculations many years ago.

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, due to a gross misperception by the involved officials of what anesthesia care involves. 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 and institutions 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 very serious matter.

John H. Eichhorn, MD
Professor of Anesthesiology
University of Kentucky College of Medicine/Medical Center
800 Rose St., N-202
Lexington, KY 40536-0293
859-323-5956, x 80095

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

Organization : GAYLA MESHEW

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

Thank you for your consideration of this serious matter.
GAYLA MESHEW

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

Organization : RORY MORGAN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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

Thank you for your consideration of this serious matter.
RORY MORGAN

Submitter : Dr. Mark DeVoss **Date:** 08/31/2007

Organization : Ozark Anesthesia Associates, Inc.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14563-Attach-1.TXT

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.

Sincerely,

Mark R. DeVoss M.D.
Ozark Anesthesia Associates, Inc.

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

Organization : **ASA**

Category : **Physician**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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

Thank you for your consideration of this serious matter.

Sicerely yours, John Keith M.D.

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

Organization : **Dr. Robert Vogel**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14565-Attach-1.PDF

14565

ROBERT A. VOGEL, M.D.
Professor of Medicine
Director Clinical Vascular Biology

UNIVERSITY OF MARYLAND
SCHOOL OF MEDICINE

August 31, 2007

BY ELECTRONIC DELIVERY

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1385-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008)

Dear Acting Deputy Administrator Kuhn:

I appreciate the opportunity to comment on a proposal related to the reporting of cardiac rehabilitation services contained in the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding revisions to payment policies under the physician fee schedule and other Part B payment policies for calendar year 2008 (the "Proposed Rule").[1] My name is Robert A. Vogel and I am Professor of Medicine and Director of Clinical Vascular Biology at the University of Maryland School of Medicine. I have published numerous articles and chapters on cardiovascular disease, including articles on the treatment provided to Medicare patients with acute myocardial infarction.[2] I have also served on the Medicare Oversight Committee for the Ornish Diet Demonstration project.

I am writing to express my strong support for the proposed changes to coding for cardiac rehabilitation services under the physician fee schedule. I also would like to recommend additional changes that would help to further protect beneficiary access to these services. In 2006, CMS revised its National Coverage Determination (NCD) for cardiac rehabilitation services in 2006 to extend Medicare coverage beyond exercise to include other critical services that, together with exercise, help patients prevent and reverse heart disease. Under the revised

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1 72 Fed. Reg. 38,122 (July 12, 2007).

2 Ellerbeck E, Jencks S, Radford M, Kresowick T, Craig A, Gold J, Krumholtz H, *Vogel R.* Treatment of Medicare patients with acute myocardial infarction: Report on a four state pilot of the Cooperative Cardiovascular Project. JAMA 1995;273:1509-1514; Marciniak TA, Ellerbech EF, Radford MJ, Kresowik TF, Gold JA, Krumholz HM, Kiefe CI, Allman RM, *Vogel RA,* Jencks SF. Improving the quality of care for Medicare patients with acute myocardial infarction. Results from the Cooperative Cardiovascular Project. JAMA 1998;279:1351-1357

22 South Greene Street • Baltimore, Maryland 21201-1595 • 410 328 8795 • 410 328 4382 *fax*

NCD, Medicare requires cardiac rehabilitation programs to provide a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education, and counseling.[3] As a physician who has extensively studied cardiovascular disease and cardiac rehabilitation, I am pleased that Medicare now covers the range of services that are essential to cardiac rehabilitation. I also support the discretion granted to Medicare's contractors by the revised NCD to extend coverage, on a case-by-case, to 72 sessions, instead of the 36 sessions that were usually covered under the former NCD.

I support CMS's proposal to create two new Level II Healthcare Common Procedure Coding System (HCPCS) G-Codes for cardiac rehabilitation services when billed under the physician fee schedule.[4] I agree that this change will help to clarify coding and describe the services provided more accurately because, unlike the current codes (93797 and 93798), they would describe one hour of service rather than an undefined "session." In cardiac rehabilitation programs with demonstrated results in peer-reviewed and published research, such as the Pritikin Program, patients undergo several modalities of cardiac rehabilitation in a single day. The new codes would clearly instruct physicians to report each hour of the program separately, rather than grouping different services together into a "session." This will help ensure that all providers of cardiac rehabilitation report their services consistently and will help Medicare to set accurate rates for all of the services now covered under the NCD. I strongly recommend that CMS implement the new codes in the final rule.

Although I support the new codes, I also ask CMS to revise the abbreviated descriptions of the codes used in Addendum B of the Proposed Rule. The proposed G-codes have the same description as the existing Current Procedural Terminology (CPT) codes have the same descriptions, with the substitution of "per hour" for "per session," but CMS uses different abbreviated descriptions of the new G-codes in Addendum B of the Proposed Rule. The proposed abbreviations are, "MD serv cardiac rehab wo ECG" and "MD serv cardiac rehab w ECG"[5] instead of, "Cardiac rehab" and "Cardiac rehab/monitor." These descriptions could be interpreted to mean that a physician must personally provide the service, although, like other services furnished by auxiliary personnel incident to a physician's service, Medicare does not require the physician to be in the same room as the auxiliary personnel during cardiac rehabilitation. Medicare requires only that the physician be present in the office suite and immediately available to provide assistance and direction during cardiac rehabilitation.[6] Because these abbreviations could confuse Medicare's contractors about the supervision requirements for these services, CMS should revise them to match the abbreviations of the existing CPT codes.

---

3 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10.

4 72 Fed. Reg. at 38,149. The new codes would be: Gxxx1, Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour), and Gxxx2, Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour).

5 Id. at 38,361.

6 See Medicare Benefit Policy Manual, ch. 15, § 60.1.

reasonable and necessary where beneficiaries receive cardiac rehabilitation from programs that provide several one-hour sessions per day of the various modalities that are included in the cardiac rehabilitation NCD.

Finally, CMS should encourage contractors to consider a program's proven results when they make their coverage decisions. For example, the Pritikin Program has peer-reviewed and published research showing that it achieves quantifiable results on important metrics, such as reductions in LDL-cholesterol, triglycerides, blood pressure, blood glucose, and weight, or that it affects the progression of coronary heart disease and/or reduce the need for bypass surgery, angioplasty, or stents and/or reduce the need for medication. Contractors should consider 72 sessions to be presumptively covered when they are provided by a program, such as Pritikin, with this kind of published support. Factoring proven results into coverage decisions is consistent with CMS's goals of furthering evidence-based medicine and improving actual health outcomes and will help ensure that Medicare's resources are used appropriately for programs that have demonstrated positive results.

* * *

I greatly appreciate the opportunity to comment on the proposed changes to coding for cardiac rehabilitation services and to recommend additional changes that will help Medicare beneficiaries to receive the benefits of successful cardiac rehabilitation programs, such as the Pritikin Program. Please feel free to contact me at (410) 328-8795 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Robert A Vogel MD.

Robert A. Vogel, M.D.

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

Organization : JENNIE MORGAN

Category : Health Care Professional or Association

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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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.
JENNIE MORGAN

Submitter : **Mrs. Kristen Mason** **Date: 08/31/2007**

Organization : **Rehabilitation Centers of Charleston**

Category : **Physical Therapist**

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

To whom it may concern:
My name is Kristen Mason and I am a Physical Therapist in Moncks Corner, SC. I urge you to remove physical therapy from the in-office ancillary services exception to the federal physician self-referral laws. In the state of South Carolina, we fought extremely hard to rid the state of Physician Owned Physical Therapy Practices (POPTS), and the continuation of this practice negates all of this hard work.
POPTS are harmful to patients for many reasons. 1.) POPTS promote the referral of patients for self-profit. 2.) POPTS do not provide the consumer with a choice. 3.) POPTS do not always ensure quality of care.
In the state of South Carolina it is illegal for a physical therapist to be employed by a physician. Being employed in a situation like this, places the physical therapist is a significant legal situation as well as a significant ethical dilemma. How could you provide quality care if a physician was constantly referring patients to physical therapy who were not appropriate candidates? Physical therapists in POPTS situations charge more per patient and treat patients for longer periods of time because it makes more money for their employer.
Physical therapists are now being educated at the Master s level and higher, with most new graduates receiving clinical Doctorate degrees. We as physical therapists have the knowledge and training to treat patients effectively and safely without the supervision of a physician. Physical therapists are autonomous practitioners, and should be legally allowed to practice as such.
Thank you for your consideration, and again I urge you to remove physical therapy from the in-office ancillary services exception to the federal physician self-referral laws.
Sincerely,
Kristen D. Mason, PT, MSRS

Submitter : Mr. Denis Scaia **Date:** 08/31/2007

Organization : Fernandez-Renner-Scaia Physical Therapy Clinic

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am a physical therapist in private practice and wish to comment on the 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services exception". Our practice is in the Midwest, and we have sen the proliferation of physician owned physical therapy practices. There are physician owned practices that are run by companies such as Novacare, which provides staffing for the doctors. We have seen a consisten reduction in our number of patients, as the physicians refer the majority of their Medicare and other patients to their own clinics. I questioned one physician in such a group as to why they needed to start their own therapy clinic. His response was that they need to make more money. This goes to the heart of the matter. Physicians with an inherent financial incentive will be more inclined to overutilize these services for financial gain. Patients have relayed experiences to me where their doctors encourage them to come to their clinics because they can better monitor physical therapy progress. However, when the patients go to the physician's clinic, they find that they work with a different therapist on every occasion and do not ever see the doctor. Also, older patients have told me that they do not want to offend their doctor by not going to his clinic. I believe this can be a very intimidating situation for the elderly. Our private physical therapy clinics provide eonvenient times for patients, and consistent reports are provided to their doctors. CMS can reduce the temptation of overutilization of physical therapy services under the Medicare program by closing this loophole (in which physicians utilize physical therapy as just another source of income). I feel that it is in the best interest of Medicare patients and the Medicare program to remove physical therapy from the list of "in-office ancillary services" that physicians are permitted to provide.

Submitter : Dr. Mark Cornwall **Date:** 08/31/2007

Organization : Arizona Board of Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14569-Attach-1.DOC

14569

August 31, 2007

Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-1850

Re: CMS-1385-P
Therapy Standards and Requirements

Dear Sir or Madam:

I am submiting the following comments on the proposed rules changing the definition of "physical therapist" in Section 484, Title 42 of the Code of Federal Regulations. The proposed rules are part of the 2008 Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for Calendar Year 2008, found in Volume 72 of the Federal Register, published on July 12, 2007.

Under subsection (i)(B) and (ii)(B) of the proposed definition of "physical therapist" an applicant would need to have "passed the National Examination approved by the American Physical Therapy Association." This change would adversely affect physical therapists throughout the United States. Currently, licensure is regulated by each state and all such jurisdictions recognize the National Physical Therapy Examination created by the Federation of State Boards of Physical Therapy as the sole examination for entrance into the profession. Because the Federation of State Boards is independent of the American Physical Therapy Association, a potential conflict of interest is avoided in the creation, administration and use of the exam relative to licensure of physical therapists. The proposed change would therefore create a significant conflict of interest. In addition, since all jurisdictions that regulate physical therapy licensure recognize only the examination created by the Federation of State Boards, under the proposed rule change, there would be no physical therapist in the United States eligible to treat and/or bill under Medicare. This would create a significant adverse impact upon patient care for all those elderly who rely upon physical therapy services following surgery, injury or disease.

I strongly suggest that CMS rely on current state licensure mechanisms and that the additional examination requirements contained in subsections (i)(B) and (ii)(B) of the definition of "physical therapist" be deleted from the final rule. At the very least, the Centers for Medicare and Medicaid Services ("CMS") should delay promulgation of the proposed rule until CMS has had an opportunity to understand the examination, credentialing, and licensing processes currently in place.

The FSBPT has done an outstanding job of meeting the requirements of ensuring that all physical therapists are competent practitioners and there is no need to give this responsibility to another organization, which has neither the resources or the history of doing such. CMS should not usurp the state's function of licensing physical therapists and other professionals. Health care professional credentialing and licensing is a classically state function. Licensing and credentialing is the domain of the states. CMS' proposal would inappropriately transform a state function into a federal function. There is no justification for this action, and CMS should prevent it by removing the proposed rule.

I appreciate the opportunity to comment on the proposed rules regarding physical therapist and physical therapy assistant qualification requirements.

Respectfully yours,

Mark Cornwall

Mark W. Cornwall, PT, PhD, CPed
Vice-President, Arizona Board of Physical Therapy

Submitter : Mr. G. David Mason **Date:** 08/31/2007

Organization : American Physical Therapy Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14570-Attach-1.PDF

#14570

APTA
American Physical Therapy Association

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August 31, 2007

Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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

Dear Mr. Weems:

On behalf of our 70,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit comments on the Center for Medicare and Medicaid Services (CMS) Proposed Notice regarding "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 and Other Part B Payment Policies," published in the July 12, 2007, *Federal Register*.

The physician fee schedule is currently the basis of payment for outpatient therapy services furnished by therapists in private practice, hospitals, rehabilitation agencies, public health agencies, clinics, skilled nursing facilities, home health agencies, and comprehensive outpatient rehabilitation facilities (CORFs). Therefore, the physician fee schedule rules have a significant and direct effect on payments to physical therapists.

These comments address: 1) the fee schedule update formula; 2) the therapy standards and requirements; 3) the recertification requirement; 4) the therapy cap; 5) the extension of the physician quality reporting initiative (PQRI); 6) the use of registries; 7) the physician self-referral provisions; and 8) CORF provisions. Our comments on each of these provisions are discussed in further detail in the following paragraphs.

Therapy Standards and Requirements (page 38191)

CMS proposes to update the personnel qualifications for physical therapists (PTs), physical therapist assistants (PTAs), occupational therapists (OTs), and occupational therapist assistants (OTAs). Specifically, the Agency is proposing to broaden the current grandfathering requirements to recognize practicing physical therapists, occupational therapists, physical therapist assistants, and occupational therapist assistants who meet their respective state qualifications (e.g., have been

licensed, certified, registered, or otherwise regulated by their state as PTs, OTs, PTAs, or COTAs) before January 1, 2008, and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than two years. Individuals who begin practicing as physical therapists, physical therapist assistants, occupational therapists, and occupational therapy assistants after January 1, 2008, would be required to meet the new qualifications proposed in the regulation at section 484.4. CMS does not propose to broaden the grandfathering provisions for physical therapists working in home health agencies.

In the rule, CMS seeks comments regarding the following:

1) Appropriate grandfathering provisions relating to qualifications of therapists and assistants to assure that skilled therapists and assistants with comparable and appropriate education and training treat Medicare beneficiaries in all settings.
2) Whether the personnel qualifications in section 484.4 should be applicable to other settings.
3) Qualifications for PTs that include a curriculum and a national examination each approved by the APTA
4) Appropriate qualifications for PTAs.

APTA's response to the information requested by CMS is included below.

"New Grandfathering Provisions for Physical Therapists and Physical Therapist Assistants"

In the rule, CMS adds grandfathering provisions for physical therapists and physical therapist assistants in sections 409.17, 409.23, 410.60, 485.70, 485.705, 491.9. The regulatory text below is proposed in the rule.

> *A physical therapist and a physical therapist assistant must meet one of the following qualifications:*
> *(1) As set forth in §484.4 of this chapter.*
> *(2) **Qualified physical therapists (emphasis added)** or physical therapist assistants must have been licensed, certified, registered, or otherwise recognized as physical therapists or physical therapist assistants by the State in which practicing before January 1, 2008, and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than 2 years.*

APTA strongly recommends that CMS amend the new grandfathering language (referenced above) to remove "qualified physical therapists" from this provision. All physical therapists currently practicing meet the education and licensure requirements included in section 484.4. Therefore, it is unnecessary to include qualified physical therapists in this "new" broadened grandfathering provision.

However, we agree with CMS that this new grandfathering provision is necessary for physical therapist assistants. The definition of physical therapist assistants included in the existing section 484.4 requires that after 1977 a PTA be a graduate of a two-year college level program approved by the American Physical Therapy Association. The existing provision does not address PTAs

who are trained outside the United States or trained in the military. Some states, such as California, allow individuals who are not graduates of a two-year college level physical therapist assistant program to be licensed and practice as physical therapist assistants if the individual successfully passes the licensure exam in the state in which he or she practices and meets certain training or education requirements. We believe that these individuals who have been licensed, registered, certified, or otherwise recognized by their state as a physical therapist assistant prior to January 2008 should be able to continue to provide covered services to Medicare beneficiaries. This grandfathering clause would enable them to do so.

The proposed regulations would require that, in order for the new grandfathering clause to apply, the PTA must "continue to furnish Medicare services as least part time without an interruption in furnishing services of more than 2 years." **We recommend that CMS clarify in the final rule that the two year requirement applies to services furnished after January 2008. The requirement should not apply prior to January 2008.**

In the rule, CMS states that this broadened grandfathering provision would apply to all settings except for home health agencies and hospices. **We recommend that CMS make the definitions uniform and apply the new grandfathering provision to home health agencies and hospices in addition to the other settings.** There is no reason to have different standards for personnel in home health and hospice compared to other settings.

Qualifications for Physical Therapists in 484.4

CMS proposes to amend the language in section 484.4 to establish new requirements for individuals beginning their practice on or after January 1, 2008. APTA has several recommendations for amendments to the proposed definition of physical therapist.

First, we recommend that CMS remove the requirement that a physical therapist pass a National Examination approved by the American Physical Therapy Association. The proposed language would require that all physical therapists be licensed in their state. Currently, all states require individuals to pass a national licensing exam in order to be licensed. Therefore, we do not believe this language is necessary.

Second, we recommend that CMS remove the equivalency requirement for individuals trained in the United States military. All physical therapists trained in the United States military are graduates of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE). Therefore, it is unnecessary to establish a credentials evaluation process for physical therapists trained in the military.

It is necessary, however, to revise the regulations to require a credentials evaluation process for individuals educated outside of the United States who want to be recognized as physical therapists to ensure that the education of a foreign educated physical therapist is substantially equivalent to that of a physical therapist educated in the United States. The language pertaining to physical therapists educated outside the United States included in the existing section 484.4 is outdated and does not require that foreign trained physical therapists have education that is comparable to U.S. trained physical therapists. This language has two prongs, one relating to

education and the other to the individual's personal characteristics. As to the education prong, the clause applies to any foreign-educated individual who graduated from a program "approved in" any country in which there is a membership organization of the World Confederation for Physical Therapy (WCPT). The education prong does not say what or who must have "approved" the curriculum. It merely states that the individual must "meet the requirements for membership" in one of the national associations. This prong does not even require that the individual be a member, only that he or she "meet the requirements" Therefore, under this definition, many foreign educated individuals would be able to qualify as a Medicare "physical therapist" under this clause, even if their education is not comparable to U.S. trained physical therapists.

APTA recommends that CMS modify the proposed language to clarify that a foreign educated physical therapist must be a "graduate of an education program that by credentials evaluation conducted by an organization approved by the APTA is deemed to be substantially equivalent with respect to physical therapist entry level education in the United States. We recommend that the approval be of the "credentialing organization" rather than the "credentialing process."

As the national professional organization representing physical therapists, APTA strongly recommends that we be recognized to approve the organizations evaluating the credentials. APTA's goal is to ensure that physical therapy services are furnished by physical therapists who meet professional standards with respect to education and training. If APTA were to approve credentialing evaluations organizations, we would be able to ensure that appropriate decisions are made regarding whether foreign educated physical therapists have met the educational standards of U.S educated physical therapists. As a national professional organization, APTA would have a broad perspective regarding all the available credentialing organizations.

The Commission on Accreditation in Physical Therapy Education (CAPTE), a standing committee of the APTA, sets standards for qualifications of physical therapists domestically and for curricula for physical therapist and physical therapist assistant education programs. The Association's goal is to advance academic quality through the CAPTE accreditation process. APTA also has access to the expertise of CAPTE in curricular assessment and therefore can make determinations regarding whether credentialing organizations have processes in place that result in appropriate decisions regarding whether a foreign educated physical therapist's coursework is substantially equivalent to that of a CAPTE accredited program. Although APTA through CAPTE develops standards for physical therapist and physical therapist assistant education programs, neither APTA nor CAPTE performs credentials evaluation itself. Therefore, APTA has no financial interest in performance of credentials evaluation.

APTA has a proven record of developing formalized, equitable, transparent, open, consensus-based processes for development of professional standards and CAPTE, a standing committee of APTA, has a similar record of developing accreditation standards for physical therapist and physical therapist assistant education programs. CAPTE has the highest level of approval from the United States Department of Education and the Council for Higher Education Accreditation (CHEA).

With respect to the education program, CMS proposes that it be determined to be comparable with respect to physical therapist entry level education in the United States. Rather than using the term "comparable" we recommend that CMS replace it with the term "substantially equivalent." Most states use the term "substantially equivalent" in their practice acts when referencing foreign trained programs. This term is also used by APTA in its policies regarding licensure and regulation (refer to PHYSICAL THERAPIST AND PHYSICAL THERAPIST ASSISTANT LICENSURE/ REGULATION HOD P05-07-09-10 (Program 32) [Amended HOD 06-99-13-16; Initial HOD 06-91-25-33] [Position on Physical Therapist and Physical Therapist Assistant Licensure].

In the rule, CMS includes draft text of the regulation defining physical therapists at section 484.4. In this text the following language is included:

> *(iv)(e) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977;*

We strongly recommend that CMS delete the text above from the rule. As worded, it would allow an individual with two years of experience as a physical therapist who has **not** graduated from a physical therapist education program to provide services to Medicare beneficiaries. We recognize that this language is included in the current version of 484.4, but it is outdated and should not be included.

To ensure that qualified physical therapists furnish physical therapy services to Medicare beneficiaries, we recommend that CMS revise the definition of physical therapist to state the following:

> **Physical therapist.** *A person who is licensed by the State in which practicing, and meets one of the following requirements:*
>
> *~~(1) Requirements for individuals beginning their practice on or after January 1, 2008. Meets all practice requirements set forth by the State in which the physical therapy services are furnished and meets one of the following educational/training requirements on or after January 1, 2008:~~*
>
> *(a) Has Graduated after successful completion of a ~~college or university~~ physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); ~~and~~ or*
>
> *~~(B) Passed the National Examination approved by the American Physical Therapy Association.~~*
>
> *(b) If educated outside the United States ~~or trained by the United States military~~ graduated after successful completion of an education program that~~, by~~ a credentials evaluation **organization** ~~process~~ approved by the American Physical Therapy Association, is determined to be **substantially equivalent** ~~comparable with respect~~ to physical therapist entry level education in the United States; ~~and~~ or*

~~*(B) Passed the National Examination approved by the American Physical Therapy Association.*~~

~~*(2) Requirements for individuals beginning their practice after December 31, 1977 and before January 1, 2008. Has graduated from a physical therapy curriculum approved by one of the following after December 31, 1977 and before January 1, 2008:*~~

(c) Has graduated prior to January 1, 2008 from a physical therapy curriculum approved by:

~~*(i)*~~ *(1)The American Physical Therapy Association,* ***or***

~~*(ii)*~~ *(2) The Committee on Allied Health Education and Accreditation of the American Medical Association,* ***or***

~~*(iii)*~~ *(3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association;* ***or***

~~*(3) Requirements for individuals beginning their practice on or after January 1, 1966 and on or before December 31, 1977. Had 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service on or before December 31, 1977.~~*

(d) Prior to January 1, 1966,

~~*(4) Requirements for individuals beginning their practice before January 1, 1966. Meets one of the following requirements before January 1, 1966:*~~

~~*(i)*~~ ***(1)*** *Was admitted to membership by the American Physical Therapy Association,* ***or***

~~*(ii)*~~ ***(2)*** *Was admitted to registration by the American Registry of Physical Therapists,* ***or***

~~*(iii)*~~ ***(3)*** *Graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education;* ***or***

~~*(iv)(e) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or*~~

(e) *Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy;* ***or***

(5) ~~*Requirements for individuals trained outside of the United States before January 1, 2008.*~~ *If trained outside the United States before January 1, 2008 meets the following requirements:*

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

Qualifications for Physical Therapist Assistants in section 484.4

CMS proposes to amend the language in section 484.4 related to physical therapist assistants who begin practicing after January 2008. **APTA supports this proposed language.**

The existing section 484.4 would not allow individuals educated outside the United States or individuals trained by the military to be recognized as physical therapist assistants under the Medicare program. **We believe CMS should adopt a policy that allows for the evaluation of educational programs and military training to determine whether that education is substantially equivalent to physical therapist assistant entry level education in the United States.** If individuals meet these educational requirements along with licensure or other applicable state laws, then they should be recognized.

It is critical that CMS require that the credentials evaluations organization be approved by the American Physical Therapy Association to ensure that foreign trained physical therapist assistants receive an education equivalent to PTAs educated in the U.S. CAPTE, a standing committee of the APTA, sets standards for curricula for physical therapist assistant education programs. APTA has a proven record of developing formalized, equitable, transparent, open, consensus-based processes for development of professional standards and CAPTE has a similar record for development of accreditation standards for physical therapist and physical therapist assistant education programs. As noted above, CAPTE has the highest level of approval from the United States Department of Education and CHEA. The Association has no financial interest in credentials evaluation and therefore is impartial. Thus, it is logical that APTA would be in a position to make determinations regarding bodies that evaluate credentials for other education programs.

APTA recommends that section 484.4 be revised to read:

Physical therapist assistant. ***A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the State in which practicing, and*** *meets one of the following requirements:*

~~*(1) Requirements for individuals beginning their practice on or after January 1, 2008. A person who provides certain physical therapy services under the supervision of a qualified physical therapist and is licensed, registered, certified or otherwise recognized as a physical therapist assistant, if applicable, by the State in which practicing, continues to meet all practice requirements set forth by the State in which physical therapy services are furnished, and meets one of the following educational/training requirements:*~~

(a) ***Has graduated from*** ~~*Graduated after successful completion of*~~ *a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association;* ***or***

(b) If educated outside the United States or trained in the United States military, graduated ~~*after successful completion of*~~ ***from*** *an education program that by a credentials evaluation* ~~*process*~~ ***organization*** *approved by the American Physical Therapy Association, is determined to be* ***substantially equivalent*** *to physical therapist assistant entry level education in the United States;* ***or***

~~*(c) Prior to January 1, 2008 Requirements for individuals beginning their practice before January 1, 2008. s licensed as a physical therapist assistant, if applicable, by the State in which practicing, meets either of the following requirements:*~~

~~*Has graduated prior to 2008 from a 2-year college-level program approved by the American Physical Therapy Association, or*~~

(c) ***Prior to 2008,*** *has 2 years of appropriate experience as a physical therapist assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapist assistant after December 31, 1977.*

Application of Consistent Therapy Standards

In the rule, CMS states that it believes therapy services should be provided according to the same standards and policies in all settings to the extent possible. Therefore, the Agency revises the regulations (sections 409.17 and 409.23, etc) that pertain to services furnished at inpatient hospitals and skilled nursing facilities (SNFs), and several other settings to state that "physical therapy, occupational therapy or speech-language pathology services must be furnished by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants or speech-language pathologists who meet the requirements specified in 484.4. **APTA strongly supports CMS's decision to establish the same definitions for physical therapists and physical therapist assistants in all settings. In addition, it is our position that physical therapy services should be furnished by a physical therapist or appropriately supervised physical therapist assistant.**

As CMS moves forward with this revised language, it is imperative that the Agency not inadvertently develop a policy that prevents students from receiving their clinical training. CMS must recognize that providers that accept students from clinical education programs incur significant additional expenses associated with staff/supervisor teaching time related to patient care. It is extremely important for therapy students to have the opportunity to receive clinical experience in SNFs, hospitals, and outpatient therapy settings. Working with Medicare beneficiaries provides students with the clinical training needed to appropriately render physical therapy services to the geriatric population. Because the elderly population often needs rehabilitation and is rapidly growing in the United States, it is crucial to have professional therapists clinically trained in providing care to this population. CMS should ensure that policies do not prevent or discourage therapy students from receiving the clinical experience that they need in order to safely and effectively treat geriatric patients.

CMS may want to consider delaying implementation of the policy requiring that physical therapy, occupational therapy or speech-language pathology services be furnished by individuals meeting requirements specified in section 484.4. In certain settings, such as skilled nursing facilities, the proposed policy would result in confusion because it is inconsistent with language previously issued by CMS in rules pertaining to the SNF setting that allowed services provided by aides and students in the "line of the sight" of the therapist to be counted as therapy minutes on the Minimum Data Set (MDS). For that reason, it would be appropriate for CMS to consider a reasonable delay in implementation of the policy to avoid disruption and confusion.

Plan of Care

CMS proposes additional regulations for inpatient hospital services and skilled nursing facility services to require a plan of treatment for therapy services consistent with the plan currently required for outpatient therapy services. CMS invites comment on PT, OT, and SLP plan of treatment policies that are appropriately applied to all therapy services in both Part A and Part B.

Section 409.23 references section 409.16(b) through (e) regarding the plan of care. We presume that CMS intended section 409.23 to reference section 409.17 (b) through (e). If so, this reference in the rule should be amended.

CMS explains that since inpatient hospital services are always provided under the care of a physician, the agency believes that the physician's review and certification of the therapy plan of treatment is implied by the physician's review and approval of a facility plan that includes therapy services. Therefore, there would be no additional certification requirements for the inpatient hospital setting.

We agree with CMS that in the hospital setting the physician's review and approval of a therapy plan should be implied by the physician's review and approval of a facility plan that includes therapy services. We believe the same rationale applies to services provided in skilled nursing facilities and urge CMS to state that in the SNF Part A setting, review of the therapy plan is implied by the physician's review of the facility plan.

Although CMS states that there should be no additional certification requirements for the inpatient hospital setting, the language proposed in section 409.17(e) appears to be inconsistent with this policy. Specifically, section 409.17(e) states

> *(e) Review of the plan. The physician, nurse practitioner, clinical nurse special or physician assistant reviews the plan as often as the individual's condition requires, but at least prior to certification.*

We request that CMS amend this language to clarify further. We are concerned that as written the policy would be interpreted to require specific review of the therapy plan rather than the facility plan. Requiring a review of the therapy plan in the inpatient hospital setting and skilled nursing facility (Part A) setting could result in significant delays in treatment.

As CMS revises policies related to the plan of care, CMS should recognize that it is necessary in the IRF and SNF setting to have the flexibility to modify the utilization of rehabilitation services so that they are appropriate to fit the patient's medical condition on a particular day. In the IRF and SNF setting there is frequently the need to adjust the type (PT, OT, or SLP) and extent of therapy services delivered by a particular discipline from day to day. Due to unstable medical conditions, delivery of services is based on the patient's needs as well as tolerance and endurance.

Outpatient Therapy Certification Requirements

In the rule, CMS proposes to amend the regulations to change the plan of treatment recertification schedule. Currently, the physician must initially certify a plan of treatment at the time the plan is established or as soon thereafter as possible. If the need for treatment continues beyond 30 days, the plan of treatment must be recertified every 30 days. CMS proposes that the physician (or non-physician provider, as appropriate) recertify the plan of care every 90 days.

APTA commends CMS on its recognition that it is unnecessary for a physician to recertify a plan of care every 30 days. In fact, it is APTA's position that Medicare beneficiaries should be able to directly access the services of a physical therapist without unnecessary referral or certification requirements. Physical therapists are well-qualified, both through formal education and clinical training, to evaluate a patient's condition, assess his or her physical therapy needs and, if appropriate, safely and effectively treat the patient. Physical therapists are also well-qualified to recognize when patients demonstrate conditions, signs, and symptoms that should be evaluated by other health care professionals before therapy is instituted. Physical therapists recognize when it is appropriate to refer patients to these other health care professionals for consultation. The professional training and expertise which characterize physical therapists has been recognized by 44 states which have removed the out-dated provisions requiring a referral by a physician, from their statutes.

We recognize that Congress would need to pass legislation to enable Medicare beneficiaries to have direct access to physical therapist services. We commend CMS on the steps it has taken in this proposed rule to eliminate unnecessary barriers to access. **APTA strongly supports the proposal to extend the 30 day recertification requirement to 90 days. To ensure that standards are consistent, APTA also recommends that the CORF regulations be amended to change the 60 day certification period to 90 days.** The 30 day recertification is overly burdensome for physicians and physical therapists and is not an effective means of controlling utilization of therapy services. In recent years CMS has implemented many other policies that have ensured that utilization of therapy services is appropriate. As CMS states in the rule, therapy services are subject to a therapy cap, there are many local medical review policies pertaining to therapy services, and there are a number of system edits such as the "Correct Coding Initiative" (CCI) edits that have been implemented. In addition, the Agency has set forth extensive documentation requirements in its Medicare Benefit Policy Manual that physical therapists must follow to justify the medical necessity of services.

Requiring recertification can result in delays in care if the referring physician is not available to review the plan and recertify at the 30-day interval. Physical therapists are well-trained professionals who are able to use their professional judgment to identify whether services are medically necessary. APTA commends CMS on its proposal to make a change that will protect patient's access to physical therapy services and reduce unnecessary administrative burdens on physicians, physical therapists, and Medicare contractors.

TRHCA – Section 201: Therapy Caps

In the rule, CMS discusses implementation of the therapy cap in 2008. The Agency states that in accordance with the statute, it will continue to implement the therapy caps, but the therapy cap exceptions process will no longer be applicable beginning January 1, 2008. Congressional action is necessary to repeal the therapy cap, place a moratorium on its implementation, or extend the exceptions process in 2008. The dollar amount of the therapy caps in 2008 will be the 2007 rate ($1780) increased by the percentage increase in the Medicare Economic Index (MEI) (rounded to the nearest multiple of $10).

APTA is deeply concerned about the negative impact that implementation of the financial limitations on therapy services without the extension of the exceptions process will have on Medicare beneficiaries needing therapy services. As CMS is aware, the *AdvanceMed* study published in November 2004 indicated that in 2002 14.5% of patients would exceed the physical therapy cap. Once exceeded, if there is no exceptions process in place beneficiaries will not receive services that are medically necessary unless they seek treatment from hospital outpatient departments or pay out-of-pocket for their care. As a result, the cap can be expected to have a significant detrimental effect on beneficiaries needing rehabilitation services and could lead to complications, ultimately resulting in greater costs to the Medicare program. We recognize that it will take Congressional action to provide additional statutory authority and prevent the implementation of the therapy caps, and we continue to strongly urge Congress to take timely action to pass legislation that would repeal the therapy cap or, at a minimum, extend the exceptions process if repeal is not feasible.

APTA commends CMS on the significant amount of work that the Agency has conducted over the past few years in an effort to identify an alternative to the therapy cap. We strongly believe that therapy care should be based on the needs of the patient, not governed by an arbitrary financial limit. **We urge CMS to place a high priority in resources and funding on continuing to conduct research that could be used to identify alternatives to the cap that would ensure that patients receive medically necessary therapy services.** While we recognize that the Agency faces many important priorities in allocating limited funds for research and pilot projects, we believe that few would have as direct and immediate impact on beneficiaries as finding an appropriate alternative to the therapy cap. This research is a key factor in identifying more clinically appropriate ways to control the growth in Medicare spending.

Before making any major reforms to the payment system for outpatient therapy services, we urge CMS to obtain more information about therapy users and their outcomes. This could involve the use of patient assessment tools that gather relevant information regarding patients that would impact the need for therapy services. CMS also would need to consider differences in patients and risk adjust to account for those differences.

Based on discussions we have had with CMS, we are aware that there is a plan to release a statement of work that would involve gathering more information regarding therapy users. We urge CMS to move forward with this initiative and to ensure that the national professional organizations, such as the American Physical Therapy Association, have a meaningful

opportunity to participate and provide input as your proceed with research. We look forward to assisting the Agency as you proceed with these studies and the development of alternatives to the therapy cap.

APTA has discussed with the Agency its concept for a possible alternative based on patient assessment according to the severity of the patient's condition and the intensity of the physical therapist's mental effort and judgment, technical skill and physical effort, and stress. The Association intends to conduct independent research to develop and validate this "severity/intensity" structure, but we encourage CMS to include evaluation of this system in any research projects it conducts to gather meaningful information regarding patient use of therapy services. We look forward to working with the Agency and its contractors to develop this concept.

Lastly, **we recommend that CMS analyze the claims data from 2006 and 2007 to determine the impact of the therapy cap exceptions process on utilization.** Such analysis is critical to determine whether the therapy cap exception process has been effective and in making decisions regarding any refinement of the therapy cap exceptions process in the future if Congress passes legislation extending the exceptions process.

Medicare Payment Rate for 2008: SGR methodology

APTA is also alarmed at the potential impact of the 9.9% reduction in payment that CMS is predicting for 2008. As the Agency is aware, the "sustainable growth rate" (SGR) is a seriously flawed formula that will continue to result in significant, unsustainable payment cuts in the future. These cuts are forecasted to total 37 % or more by 2015, while the practice costs faced by physical therapists and other providers continue to rise.

The potential impact of SGR cuts are further magnified this year when combined with the proposed budget neutrality adjustment to the work relative value units (RVUs). The combination of these adjustments would result in a cut in payments of around 9% for physical therapists and even more significant cuts for many other health care professionals in 2008. APTA is deeply troubled that these cuts will significantly hinder the ability of physicians to care for their patients and of physical therapists to care for Medicare beneficiaries needing rehabilitation services.

These proposed cuts undermine the goal of Congress and CMS to create a Medicare payment system that preserves patient access and achieves greater quality of care. If health care professionals experience significant and compounding cuts in payment at a time of rising practice costs, access to care for millions of elderly and disabled will be jeopardized.

Clearly, a new formula that bases updates on the increases in the cost of delivering health care services is needed. We recognize that it will be necessary for Congress to act to change the formula. However, until a new formula is adopted CMS should assist Congress in resolving the SGR problem by taking administrative actions that would reduce the size of the projected cuts.

To reduce the cost of an SGR solution, CMS should remove spending on physician-administered drugs from calculations of the SGR, retroactive to 1996. Drugs should not be considered

physician services and therefore should not be included in the physician SGR pool. In addition, when establishing the SGR spending target, we urge CMS to take into account regulatory changes such as national coverage decisions that result in increases in spending. When the impact of the regulatory changes are not taken into account, the cost of the new benefits and program changes are financed by cuts in payments to physicians, physical therapists, and other health care professionals.

TRHCA – Section 101(B): PQRI

The proposed rule discusses in detail plans for implementing the second year (2008) of the Physician Quality Reporting Initiative (PQRI) for physicians, physical and occupational therapists, speech-language pathologists, and other practitioners billing under the physician fee schedule. CMS is proposing a significantly expanded list of clinical and structural measures and identifies sources for these measures in the rule

With the exception of those measures previously endorsed or adopted by the National Quality Foundation (NQF) or Ambulatory Quality Alliance (AQA), the proposed rule states that no measure will be used for the 2008 measure set that has not been endorsed by NQF or adopted by AQA by November 15, 2007. The preamble to the proposed rule includes a lengthy discussion of the criteria that must be met by organizations proposing quality measures. Organizations must develop measures through the use of a consensus-based process. The statute references two organizations – NQF and AQA – as examples of such organizations but leaves the Secretary discretion to recognize other organizations.

As CMS proceeds with the Physician Quality Reporting Initiative, APTA urges the Agency to ensure that non-physician groups such as physical therapists have a meaningful opportunity to participate in the development of measures.

In the rule, CMS is proposing that there be approximately 161 measures for 2008. **APTA strongly urges the Agency to provide sufficient advance notice to providers regarding the new measures and their specifications.** Providers need to be able to understand the new measures if they choose to report to CMS on them in 2008. In addition, providers need adequate notice to make any necessary changes to their procedures and systems to report on any new measures.

APTA is concerned that physical therapists who work in certain outpatient therapy settings such as hospitals, rehabilitation agencies, and skilled nursing facilities (Part B), are unable to participate in the PQRI initiative. Section 101 of the Tax Relief and Health Care Act of 2006 identified covered professional services and eligible professionals who could participate in the PQRI program. Specifically, section 101 states:

> *(3) COVERED PROFESSIONAL SERVICES AND ELIGIBLE PROFESSIONALS DEFINED- For purposes of this subsection:*
>
> *`(A) COVERED PROFESSIONAL SERVICES- The term `covered professional services' means services for which payment is made under, or is based on, the fee schedule established under this section and which are furnished by an eligible professional.*

`(B) ELIGIBLE PROFESSIONAL- The term `eligible professional' means any of the following:

`(i) A physician.

`(ii) A practitioner described in section 1842(b)(18)(C).

`(iii) A physical or occupational therapist or a qualified speech-language pathologist.

Clearly, physical therapists are included as eligible professionals. Physical therapy services provided by physical therapists in hospitals, SNFs (Part B), rehabilitation agencies, and comprehensive outpatient rehabilitation facilities (CORFs) are reimbursed under the physician fee schedule. Therefore, CMS should allow these settings to participate in the PQRI initiative. The Agency has stated that these practice settings cannot participate in the PQRI program because they do not use the 1500 or 837-P claim form. Instead, they submit claims using the UB-04 or 837-I and there is no place on this claim form to report the individual NPI of the physical therapist furnishing the service. **APTA strongly urges CMS to identify a method to enable physical therapists providing services in these settings to report on these quality measures.** It is in the best interest of the Medicare program to take steps to improve quality in all settings.

Registries

The proposed rule includes a discussion of CMS plans to evaluate and test mechanisms for collecting quality measures from medical registries or electronic health records (EHR). This approach to reporting data would be an alternative to submitting data through the claims processing system. CMS describes five options for data submission from medical registries to CMS:

- Registries could provide measurement codes and beneficiary/service identifiers that could be linked with Medicare claims data;
- Registries could provide quality measure codes and diagnosis codes that could be linked to beneficiary claims data;
- Registries could calculate and submit directly to CMS measures and performance rates for Medicare beneficiaries by NPI and tax identifiers;
- Registries could provide all of the claims data elements using the Part B claims process; or
- Registries could provide their Medicare data ("data dump") to CMS.

APTA strongly supports the use of registries and EHR as a means to measure and report quality and outcomes of care. By using systems that are easily incorporated into clinical practice, CMS will circumvent the need for redundant data collection methods and may address the immediate needs of the PQRI while establishing a framework for quality control and program effectiveness for the future. Linking PQRI data with comprehensive clinical and demographic data that can be found within EHR and comprehensive data registries will significantly increase the potential to assess this quality measures program and may lead to the development of new or enhanced quality indicators. Furthermore, APTA supports the view that national professional associations should become intimately involved in registry and EHR selection or development for the PQRI. Professional expertise is essential in determining appropriate data points to assess in determining provider and patient care quality.

In addition, APTA views the use of registries as a way to address limitations that prevent certain practitioners from reporting on quality measures to Medicare. Presently, some physical therapists in hospital outpatient departments, skilled nursing facilities (SNFs), rehabilitation agencies, and CORFs cannot participate in the PQRI program because there is no place on the claim form for their individual National Provider Identifier (NPI). By accepting data directly from registries and EHRs, CMS will enable a greater proportion of physical therapists to participate in this quality initiative resulting in greater impact on patient care.

APTA firmly believes that developing a health information technology infrastructure to support quality improvement, providing physical therapists with evidence-based clinician decision support, and tools to ensure compliance and incorporate quality performance measurement in their practices, are all key to improving the quality of care. To this end, we have dedicated significant resources to improve the access of evidence based information, including quality measures, to practicing physical therapists. As an example, we have developed an EHR that houses our national outcome database system and has incorporated the quality indicators approved by the PQRI. This system, called APTA CONNECT, has the ability to analyze a comprehensive set of demographic and clinical data that can be tied to the PQRI quality indicators. Hence, the provider can determine in real time if the quality indicator affects the quality of patient care on an individual and patient population basis. This system can easily incorporate new quality measures, analyze their effects on other measures, and report the findings immediately. APTA CONNECT has the potential to perform the data collection and analysis detailed in all five options suggested in the proposed rule if increased communication between the CMS claims and CONNECT databases are enabled.

In the rule, CMS discusses its plans to evaluate and test the mechanisms to use registries for the reporting of PQRI data. APTA is interested in participating in the testing of the registry-based quality data submission mechanism and looks forward to seeing more details from CMS in the near future.

Physician Self-Referral Issues

Abusive Physical Therapy Practice Arrangements under the In-Office Ancillary Services Exception

In the proposed rule, CMS addresses revisions to the federal physician self-referral laws (also known as the Stark laws) to minimize fraudulent and abusive practices permitted under the law. In particular, the rule addresses growing concerns for loopholes created by the "in-office ancillary services exception". APTA applauds the Agency's efforts to enforce the Stark laws to eliminate abusive financing arrangements that undermine the intent of the Congress when creating these laws. We strongly support any efforts to eliminate abusive financing arrangements under the Stark law that are created solely for profit without regard to the best interest of the Medicare beneficiary.

CMS, in this proposed rule, specifically states that, "In response to [Stark] Phase II, [the Agency] received hundreds of letters from physical therapists and occupational therapists stating that the in-office ancillary services exception encourages physicians to create physical and occupational

therapy practices." This comment stills stands true and is becoming an even larger problem. **We strongly urge the Agency to remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.**

As illustrated in the white paper, *Why Physician-Owned Physical Therapy Services Should Be Unlawful Under the Stark Law*, provided to the Agency in our August 22 meeting, physician ownership or interest in physical therapy, other specialty services and medical equipment has become a growing problem and often leads to overutilization and a decline in quality health care. This has been evidenced in OIG studies[1] and reports published by the Medicare Payment Advisory Committee (MedPAC)[2]. Of particular concern to the profession of physical therapy are the increasing instances of physician-owned physical therapy service (POPTS) models appearing across the country. POPTS is a financial relationship in which a physician refers patients for physical therapy treatment and gains financially from the referral and are generally created under the cloak of the in-office ancillary exception to the Stark law.

By eliminating physical therapy as a DHS furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, overutlization of physical therapy services under the Medicare program, and enhance the quality of patient care.

In the proposed rule, CMS has posed the following question regarding the in-office ancillary exception to the Stark rule:

> *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)?*

The in-office ancillary services exception allows patients of a sole practitioner or physician in a group practice to receive ancillary services in the same building in which the referring physician or his or her group practice furnishes medical services. This practice was designed to allow flexibility and convenience for the patient while receiving care. We contend that physical therapy services do not meet the criteria or stated purpose of the exception.

Physical therapy services are recurring services and are administered over a prolonged period of time that requires the patient to return up two to three times a week for therapy. In the course of this treatment, it is very rare that the patient is seen by the physician. Generally, the physical therapist develops the plan of care and consults with the physician for their input. After consultation, the physical therapist proceeds with the plan of care and the physician may, at their discretion, check on the status and progress of the patient on a periodic basis. Therefore, we contend, based on the general model of physical therapy treatment, that it is no more convenient

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[1] Office of the Inspector General, Department of Health and Human Services. 1994. *Physical Therapy in Physician's Offices*, no. OEI-02-90-00590. Washington, DC: OIG and OIG, Physical Therapy Billed By Physicians (May 1, 2006).

[2] Medicare Payment Advisory Committee. 2004. *Report to Congress: Growth in the Volume of Physician Services*. Washington, DC: MedPAC.

for the patient to receive physical therapy services in the physician's office than it is for the physician to refer the patient to an independent physical therapy clinic in which the physician has no financial ties.

One general commonality behind the in-office ancillary services exception is that the services furnished under the exception are incident-to services; meaning that services are integral and necessary to the physicians primary treatment and therefore require direct physician supervision. To the contrary, it is becoming commonplace that physician-owned physical therapy services are not furnished under the Medicare incident-to provisions. Physicians are employing physical therapists who are obtaining their own individual provider numbers from Medicare and then furnishing and billing for these services under their individual provider numbers and benefits are then reassigned to the physician group practice for payment. Under this structure, there is little physician involvement during physical therapy treatment and the physical therapist treats the patient independent of physician supervision.

Thus, it can only be concluded that physical therapy services can be effectively delivered independent of the physician and that these services are not needed at the time of the physician visit to determine the diagnoses of the patient or the plan of care. As illustrated above, there is no prevailing quality of care need or added patient convenience realized by including physical therapy as a permissible service under the in-office ancillary services exception. Therefore, it is evident that that physical therapy should be removed as a DHS under the in-office ancillary exception.

Secretary Authority to Remove Physical Therapy from the In-Office Ancillary Services Exception

There is no doubt that CMS has ample authority to revise the Stark regulations in the manner suggested, both under the Secretary's general rulemaking authority, and under specific authority conferred in the Stark law itself.

The Social Security Act grants the Secretary authority to promulgate such rules "as may be necessary to carry out the administration of the [Medicare program]." [3] In the face of an agency's exercise of such expressly-delegated rulemaking authority, the agency's decisions about what regulations are necessary are subject to judicial deference, and will be overturned only if they are arbitrary, capricious, or "manifestly contrary to the statute."[4] In the case of the Medicare program, which involves the public as well as the health and welfare of a vulnerable population, it has also been observed that the Secretary "retains a large reservoir of express and implied power to adopt rational requirements that guard against waste and fraud. Such

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3 42 U.S.C. § 1395hh(a)(1), SSA 1871(a)(1) ("The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title [XVIII].").

4 Chevron v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984)

regulations may include reasonably based presumptions and policy determinations reflecting the Secretary's judgment as to what is required to make the program work." [5]

As discussed in the *White Paper*, the evidence is overwhelming that POPTS is an overutilized service, leading to significant Medicare overpayments, and that it offers no offsetting patient care or convenience benefits. The *White Paper* also makes clear that this situation derives from the financial conflict of interest that is inherent in the POPTS business model. As such, there is no case to be made that excluding physical therapy from the permissible in-office ancillary services would be arbitrary or capricious. Quite the contrary, it would be a reasonable and prudent response to a documented abuse of the Medicare program.

Nor can it reasonably be argued that removing physical therapy from the permissible in-office ancillary services would be contrary to law. The best articulation of this argument would be that because Congress acted to exclude certain items of durable medical equipment and enteral and parenteral nutrients from the permissible in-office ancillary services,[6] CMS is precluded from making any subsequent exclusion in the exercise of its regulatory authority.[7] This argument is wholly unconvincing. It suggests that because Congress at one time identified a programmatic abuse that required statutory action, the agency charged with administering the statute is thereafter precluded from finding and acting to stem additional related abuses by regulation. As noted above, the Medicare law's express delegation of rulemaking power to the Secretary is considerable, and we are aware of no legal authority that this rulemaking power could be considered limited in this way.

Moreover, the statutory language of the in-office ancillary services exception itself gives the Secretary additional and more specific, authority to exclude services from the permissible in-office ancillary services. After all, the Stark law defines physical therapy as a designated health service, self-referral for which is prohibited unless the service satisfies one of the exceptions. Here, the pertinent exception *only* allows physicians to self-refer for in-office ancillary services "if the ownership or investment interest . . . meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse." [8]

Thus, all that is required for the Secretary to exclude a service from the permissible in-office ancillary services is for the Secretary to conclude that a program abuse exists, and that removing the service is needed to protect against that abuse. Like all agency decisions, this one will be lawful as long as it is not arbitrary, capricious, or contrary to law. As discussed in the *White Paper*, the evidence is more than sufficient to show the abuses with POPTS. In light of that, **a CMS decision to prohibit POPTS under the in-office ancillary exception would be a**

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5 See Hosp. San Jorge v. Sec'y of Health, Educ., and Welfare, 616 F.2d 580, 590 (1st Cir. 1980) (Campbell, J., concurring).

6 42 U.S.C. § 1395nn(b)(2)(B)

7 This argument might also be viewed as an argument that the agency rule would be arbitrary and capricious because "the agency has relied on factors which Congress has not intended it to consider." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins., 463 U.S. 29, 43 (1983).

8 42 U.S.C. § 1395nn(b)(2)(B) (end).

manifestly reasonable, and therefore lawful, exercise of the Secretary's rulemaking authority.

Tightening Additional Requirements under the In-Office Ancillary Services Exception

As stated earlier, APTA believes that the in-office ancillary services exception, in its entirety, is problematic and creates significant loopholes for fraud and abuse in the Medicare program, but there are also statutory definitions that must be adhered to under the exception that when examined, individually, should be revised to curb abusive practices created by the exception. In the proposed rule, CMS poses the following question:

> *Whether and how changes should be made to the definitions of same building and centralized building under the in-office ancillary services exception?*

The Agency's interpretation of the "centralized building" requirement creates a significant loophole for fraudulent and abusive behavior. The present definition allows the physician group practice to utilize multiple off-site locations to furnish DHS such as physical therapy. CMS only requires that these off-site locations are exclusively used by the group practice.

As stated earlier, this allows a physician group practice to employ a physical therapist, who has obtained an individual provider number from Medicare, to provide services and reassign benefits to the physician practice for payment. This directly conflicts with the original intent of the in-office ancillary exception which was to provide DHS in the physician's own office to their patients.[9]

We strongly urge CMS tighten the restrictions under the definition of "centralized building" to reflect the original intent of the law in which services under the in-office ancillary exception are only allowed when they are delivered in the physician's own office thus eliminating the use of multiple off-site locations. The current definition and interpretation leads to potentially abusive behavior and creates an environment for overutilization of services.

Unit-of-Service Payments in Space and Equipment Leases

In this proposed rule, CMS expresses its concern with lease arrangements that are structured so that a physician is rewarded for each referral he or she makes for designated health services (DHS). Such arrangements could take the form of physician leasing equipment that he or she owns to a hospital and receiving per-use fee each time a patient is referred by the physician-owner to the hospital for use of the equipment. CMS states that it also concerned about arrangements where the physician is the lessee and rents space or equipment from a hospital or other DHS entity on a per-click basis.

CMS proposes that space and equipment leases may not include unit-of-service-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a

[9] CMS, Medicare Program; Physicians' Referrals to Health Care Entities with which They Have Financial Relationships (Phase II): Interim Final Rule, 69 Fed. Reg. 16056 (March 6, 2204)

physician lessor to the entity. CMS believes that these situations are inherently abusive because of the incentive to profit by the volume of patients referred to the lessee.

We applaud CMS on identifying this potential area for fraud and abuse. We agree that these types of arrangements are inherently abusive due to incentive nature, and APTA urges the Agency to finalize the proposed change in the final rule.

Comprehensive Outpatient Rehabilitation Facility (CORF) Issues

In the proposed rule, CMS discusses several changes to the structure, payment, and administration of comprehensive outpatient rehabilitation facilities (CORFs). The purpose of a CORF is to permit the beneficiary to receive multidisciplinary rehabilitation services at a single location in a coordinated fashion.

Specifically, we would like to highlight the following proposed changes:

1) The proposed rule seeks to revise the CORF regulations to clarify that CORF services are covered only if they relate directly to the rehabilitation of injured, disabled, or sick patients. CMS states that it believes that this is consistent with congressional intent that services provided in a CORF setting be covered as CORF services only if such services relate directly to the rehab of the patient.

   APTA supports this proposed revision. It is directly aligned with the goals and purpose of physical therapy. Physical therapists examine each individual and develop a plan using treatment techniques to promote the ability to move, reduce pain, restore function, and prevent disability. In addition, physical therapists work with individuals to prevent the loss of mobility before it occurs by developing fitness- and wellness-oriented programs for healthier and more active lifestyles.

2) The proposed rule seeks to clarify that physical therapy, occupational therapy, and speech-language pathology services can be furnished in the patient's home when payment for those therapy services is not otherwise covered under the Medicare home health benefit. In addition, the proposed rule seeks to clarify that the patient must be present during the home environment evaluation that is performed by the therapist. CMS states that this necessary to fully evaluate the potential impact of the home situation on the patient's rehabilitation goals.

   APTA supports these proposed revisions. We believe that both of these provisions are positive updates that allow physical therapists to provide comprehensive and an improved quality of care to Medicare beneficiaries in the home environment.

The APTA appreciates the opportunity to offer these comments to CMS. If you need further information, please contact Gayle Lee, Director of Regulatory Affairs at 703-706-8549. We look forward to working with you on the issues raised in these comments.

Sincerely,

Dave Mason

G. David Mason
Vice President, Government Affairs

Attachments

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

Organization : **BILL MOYER**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
BILL MOYER

Submitter : Mr. Paul Lehr **Date:** 08/31/2007

Organization : Nathan Pritikin Research Foundation

Category : Other

Issue Areas/Comments

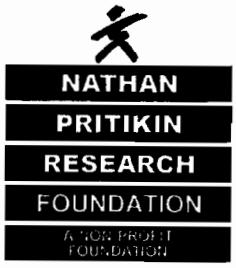
GENERAL

GENERAL

See attachment

CMS-1385-P-14572-Attach-1.PDF

14572



BY ELECTRONIC DELIVERY

August 30, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1385-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008)

Dear Acting Deputy Administrator Kuhn:

The Pritikin Research Foundation (Pritikin) appreciates this opportunity to comment on a proposal related to the reporting of cardiac rehabilitation services contained in the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding revisions to payment policies under the physician fee schedule and other Part B payment policies for calendar year 2008 (the "Proposed Rule").[1] The Pritikin Program helps prevent and reverse heart disease and other health concerns through its focus on daily exercise and an eating plan based on natural, whole foods like fruits, vegetables, whole grains, seafood rich in omega 3s, and limited lean animal protein. More than 110 studies in prestigious medical journals like *The New England Journal of Medicine, Archives of Internal Medicine* and *Circulation* have documented the Pritikin Program's success in helping patients dramatically reduce total and LDL cholesterol, lower blood pressure to the point where medication is no longer necessary, eliminate the need for bypass surgery and angioplasty, and substantially reduce the risk of heart disease, hypertension, obesity, diabetes, and risk factors for cancers of the breast, colon, and prostate.

We are writing to comment on the proposal regarding reporting of cardiac rehabilitation services under the physician fee schedule. We are pleased that CMS recognizes the need to clarify coding and payment for these services that can dramatically improve the health and quality of life for the growing numbers of Medicare beneficiaries with heart disease, but we believe that CMS must do more to support the expanded use of cardiac rehabilitation programs – especially those with published, peer-reviewed research showing that they achieve quantifiable results. Pritikin appreciates the time and effort CMS has dedicated considering our recommendations for ensuring that Medicare beneficiaries can participate in proven cardiac

[1] 72 Fed. Reg. 38,122 (July 12, 2007).

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rehabilitation programs under the national coverage determination (NCD) issued last year.[2] Under that revised NCD, Medicare requires cardiac rehabilitation programs to provide a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education, and counseling. This contrasts markedly with the prior NCD for cardiac rehabilitation, under which only exercise was reimbursed by Medicare. In addition, the revised NCD contemplates contractors extending coverage, on a case-by-case, to 72 sessions. Under the former NCD, coverage of more than 36 sessions was highly exceptional, with contractors required to have significant documentation of the need for sessions beyond 36.

As you know, we are concerned that Medicare's current reimbursement for cardiac rehabilitation services may make it difficult for providers to offer effective programs, such as the Pritikin Program, to Medicare beneficiaries in a sustainable manner. Over the past year or so, we have recommended that CMS take certain specific steps to support access to these programs.

We are pleased to see that CMS proposes to implement one of our recommended steps by creating two new Level II Healthcare Common Procedure Coding System (HCPCS) G-Codes for cardiac rehabilitation services.[3] These codes are Gxxx1, Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour), and Gxxx2, Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour), and would replace the Current Procedural Terminology (CPT) codes, 93797 and 93798, respectively, for these services when billed under the Medicare physician fee schedule.[4] The G-codes would have the same descriptions as 93797 and 93798, except that they would apply to an hour of cardiac rehabilitation services instead of a "session." We agree that this change will help to "clarify the coding and payment for these services"[5] by more accurately describing the services provided. Those furnishing cardiac rehabilitation will be able to use these codes to bill for one hour of a modality of cardiac rehabilitation identified in the NCD, such as prescribed exercise or education, rather than an undefined "session" of services. We support this proposal and we ask CMS to implement it in the final rule.

We also are concerned that Medicare's contractors may misinterpret the descriptions of the proposed new codes in Addendum B, "MD serv cardiac rehab wo ECG" and "MD serv cardiac rehab w ECG,"[6] as requiring the physician to be present in the room during these services when they are furnished by auxiliary personnel. When cardiac rehabilitation is provided incident to a physician's service by auxiliary personnel, Medicare requires the physician to be present in the office suite and immediately available to provide assistance and direction, but not necessarily to be in the same room as the auxiliary personnel.[7] We ask CMS to modify the descriptions of the new codes in Addendum B of the Proposed Rule to match the abbreviated

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2 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10.

3 72 Fed. Reg. at 38,149.

4 Id.

5 Id.

6 Id. at 38,361.

7 See Medicare Benefit Policy Manual, ch. 15, § 60.1.

descriptions used for 93797 and 93798, respectively: "Cardiac rehab" and "Cardiac rehab/monitor." This change would help to prevent confusion about the level of physician supervision required for cardiac rehabilitation services that are provided incident to a physician's services.

While we applaud CMS's proposal to create new G-codes, we believe that beneficiary access to proven cardiac rehabilitation programs will be limited unless CMS implements our other recommendations. First, we ask CMS to state in the final rule that multiple sessions of cardiac rehabilitation can be covered on the same day. In our program, patients participate in several modalities of cardiac rehabilitation, such as a medical evaluation, prescribed exercise, education, and counseling, in a single day. Providers of our program should be reimbursed for each hour of each modality a beneficiary receives. Fortunately, Medicare already has a mechanism to recognize when a code is billed multiple times in a single day for distinct services. Modifier 59 indicates that "a procedure or service was distinct and independent for other services performed on the same day."[8] CMS should facilitate payment for these services by stating in the final rule that payment may be made for each session when modifier 59 is used and documentation in the patient's record explains that each use of the code represents an hour of a component of the cardiac rehabilitation program.

Second, CMS proposes to crosswalk the new G-codes to payment for 93797 and 93798, respectively. We recommend that both codes be crosswalked to payment for 93798 to ensure that Medicare reimbursement is adequate to support the full range of modalities provided in these programs. The current payment rates are based on the resources associated with supervised exercise, not the other services, such as medical evaluation, education, and counseling, that are now covered by the NCD. As CMS acknowledges in the Proposed Rule, the new codes will help the agency set appropriate payment rates by more accurately measuring the services provided.[9] Until new data regarding the costs of providing the full range of cardiac rehabilitation services are available from a significant number of providers, CMS should set the payment for both new G-codes equal to the current rate for 93798 to protect beneficiary access to these services in the physician office setting.

Third, we ask CMS to explain in the final rule that it is likely to be reasonable and necessary to cover 72 cardiac rehabilitation sessions when multiple sessions are provided in one day. The NCD gives contractors the discretion to cover up to 72 sessions of cardiac rehabilitation.[10] Unlike many cardiac rehabilitation programs in which "patients generally receive 2 to 3 sessions per week,"[11] which has traditionally been comprised of only exercise, in our program, patients typically receive multiple sessions per day, not just limited to exercise. When a beneficiary participates in a program of several one-hour sessions of various modalities

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8 American Medical Association, CPT 2007, at 438.

9 72 Fed. Reg. at 38,149.

10 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(D).

11 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(B)(1)(a).

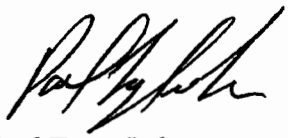
in a single day, coverage of 72 sessions is necessary to provide enough hours of each modality for the patient to receive the full benefit of the program. By advising contractors that 72 sessions are likely to be reasonable and necessary for programs providing multiple sessions per day, CMS will ensure that the goals behind the revised, expanded NCD can be met. In view of the fact that 36 sessions – only of exercise – were covered under the prior NCD, it makes little sense to limit coverage to 36 sessions for programs such as Pritikin. We ask CMS, in the final rule or other guidance, to remind contractors of their discretion to cover up to 72 sessions and to explain that 72 sessions are likely to be reasonable and necessary where beneficiaries receive cardiac rehabilitation from programs that provide several one-hour sessions per day of the various modalities that are included in the cardiac rehabilitation NCD.

Finally, we ask CMS to encourage contractors to factor the proven results of a program into their coverage decisions. For example, 72 sessions should be presumptively covered when they are provided by a program, such as Pritikin, with peer-reviewed and published research showing that it achieves quantifiable results on important metrics, such as reductions in LDL-cholesterol, triglycerides, blood pressure, blood glucose, and weight, or that it affects the progression of coronary heart disease and/or reduce the need for bypass surgery, angioplasty, or stents and/or reduce the need for medication. This consideration of a program's proven results would help to prevent overutilization of programs that have not demonstrated positive results and is consistent with CMS's goals of furthering evidence-based medicine and improving actual health outcomes.

* * *

Pritikin greatly appreciates the opportunity to comment on the proposed changes to coding for cardiac rehabilitation services and to recommend additional changes that will help Medicare beneficiaries to receive the benefits of successful cardiac rehabilitation programs, such as the Pritikin Program. Please feel free to contact me at 305-935-7122 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Paul Tager Lehr
President
Nathan Pritikin Research Foundation

PTL:pc

Submitter : **Dr. Tsuchiya** **Date: 08/31/2007**

Organization : **Medical Anesthesia Consultants**

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)

Dcar Ms. Norwalk:

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

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to othcr physician scrvices. 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 Medicarc 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 pleascd that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

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

Thank you for your consideration of this serious matter.

Sincerely,

H. Tsuchiya MD

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

Organization : **Carthel Wiley**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

Sincerely,

Carthel Wiley

Submitter : **Ms. Abby Schreiter** **Date: 08/31/2007**

Organization : **Clemson University Sports Medicine**

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a certified athletic trainer, and a member of the National Athletic Training Association. I currently work at Clemson University as an athletic trainer. I am also enrolled in school and working towards my master's degree. My educational background includes a BS in Athletic Training, and Health and Physical Education teaching licensure.

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,

Abby T. Schreiter, ATC, L-ATC

Submitter : Mrs. Brenda Gross **Date:** 08/31/2007

Organization : AANA

Category : Other Practitioner

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
_Brenda Gross, CRNA_____
Name & Credential
_1601 64th Ave. North_____
Address
Fargo, N.D. 58102

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

Organization : **Wisdom Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To whom it may concern:

Let me voice informally my experience with physician owned physical therapy services (POPTS). I am an independent private practitioner for physical therapy and have seen physicians stop a patient from going to my clinic in mid treatment when the physician opens his own physical therapy service. The patients were happy with my service and were paying one third of the physician s charges billed by his physical therapy. I have had physicians give a prescription to the patient for 3x per week for 4 weeks physical therapy and then when he finds out the patient has chosen my service instead of his, he rewrites the prescription for 2x per week for 2 weeks.

My state has regulations about notifying the patient about physician conflict of interest through ownership of physical therapy practices. This is circumvented by placing the notification on the back of the prescription that goes across the hall to the POPTS and the patient never sees it. By the way the state regulation calls for this written notification to be on 8 ? x 11 inch full sheet. This is blatantly disregarded.

Please note that for whatever euphemism is being used at present time, be it joint venture, vertical integration or some other nicety, POPTS is a corruption of the physician s responsibility to the patient. The physician s patients go to him or her to get medical advice and that is what they pay for (or Medicare pays for). When there are POPTS, patients get medical advice tainted by the physician s own business interest. Also note that healthcare is not directed by free enterprise in this regard. With physicians as gatekeepers, healthcare is more of a fiefdom whereby the aristocracy controls where the patient goes for care. Tribute is paid in the form of an unearned fee to the physician.
POPTS does not increase competition by arithmetically adding another provider, it eliminates competition. POPTS physicians are not going to refer outside their business interest regardless of cost, or quality of care.

For those of us who have withstood the temptations of POPTS, it has been a long and costly battle both monetarily and catastrophically in stress and personal loss. I have fought POPTS for decades because I thought it corrupt. Believe me I could have made a fortune by selling out. There are many times when I have thought the sacrifice and pain associated was for nothing. I think that the least that the government could do is to have the Stark legislation function as intended without loopholes that make it meaningless.

Respectfully submitted,

Michael R. Wisdom PT
630 Orange St.
Macon, Georgia 31201

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

Organization : MARY MOYER

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
MARY MOYER

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

Organization : **Dr. Robert Bauer**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14579-Attach-1.PDF

14579

SEASIDE MEDICAL GROUP, P.A.

AT THE

PRITIKIN LONGEVITY CENTER® & SPA

DAVID LEHR, M.D
(1929-1996)

Robert E. Bauer, M.D.
Michelle Bauer, M.D.
Norman Blum, M.D.
Danine Fruge, M.D.

Maurice Laszlo, M.D.
Ronald J. Scheib, M.D.
William Sherman, M.D.
Sam J. Sugar, M.D.
Susan E. Grober, Ph.D.

August 30, 2007

BY ELECTRONIC DELIVERY

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Service, Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1385-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008)

Dear Acting Deputy Administrator Kuhn:

I appreciate the opportunity to comment on a proposal related to the reporting of cardiac rehabilitation services contained in the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding revisions to payment policies under the physician fee schedule and other Part B payment policies for calendar year 2008 (the "Proposed Rule").[1] I am a physician specializing in Internal Medicine with training in Endocrinology and Cardiology who practices at the Seaside Medical Group at the Pritikin Longevity Center in Aventura, FL. In 61 years of experience, I have treated a large number of patients who are need of cardiac rehabilitation services, and I have seen first-hand the benefits of the Pritikin Program. My patients have successfully used the Pritikin Program to help prevent and reverse heart disease and other health concerns, dramatically reduce total and LDL cholesterol, lower blood pressure to the point where medication is no longer necessary, eliminate the need for bypass surgery and angioplasty, and substantially reduce the risk of heart disease, hypertension, obesity, diabetes, and risk factors for cancers of the breast, colon, and prostate. The results I have witnessed are supported by more than 110 studies of the Pritikin Program in prestigious medical journals like *The New England Journal of Medicine, Archives of Internal Medicine* and *Circulation.*

I am writing to thank CMS for proposing new coding for cardiac rehabilitation services under the physician fee schedule and to recommend additional changes that would help to further protect beneficiary access to these services. I was delighted that CMS revised its National Coverage Determination (NCD) for cardiac rehabilitation services in 2006 to extend Medicare coverage beyond exercise to include other critical services that, together with exercise, help patients prevent and reverse heart disease. Under the revised NCD, Medicare requires cardiac rehabilitation programs to provide a medical evaluation, a program to modify cardiac risk factors

[1] 72 Fed. Reg. 38,122 (July 12, 2007).

(e.g., nutritional counseling), prescribed exercise, education, and counseling.[2] As a physician who works with patients throughout the Pritikin Program, I firmly believe that exercise alone is not sufficient to achieve significant cardiac rehabilitation results, and I am glad that Medicare now covers the other services that are essential to cardiac rehabilitation. I also support the discretion granted to Medicare's contractors by the revised NCD to extend coverage, on a case-by-case, to 72 sessions, instead of the 36 sessions that were usually covered under the former NCD.

In the Proposed Rule, CMS explains that it will "clarify the coding and payment" for cardiac rehabilitation services by creating two new Level II Healthcare Common Procedure Coding System (HCPCS) G-Codes for these services when billed under the physician fee schedule.[3] I believe that the G-codes would describe the services provided more accurately because, unlike the current codes (93797 and 93798), they would describe one hour of service rather than an undefined "session." In my practice, patients undergo several modalities of cardiac rehabilitation in a single day. The new codes would clearly instruct physicians to report each hour of the program separately, rather than grouping different services together into a "session." This will help ensure that all providers of cardiac rehabilitation report their services consistently and will help Medicare to set accurate rates for all of the services now covered under the NCD. I strongly recommend that CMS implement the new codes in the final rule.

I am concerned, however, that the abbreviated descriptions of the new G-codes in Addendum B of the Proposed Rule could cause confusion among Medicare's contractors about the services. Although the G-codes and the Current Procedural Terminology (CPT) codes have the same descriptions, with the substitution of "per hour" for "per session," CMS has used different abbreviations for the G-codes in Addendum B. The proposed abbreviations are, "MD serv cardiac rehab wo ECG" and "MD serv cardiac rehab w ECG"[4] instead of, "Cardiac rehab" and "Cardiac rehab/monitor." Medicare's contractors could interpret these descriptions as requiring the physician to be present in the room during these services when they are furnished by auxiliary personnel, even though CMS has not changed the supervision requirements for these services. Like other services furnished by auxiliary personnel incident to a physician's service, Medicare requires the physician to be present in the office suite and immediately available to provide assistance and direction during cardiac rehabilitation, but not necessarily to be in the same room as the auxiliary personnel.[5] I ask CMS to modify the descriptions of the new codes in Addendum B of the Proposed Rule to match the abbreviated descriptions used for 93797 and 93798, respectively: "Cardiac rehab" and "Cardiac rehab/monitor." This change would help to prevent confusion about the level of physician supervision required for cardiac rehabilitation services that are provided incident to a physician's services.

---

2 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10.

3 72 Fed. Reg. at 38,149. The new codes would be: Gxxx1, Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour), and Gxxx2, Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour)

4 Id. at 38,361.

5 See Medicare Benefit Policy Manual, ch. 15, § 60.1.

The proposed G-codes are an important first step toward protecting and promoting access to these life-changing services, but the NCD's potential to expand access to these services and prevent future hospitalizations could be frustrated if CMS does not take these additional steps. I make the following recommendations to further support Medicare beneficiaries' use of effective cardiac rehabilitation programs, such as the Pritikin Program. First, I ask CMS to clarify in the final rule that multiple sessions of cardiac rehabilitation can be covered on the same day. As explained above, my patients participate in several modalities of cardiac rehabilitation, such as a medical evaluation, prescribed exercise, education, and counseling, in a single day. In order to be reimbursed appropriately for each modality, we need to be able to bill multiple units of the G-codes on one day. Including a statement in the final rule that modifier 59 may be used with the G-codes would allow us to bill for each "distinct and independent" procedure performed on the same day.[6] I ask CMS to provide this instruction in the final rule.

Second, CMS must set payment for the G-codes at a level that will allow physicians to provide all of the services required for an effective cardiac rehabilitation program. CMS proposes to set payment for the Gxxx1 and Gxxx2 equal to payment for 93797 and 93798, respectively. I am concerned that the current rates for 93797 are not adequate for all of the cardiac rehabilitation services we provide in the Pritikin Program, and I recommend that both G-codes be paid at the rate for 93798. When CMS set the current payment rates for 93797 and 93798, it considered only the resources necessary to provide supervised exercise. Now that medical evaluation, education, and counseling also are covered, CMS will need to calculate new rates that include the resources involved in providing those services. While CMS collects data using the new G-codes, it should set the payment for both new G-codes equal to the current rate for 93798 to protect beneficiary access to these services in the physician office setting.

Third, to ensure that beneficiaries can receive a sufficient number of sessions of cardiac rehabilitation, CMS should explain in the final rule that it is likely to be reasonable and necessary to cover 72 cardiac rehabilitation sessions when multiple sessions are provided in one day. Under the old NCD, which covered only exercise, a cardiac rehabilitation program consisted of 36 sessions of supervised exercise, typically provided in two to three sessions per week. The new NCD recognizes not only that medical evaluation, education, and counseling are necessary, but also that up to 72 sessions of cardiac rehabilitation may be necessary to achieve the full benefits of cardiac rehabilitation, and it gives contractors the discretion to cover the additional 36 sessions.[7] These additional sessions are necessary for my patients because they typically participate in multiple sessions per day, and for each session of exercise, they participate in at least one session of another modality. In this kind of program, patients are likely to need the full 72 sessions to provide enough hours of each modality for the patient to receive the full benefit of the program. I ask CMS to advise its contractors that 72 sessions are likely to be reasonable and necessary for programs providing multiple sessions per day. CMS should remind contractors of their discretion to cover up to 72 sessions and to explain that 72 sessions are likely to be reasonable and necessary where beneficiaries receive cardiac rehabilitation from programs that provide several one-hour sessions per day of the various modalities that are included in the cardiac rehabilitation NCD.

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[6] American Medical Association, CPT 2007, at 438.

[7] NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(D).

Finally, CMS should encourage contractors to consider a program's proven results when they make their coverage decisions. My patients participate in the Pritikin Program, which has peer-reviewed and published research showing that it achieves quantifiable results on important metrics, such as reductions in LDL-cholesterol, triglycerides, blood pressure, blood glucose, and weight, or that it affects the progression of coronary heart disease and/or reduce the need for bypass surgery, angioplasty, or stents and/or reduce the need for medication. Contractors should consider 72 sessions to be presumptively covered when they are provided by a program, such as Pritikin, with this kind of published support. Factoring proven results into coverage decisions is consistent with CMS's goals of furthering evidence-based medicine and improving actual health outcomes and will help ensure that Medicare's resources are used appropriately for programs that have demonstrated positive results.

* * *

I greatly appreciate the opportunity to comment on the proposed changes to coding for cardiac rehabilitation services and to recommend additional changes that will help Medicare beneficiaries to receive the benefits of successful cardiac rehabilitation programs, such as the Pritikin Program. Please feel free to contact me at 305-935-7131 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Robert E. Bauer, M.D.

REB:pc

Submitter : **Dr. Theodoros Papalimberis** **Date: 08/31/2007**

Organization : **Maine Medical Center**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

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

Re: CMS-1385-P
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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.

Ted Papalimberis, MD
Maine Medical Center
22Bramhall St
Portland, ME 04101
207-662-2526

Submitter : Mr. Gregg Macek **Date:** 08/31/2007

Organization : Barrington Orthopedic Specialists, Ltd.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14581-Attach-1.TXT

14581

August 31, 2007

Dear Sir or Madam:

My name is Gregg Macek. I am an athletic trainer and the Director of Rehabilitation for a large orthopedic physician group in the northwest suburbs of Chicago. I have been in this role for 5 years and I have been practicing as an athletic trainer for 12 years. I received my degree in Kinesiology –Bioscience from the University of Illinois in Urbana-Champaign with completion of an accredited Athletic Training curriculum. I am certified by the National Athletic Trainers Association Board of Certification and I am a licensed health care provider in the state of Illinois with a NPI number.

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, especially in the state of Illinois. 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,

Gregg Macek, ATC

Submitter : Dr. Gary Kirsh **Date:** 08/31/2007

Organization : American Association of Clinical Urologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1385-P-14582-Attach-1.PDF

#14582

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue
Washington, DC 20201

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the CMS-1385-P - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008.

The American Association of Clinical Urologists (AACU) is a non-profit corporation representing over 4500 urologists nationwide. As physicians, we take pride in our calling to provide care to patients. It is an honor and a privilege to improve the lives of Medicare beneficiaries and we are reminded of the following preamble to the original Medicare law:

"Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person."

42 U.S.C. 1395 (OSCN 2007), CHAPTER 7 - SOCIAL SECURITY;
SUBCHAPTER XVIII - HEALTH INSURANCE FOR AGED AND DISABLED

Payment Rates for 2008

In 2008, urologists, like other physicians who treat Medicare beneficiaries face a 10% payment rate cut. AACU asks, as it has for many years, for CMS to work with members of Congress to avert this cut and ensure payment updates next year and subsequent years truly reflect the costs of delivering healthcare services in America.

Payments for services to urologists and all physicians right now are essentially the same as they were six years ago in 2001. Despite even the efforts of Congress, the flat line fixes have not kept pace with inflation and it appears that no long term solution. Because of this, 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%.

Only physicians and other health professionals face big cuts under this payment formula. Other providers – nursing homes and hospitals have payment updates that reflect the cost of inflation. We cannot help but notice the 10% cut in

payment rates facing physicians is in grim 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 and are a poor use of limited resources.

Urologists, like other specialists, are a part of America's healthcare delivery system, and thus a stable payment environment for their services is critical. We believe CMS must work with Congress to avert Medicare fee-for-service physician pay cuts by enacting positive physician payment updates that accurately reflect increases in medical practice costs, as indicated by the Medicare Economic Index (MEI). In addition, over the long-term, CMS must work with Congress to repeal the SGR and replace it with a system that keeps pace with increases in medical practice costs

Stark In Office Exception
Although no specific proposals exist from CMS, any change to the Stark "in-office" ancillary exception would unduly harm the ability of urologists to provide efficiencies and needed services to patients. Services provided under the exception are important to healthcare delivery. CMS should not further limit this already complex and burdensome regulation. Additionally, CMS should carefully consider any new restrictions on the in-office exception only after accumulation of first hand evidence and indication that such restrictions would improve not only access to care and services for Medicare beneficiaries but also the bottom line of the Medicare Trust Fund.

Markup and Reassignment
Under the proposed rule regarding reassignment and diagnostic testing, the only technical or professional services a medical group could mark-up would be those performed by the group's full time employees. This would significantly hurt the ability of group practices with in-office imaging equipment to utilize independent contractors and part-time employees to perform professional interpretation services. We understand CMS desire to prevent markups and gaming the system but offices with in-office imaging equipment utilize independent contractors and part time employees to perform high-quality professional interpretation services. CMS appears to believe these arrangements that permit physician groups to bill for services provided by a contractor in a centralized building may lead to program abuse. AACU does not think the proposed rule represents a sensitivity to how group practices and how physicians are compensated.

Regarding the reassignment proposal, CMS doesn't appear to understand the nature of how reassignment of the right to bill and receive payment for the professional component occurs throughout the health care system. Physicians regularly reassign for their professional interpretations to other medical groups as independent contractors. Often, physicians are paid an aggregate monthly or annual amount for their services and therefore there is no "charge" to report on a claim. The proposed rules do not address how the billing physician or medical group can determine the amount to declare on the claim as the charge for any

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

Organization : **Maine Medical Center and ASA**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

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

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

Dear Ms. Norwalk:

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

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

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Ageney 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 faetor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

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

Organization : STEVE MURDOCK

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

Rc: CMS-1385-P
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STEVE MURDOCK

Submitter : **Dr. Maurice Laszlo** **Date: 08/31/2007**

Organization : **Dr. Maurice Laszlo**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14585-Attach-1.PDF

14585

SEASIDE MEDICAL GROUP, P.A.

AT THE

PRITIKIN LONGEVITY CENTER® & SPA

DAVID LEHR, M.D
(1929-1996)

Robert E. Bauer, M.D.
Michelle Bauer, M.D.
Norman Blum, M.D.
Danine Fruge, M.D.

Maurice Laszlo, M.D.
Ronald J. Scheib, M.D.
William Sherman, M.D.
Sam J. Sugar, M.D.
Susan E. Grober, Ph.D.

August 30, 2007

ELECTRONIC DELIVERY

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services. Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1385-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008)

Dear Acting Deputy Administrator Kuhn:

I appreciate the opportunity to comment on a proposal related to the reporting of cardiac rehabilitation services contained in the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding revisions to payment policies under the physician fee schedule and other Part B payment policies for calendar year 2008 (the "Proposed Rule").[1] I am a physician specializing in Cardiology who practices at the Seaside Medical Group at the Pritikin Longevity Center in Aventura, FL. In 55 years of experience, I have treated a large number of patients who are need of cardiac rehabilitation services, and I have seen first-hand the benefits of the Pritikin Program. My patients have successfully used the Pritikin Program to help prevent and reverse heart disease and other health concerns, dramatically reduce total and LDL cholesterol, lower blood pressure to the point where medication is no longer necessary, eliminate the need for bypass surgery and angioplasty, and substantially reduce the risk of heart disease, hypertension, obesity, diabetes, and risk factors for cancers of the breast, colon, and prostate. The results I have witnessed are supported by more than 110 studies of the Pritikin Program in prestigious medical journals like *The New England Journal of Medicine, Archives of Internal Medicine* and *Circulation.*

I am writing to thank CMS for proposing new coding for cardiac rehabilitation services under the physician fee schedule and to recommend additional changes that would help to further protect beneficiary access to these services. I was delighted that CMS revised its National Coverage Determination (NCD) for cardiac rehabilitation services in 2006 to extend Medicare coverage beyond exercise to include other critical services that, together with exercise, help patients prevent and reverse heart disease. Under the revised NCD, Medicare requires cardiac rehabilitation programs to provide a medical evaluation, a program to modify cardiac risk factors

[1] 72 Fed. Reg. 38,122 (July 12, 2007).

(e.g., nutritional counseling), prescribed exercise, education, and counseling.[2] As a physician who works with patients throughout the Pritikin Program, I firmly believe that exercise alone is not sufficient to achieve significant cardiac rehabilitation results, and I am glad that Medicare now covers the other services that are essential to cardiac rehabilitation. I also support the discretion granted to Medicare's contractors by the revised NCD to extend coverage, on a case-by-case, to 72 sessions, instead of the 36 sessions that were usually covered under the former NCD.

In the Proposed Rule, CMS explains that it will "clarify the coding and payment" for cardiac rehabilitation services by creating two new Level II Healthcare Common Procedure Coding System (HCPCS) G-Codes for these services when billed under the physician fee schedule.[3] I believe that the G-codes would describe the services provided more accurately because, unlike the current codes (93797 and 93798), they would describe one hour of service rather than an undefined "session." In my practice, patients undergo several modalities of cardiac rehabilitation in a single day. The new codes would clearly instruct physicians to report each hour of the program separately, rather than grouping different services together into a "session." This will help ensure that all providers of cardiac rehabilitation report their services consistently and will help Medicare to set accurate rates for all of the services now covered under the NCD. I strongly recommend that CMS implement the new codes in the final rule.

I am concerned, however, that the abbreviated descriptions of the new G-codes in Addendum B of the Proposed Rule could cause confusion among Medicare's contractors about the services. Although the G-codes and the Current Procedural Terminology (CPT) codes have the same descriptions, with the substitution of "per hour" for "per session," CMS has used different abbreviations for the G-codes in Addendum B. The proposed abbreviations are, "MD serv cardiac rehab wo ECG" and "MD serv cardiac rehab w ECG"[4] instead of, "Cardiac rehab" and "Cardiac rehab/monitor." Medicare's contractors could interpret these descriptions as requiring the physician to be present in the room during these services when they are furnished by auxiliary personnel, even though CMS has not changed the supervision requirements for these services. Like other services furnished by auxiliary personnel incident to a physician's service, Medicare requires the physician to be present in the office suite and immediately available to provide assistance and direction during cardiac rehabilitation, but not necessarily to be in the same room as the auxiliary personnel.[5] I ask CMS to modify the descriptions of the new codes in Addendum B of the Proposed Rule to match the abbreviated descriptions used for 93797 and 93798, respectively: "Cardiac rehab" and "Cardiac rehab/monitor." This change would help to prevent confusion about the level of physician supervision required for cardiac rehabilitation services that are provided incident to a physician's services.

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2 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10.

3 72 Fed. Reg. at 38,149. The new codes would be: Gxxx1, Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour), and Gxxx2, Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour)

4 Id. at 38,361.

5 See Medicare Benefit Policy Manual, ch. 15, § 60.1.

The proposed G-codes are an important first step toward protecting and promoting access to these life-changing services, but the NCD's potential to expand access to these services and prevent future hospitalizations could be frustrated if CMS does not take these additional steps. I make the following recommendations to further support Medicare beneficiaries' use of effective cardiac rehabilitation programs, such as the Pritikin Program. First, I ask CMS to clarify in the final rule that multiple sessions of cardiac rehabilitation can be covered on the same day. As explained above, my patients participate in several modalities of cardiac rehabilitation, such as a medical evaluation, prescribed exercise, education, and counseling, in a single day. In order to be reimbursed appropriately for each modality, we need to be able to bill multiple units of the G-codes on one day. Including a statement in the final rule that modifier 59 may be used with the G-codes would allow us to bill for each "distinct and independent" procedure performed on the same day.[6] I ask CMS to provide this instruction in the final rule.

Second, CMS must set payment for the G-codes at a level that will allow physicians to provide all of the services required for an effective cardiac rehabilitation program. CMS proposes to set payment for the Gxxx1 and Gxxx2 equal to payment for 93797 and 93798, respectively. I am concerned that the current rates for 93797 are not adequate for all of the cardiac rehabilitation services we provide in the Pritikin Program, and I recommend that both G-codes be paid at the rate for 93798. When CMS set the current payment rates for 93797 and 93798, it considered only the resources necessary to provide supervised exercise. Now that medical evaluation, education, and counseling also are covered, CMS will need to calculate new rates that include the resources involved in providing those services. While CMS collects data using the new G-codes, it should set the payment for both new G-codes equal to the current rate for 93798 to protect beneficiary access to these services in the physician office setting.

Third, to ensure that beneficiaries can receive a sufficient number of sessions of cardiac rehabilitation, CMS should explain in the final rule that it is likely to be reasonable and necessary to cover 72 cardiac rehabilitation sessions when multiple sessions are provided in one day. Under the old NCD, which covered only exercise, a cardiac rehabilitation program consisted of 36 sessions of supervised exercise, typically provided in two to three sessions per week. The new NCD recognizes not only that medical evaluation, education, and counseling are necessary, but also that up to 72 sessions of cardiac rehabilitation may be necessary to achieve the full benefits of cardiac rehabilitation, and it gives contractors the discretion to cover the additional 36 sessions.[7] These additional sessions are necessary for my patients because they typically participate in multiple sessions per day, and for each session of exercise, they participate in at least one session of another modality. In this kind of program, patients are likely to need the full 72 sessions to provide enough hours of each modality for the patient to receive the full benefit of the program. I ask CMS to advise its contractors that 72 sessions are likely to be reasonable and necessary for programs providing multiple sessions per day. CMS should remind contractors of their discretion to cover up to 72 sessions and to explain that 72 sessions are likely to be reasonable and necessary where beneficiaries receive cardiac rehabilitation from programs that provide several one-hour sessions per day of the various modalities that are included in the cardiac rehabilitation NCD.

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6 American Medical Association, CPT 2007, at 438.

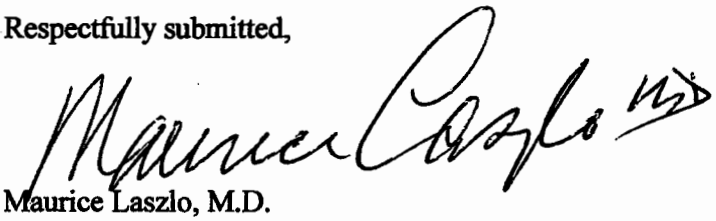
7 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(D).

Finally, CMS should encourage contractors to consider a program's proven results when they make their coverage decisions. My patients participate in the Pritikin Program, which has peer-reviewed and published research showing that it achieves quantifiable results on important metrics, such as reductions in LDL-cholesterol, triglycerides, blood pressure, blood glucose, and weight, or that it affects the progression of coronary heart disease and/or reduce the need for bypass surgery, angioplasty, or stents and/or reduce the need for medication. Contractors should consider 72 sessions to be presumptively covered when they are provided by a program, such as Pritikin, with this kind of published support. Factoring proven results into coverage decisions is consistent with CMS's goals of furthering evidence-based medicine and improving actual health outcomes and will help ensure that Medicare's resources are used appropriately for programs that have demonstrated positive results.

* * *

I greatly appreciate the opportunity to comment on the proposed changes to coding for cardiac rehabilitation services and to recommend additional changes that will help Medicare beneficiaries to receive the benefits of successful cardiac rehabilitation programs, such as the Pritikin Program. Please feel free to contact me at 305-935-7131 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Maurice Laszlo, M.D.

ML:pc

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

Organization : Immune Deficiency Foundation

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14586-Attach-1.PDF

14586

IMMUNE DEFICIENCY FOUNDATION

The National Organization Dedicated to Research, Education and Advocacy for Primary Immune Deficiency Diseases

August 30, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P; Comments on Coding—Payment for IVIG Add-On Code in the Proposed Revision to Payment Policies under the Physician Fee Schedule and Other Changes to Payment Policies under Part B for CY 2008

Dear Mr. Kuhn,

The Immune Deficiency Foundation (IDF), founded in 1980, is the national patient organization dedicated to improving the diagnosis and treatment of patients with primary immune deficiency diseases (PIDD) through research, education, and advocacy. Thousands of individuals and their families who live with primary immune deficiency diseases count on IDF for (1) education programs and materials that focus on the recognition and diagnosis of primary immune deficiency diseases, important life management, patient care resources, and support for patients and family members, (2) research and medical education programs that improve diagnosis and treatment of primary immune deficiency diseases, and (3) advocacy to promote policies that positively affect the primary immune deficiency community.

We are providing our comments on the July 12, 2007, Proposed Rule, CMS-1385-P, regarding continuation of the preadministration-related services payment for IVIG in physicians' offices.

Comments on the Proposed Continuation of the Preadministration-Related Services Payment for IVIG Infusion in Physicians' Offices

Background

Since the change in Medicare's reimbursement for IVIG beginning in January 2005, IDF has been besieged by calls from Medicare patients who have primary immune deficiency diseases and for whom IVIG is their only effective treatment. For all of these patients, IVIG is literally life-saving; without it, they would die. With the change to the ASP+6% reimbursement methodology, PIDD patients were, for the first time, being turned away from their physicians' offices, being sent to hospital outpatient departments for infusions, and having treatments postponed and intervals between treatments increased.

IDF Surveys on IVIG Issues for Medicare PIDD Patients

In order to better quantify and understand the effect the ASP+6% reimbursement change has had on PIDD patient access to care, IDF commissioned three national surveys during 2006: a national patient survey of patients from the IDF data base, including an over-sample of Medicare patients, a national survey of immunologists, conducted with the American Academy of Asthma, Allergy, and Immunology (AAAAI), and a national survey of hospital pharmacists. All surveys were conducted in the second half of 2006.

IDF Patient Survey

The 2006 IDF Patient Survey was a mail-based survey of 1,000 PIDD patients, including individuals insured through Medicare, as well as those insured through private pay insurance. Conducted between August and October 2006, the survey found:

- 32% of Medicare patients have changed site of infusion since the end of 2004, compared to 20% of private pay patients.
- Medicare patients have moved from being treated in doctors' private offices to hospital outpatient settings. This change in treatment setting for the Medicare patient with PIDD means that patients may be exposed to greater numbers of infectious agents in the hospital, they may experience greater inconvenience and more travel time in getting to that setting, and they will have higher out-of-pocket costs in the hospital outpatient setting as well.
- Reimbursement is the primary reason for changes in location for Medicare patients, but not private pay patients.
- Medicare patients are more likely to report having more trouble in getting IVIG treatments since the beginning of 2005 than private pay patients (27% vs. 12%).
- Medicare patients were much more likely than private pay patients to report:
  - Treatments postponed;
  - Treatment intervals increased;
  - Dosage decreased; and
  - Other problems since the beginning of 2005.
- PIDD patients on Medicare are more than two times more likely than private pay patients (26% vs. 10%) to report negative health effects since the beginning of 2005, as a result of problems in obtaining or paying for IVIG.
- These negative health effects experienced by Medicare patients with PIDD and needing IVIG include more infections generally, pneumonia, bronchitis, and increased use of antibiotics, among others.
- The likelihood and number of health problems experienced by PIDD patients on Medicare is directly correlated with their difficulties in obtaining IVIG therapy.

IDF will be surveying patients again later this year to determine whether their access problems have changed. We assume, however, from the number of calls we have received thus far during 2007 that PIDD patients continue to have the same access problems documented in our 2006 patient survey, with patients experiencing difficulties in finding providers who will treat them because of inadequate reimbursement from Medicare. Patients also continue to experience negative health effects that accompany delayed treatments.

IDF/AAAI Survey

The survey of immunologists, conducted in collaboration with the AAAAI, looked at the treatment of patients with PIDD and other conditions with IVIG. This survey was conducted by internet between October 13 and November 17, 2006. A total of 230 immunologists completed the survey. Its findings include the following:

- The average price physicians (immunologists) paid for liquid IVIG was 11% more than Medicare's reimbursement. Forty-four percent (44%) of the physicians paid more for the product than they were reimbursed.
- The average price physicians paid for lyophilized IVIG was 19% higher than the reimbursement at that time. Eight-one percent (81%) of the physicians paid more than they were reimbursed.
- Fifty-one percent (51%) of physicians have had patients change their site of IVIG therapy because of reimbursement.
- Thirty-six percent (36%) of physicians treating PIDD patients with IVIG reported that their IVIG-using patients have experienced additional or more severe health problems since the beginning of 2005 because of reductions in Medicare reimbursement.
- Nearly half of the doctors with IVIG-using PIDD patients believe current Medicare reimbursement rules for IVIG pose an extreme or serious risk to the health of their patients.
- Three-quarters of physicians were of the opinion that current reimbursement poses at least a moderate risk to the health their PIDD patients.

IDF Hospital Pharmacist Surveys

The IDF survey of hospital pharmacists was conducted by telephone during August-October, 2006, with 310 randomly selected pharmacies in the U.S. serving 100+ bed hospitals which dispense IVIG. The survey's findings include the following:

- Thirty percent (30%) of the pharmacists reported that their hospitals paid more for liquid IVIG than they were reimbursed. The average price paid for liquid IVIG was 4% more than Medicare reimbursement.
- Fifty-seven percent (57%) of the pharmacists reported their hospitals paid more for lyophilized IVIG than they were reimbursed. The average price paid for lyophilized was 15% more than the Medicare reimbursement rate.
- Sixty-two percent (62%) believe Medicare reimbursement is not adequate. A substantial proportion (41%) of hospitals remains uncertain or doubtful about continuing to provide IVIG therapy to patients in the future given current reimbursement policy.

During the second quarter of 2007, IDF resurveyed hospital pharmacists, conducting a telephone survey between June 13, 2007 and July 15, 2007, with 235 randomly selected pharmacies in the U.S. serving 100+ bed hospitals which dispense IVIG. The picture has changed very little:

- Forty-one percent (41%) of the hospitals pay more for the product than they are reimbursed. The average price paid for liquid IVIG was 1% more than Medicare reimbursement, with the amount varying by the size of the hospital.

- Sixty-two percent (62%) of the pharmacists reported their hospitals pay more for lyophilized IVIG than they were reimbursed. The average price paid for lyophilized was 9% more than the Medicare reimbursement rate.
- Sixty-one percent (61%) stated that Medicare does not fully reimburse the hospital for the purchase of IVIG. Almost one-third (30%) of the hospitals are uncertain or doubtful about continuing to provide IVIG therapy to patients in the future, given current reimbursement policy.

Similarities between IDF Surveys' Findings and the April 2007 Report of the Office of the Inspector General (OIG)

As summarized above, IDF's surveys have demonstrated that a significant portion of the PIDD patient population needing IVIG has encountered serious problems with continuing access to IVIG since the change to Medicare's ASP+6% reimbursement methodology. Providers have also had difficulty purchasing IVIG at a cost equal to or less than Medicare's reimbursement.

The April 2007 OIG report, *Intravenous Immune Globulin: Medicare Payment and Availability*, validates many of the findings of IDF's surveys. The OIG found that 41% of IVIG sales to physicians and 44% of sales to hospitals by the three larges distributors occurred at prices above the Medicare payment amount during the third quarter of 2006. This finding was for a time during the calendar year when ASP+6% could begin to catch up to price increases that had occurred at the beginning of the year. *The OIG observed that whatever improvement some providers saw in the relationship of Medicare reimbursement for IVIG to prices paid during the first three quarters of 2006 would be eroded if manufacturers were to increase prices for IVIG in the future.*

The OIG also reported that 61% of responding physicians indicated that they had sent patients to hospitals for IVIG treatment, largely because of their inability to purchase IVIG at prices below the Medicare reimbursement amounts, but also because they were unable to provide patients with adequate amounts of IVIG. As noted above, IDF does not believe the hospital is the most appropriate setting for PIDD patients to receive their infusion. In addition, OIG found that some physicians had stopped providing IVIG to Medicare beneficiaries altogether.

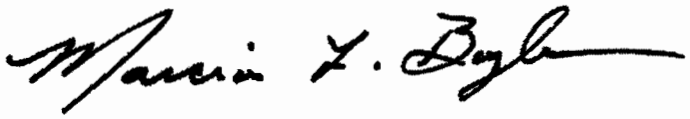
Conclusion: The Need to Continue the Preadministration-Related Services Add-On

IDF's tracking of PIDD patients' access to IVIG through surveys and its patient advocacy help-line have clearly indicated that a significant portion of Medicare beneficiaries with PIDD have experienced—and continue to experience—serious problems in finding providers who will infuse them with life-saving IVIG. The consequences of these access problems are the negative health effects discussed above. IDF applauds CMS' decision to continue the preadministration-related services add-on for IVIG infused in physicians' offices. Without continuation of the add-on, IDF believes access problems would become more severe for patients with PIDD. At the same time, we believe that the amount of the add-on is insufficient to correct the IVIG access problems our patients are having. CMS' action to create separate codes for each of the liquid IVIG products may ameliorate some of our patients' problems, but it is far too early for us to believe that this is the solution we need. In the last analysis, we do not believe that the ASP+6% methodology is working for IVIG. Too many providers serving our patients simply can not purchase IVIG for the amount Medicare pays. Patients with PIDD are the ones who suffer the consequences in the end.

As the OIG's report notes, IVIG is a unique pharmaceutical product whose production requires substantial time, resources, and special handling not generally associated with other drug products. We urge that CMS review existing data and collect whatever additional data is necessary for making recommendations on payment reforms appropriate for IVIG.

Thank you for your attention and consideration.

Sincerely,



Marcia Boyle
President & Founder
Immune Deficiency Foundation

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www.primaryimmune.org idf@primaryimmune.org

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

Organization : **David Williams**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

Thank you for your consideration of this serious matter.
David Williams

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

Organization : DENISE MURDOCK

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

Re: CMS-1385-P
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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.
DENISE MURDOCK

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

Organization : Larry Snyder

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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Thank you for your consideration of this serious matter.

Sincerely,

Larry Snyder

Submitter : **Dr. Ronald Scheib** **Date: 08/31/2007**

Organization : **Dr. Ronald Scheib**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14590-Attach-1.PDF

14590

SEASIDE MEDICAL GROUP, P.A.

AT THE

PRITIKIN LONGEVITY CENTER® & SPA

DAVID LEHR, M.D
(1929-1996)

Robert E. Bauer, M.D.
Michelle Bauer, M.D.
Norman Blum, M.D.
Danine Fruge, M.D.

Maurice Laszlo, M.D.
Ronald J. Scheib, M.D.
William Sherman, M.D.
Sam J. Sugar, M.D.
Susan E. Grober, Ph.D.

August 30, 2007

BY ELECTRONIC DELIVERY

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services, Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1385-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008)

Dear Acting Deputy Administrator Kuhn:

I appreciate the opportunity to comment on a proposal related to the reporting of cardiac rehabilitation services contained in the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding revisions to payment policies under the physician fee schedule and other Part B payment policies for calendar year 2008 (the "Proposed Rule").[1] I am a physician specializing in Cardiology who practices at the Seaside Medical Group at the Pritikin Longevity Center in Aventura, FL. In 46 years of experience, I have treated a large number of patients who are need of cardiac rehabilitation services, and I have seen first-hand the benefits of the Pritikin Program. My patients have successfully used the Pritikin Program to help prevent and reverse heart disease and other health concerns, dramatically reduce total and LDL cholesterol, lower blood pressure to the point where medication is no longer necessary, eliminate the need for bypass surgery and angioplasty, and substantially reduce the risk of heart disease, hypertension, obesity, diabetes, and risk factors for cancers of the breast, colon, and prostate. The results I have witnessed are supported by more than 110 studies of the Pritikin Program in prestigious medical journals like *The New England Journal of Medicine, Archives of Internal Medicine* and *Circulation.*

I am writing to thank CMS for proposing new coding for cardiac rehabilitation services under the physician fee schedule and to recommend additional changes that would help to further protect beneficiary access to these services. I was delighted that CMS revised its National Coverage Determination (NCD) for cardiac rehabilitation services in 2006 to extend Medicare coverage beyond exercise to include other critical services that, together with exercise, help patients prevent and reverse heart disease. Under the revised NCD, Medicare requires cardiac rehabilitation programs to provide a medical evaluation, a program to modify cardiac risk factors

[1] 72 Fed. Reg. 38,122 (July 12, 2007).

(e.g., nutritional counseling), prescribed exercise, education, and counseling.[2] As a physician who works with patients throughout the Pritikin Program, I firmly believe that exercise alone is not sufficient to achieve significant cardiac rehabilitation results, and I am glad that Medicare now covers the other services that are essential to cardiac rehabilitation. I also support the discretion granted to Medicare's contractors by the revised NCD to extend coverage, on a case-by-case, to 72 sessions, instead of the 36 sessions that were usually covered under the former NCD.

In the Proposed Rule, CMS explains that it will "clarify the coding and payment" for cardiac rehabilitation services by creating two new Level II Healthcare Common Procedure Coding System (HCPCS) G-Codes for these services when billed under the physician fee schedule.[3] I believe that the G-codes would describe the services provided more accurately because, unlike the current codes (93797 and 93798), they would describe one hour of service rather than an undefined "session." In my practice, patients undergo several modalities of cardiac rehabilitation in a single day. The new codes would clearly instruct physicians to report each hour of the program separately, rather than grouping different services together into a "session." This will help ensure that all providers of cardiac rehabilitation report their services consistently and will help Medicare to set accurate rates for all of the services now covered under the NCD. I strongly recommend that CMS implement the new codes in the final rule.

I am concerned, however, that the abbreviated descriptions of the new G-codes in Addendum B of the Proposed Rule could cause confusion among Medicare's contractors about the services. Although the G-codes and the Current Procedural Terminology (CPT) codes have the same descriptions, with the substitution of "per hour" for "per session," CMS has used different abbreviations for the G-codes in Addendum B. The proposed abbreviations are, "MD serv cardiac rehab wo ECG" and "MD serv cardiac rehab w ECG"[4] instead of, "Cardiac rehab" and "Cardiac rehab/monitor." Medicare's contractors could interpret these descriptions as requiring the physician to be present in the room during these services when they are furnished by auxiliary personnel, even though CMS has not changed the supervision requirements for these services. Like other services furnished by auxiliary personnel incident to a physician's service, Medicare requires the physician to be present in the office suite and immediately available to provide assistance and direction during cardiac rehabilitation, but not necessarily to be in the same room as the auxiliary personnel.[5] I ask CMS to modify the descriptions of the new codes in Addendum B of the Proposed Rule to match the abbreviated descriptions used for 93797 and 93798, respectively: "Cardiac rehab" and "Cardiac rehab/monitor." This change would help to prevent confusion about the level of physician supervision required for cardiac rehabilitation services that are provided incident to a physician's services.

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2 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10.

3 72 Fed. Reg. at 38,149. The new codes would be: Gxxx1, Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour), and Gxxx2, Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour)

4 Id. at 38,361.

5 See Medicare Benefit Policy Manual, ch. 15, § 60.1.

The proposed G-codes are an important first step toward protecting and promoting access to these life-changing services, but the NCD's potential to expand access to these services and prevent future hospitalizations could be frustrated if CMS does not take these additional steps. I make the following recommendations to further support Medicare beneficiaries' use of effective cardiac rehabilitation programs, such as the Pritikin Program. First, I ask CMS to clarify in the final rule that multiple sessions of cardiac rehabilitation can be covered on the same day. As explained above, my patients participate in several modalities of cardiac rehabilitation, such as a medical evaluation, prescribed exercise, education, and counseling, in a single day. In order to be reimbursed appropriately for each modality, we need to be able to bill multiple units of the G-codes on one day. Including a statement in the final rule that modifier 59 may be used with the G-codes would allow us to bill for each "distinct and independent" procedure performed on the same day.[6] I ask CMS to provide this instruction in the final rule.

Second, CMS must set payment for the G-codes at a level that will allow physicians to provide all of the services required for an effective cardiac rehabilitation program. CMS proposes to set payment for the Gxxx1 and Gxxx2 equal to payment for 93797 and 93798, respectively. I am concerned that the current rates for 93797 are not adequate for all of the cardiac rehabilitation services we provide in the Pritikin Program, and I recommend that both G-codes be paid at the rate for 93798. When CMS set the current payment rates for 93797 and 93798, it considered only the resources necessary to provide supervised exercise. Now that medical evaluation, education, and counseling also are covered, CMS will need to calculate new rates that include the resources involved in providing those services. While CMS collects data using the new G-codes, it should set the payment for both new G-codes equal to the current rate for 93798 to protect beneficiary access to these services in the physician office setting.

Third, to ensure that beneficiaries can receive a sufficient number of sessions of cardiac rehabilitation, CMS should explain in the final rule that it is likely to be reasonable and necessary to cover 72 cardiac rehabilitation sessions when multiple sessions are provided in one day. Under the old NCD, which covered only exercise, a cardiac rehabilitation program consisted of 36 sessions of supervised exercise, typically provided in two to three sessions per week. The new NCD recognizes not only that medical evaluation, education, and counseling are necessary, but also that up to 72 sessions of cardiac rehabilitation may be necessary to achieve the full benefits of cardiac rehabilitation, and it gives contractors the discretion to cover the additional 36 sessions.[7] These additional sessions are necessary for my patients because they typically participate in multiple sessions per day, and for each session of exercise, they participate in at least one session of another modality. In this kind of program, patients are likely to need the full 72 sessions to provide enough hours of each modality for the patient to receive the full benefit of the program. I ask CMS to advise its contractors that 72 sessions are likely to be reasonable and necessary for programs providing multiple sessions per day. CMS should remind contractors of their discretion to cover up to 72 sessions and to explain that 72 sessions are likely to be reasonable and necessary where beneficiaries receive cardiac rehabilitation from programs that provide several one-hour sessions per day of the various modalities that are included in the cardiac rehabilitation NCD.

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6 American Medical Association, CPT 2007, at 438.

7 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(D).

Finally, CMS should encourage contractors to consider a program's proven results when they make their coverage decisions. My patients participate in the Pritikin Program, which has peer-reviewed and published research showing that it achieves quantifiable results on important metrics, such as reductions in LDL-cholesterol, triglycerides, blood pressure, blood glucose, and weight, or that it affects the progression of coronary heart disease and/or reduce the need for bypass surgery, angioplasty, or stents and/or reduce the need for medication. Contractors should consider 72 sessions to be presumptively covered when they are provided by a program, such as Pritikin, with this kind of published support. Factoring proven results into coverage decisions is consistent with CMS's goals of furthering evidence-based medicine and improving actual health outcomes and will help ensure that Medicare's resources are used appropriately for programs that have demonstrated positive results.

* * *

I greatly appreciate the opportunity to comment on the proposed changes to coding for cardiac rehabilitation services and to recommend additional changes that will help Medicare beneficiaries to receive the benefits of successful cardiac rehabilitation programs, such as the Pritikin Program. Please feel free to contact me at 305-935-7131 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Ronald J. Scheib, M.D.

RJS:pc

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

Organization : **Lorna Willaims**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

Thank you for your consideration of this serious matter.
Lorna Williams

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

Organization : Massachusetts General Physicians Organization

Category : Physician

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

see attachment

CMS-1385-P-14592-Attach-1.DOC

believe that RVUs for those codes should be adjusted to reflect the additional physician work and practice expense required to perform 93325. In 2007, the total RVUs for the global procedure were 2.65. This is a significant outlay of resources.

The MGH agrees it is important that CMS continues to refine its program to allow all Medicare patients access to high quality cardiovascular care. To help achieve that goal, we would be happy to answer any questions.

Sincerely,

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

Organization : PAIGE NORMAN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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PAIGE NORMAN

Submitter : **Dr. Michael Deck** **Date: 08/31/2007**

Organization : **Dr. Michael Deck**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Thank you for the opportunity to submit comments on the Physician Self-Referral Provisions of CMS-1385-P entitled 'Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008'.

I am a board-certified pathologist and a member of the College of American Pathologists. I practice in Plano, Texas as part of 5-member pathology group which serves four hospitals in the area and operates an independent laboratory.

I applaud CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. I am aware of arrangements in my practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group's patients. I believe these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services.

Specifically I support the expansion of the anti-markup rule to purchased pathology interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. These revisions to the Medicare reassignment rule and physician self-referral provisions are necessary to eliminate financial self-interest in clinical decision-making. I believe that physicians should not be able to profit from the provision of pathology services unless the physician is capable of personally performing or supervising the service.

Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. I agree that the Medicare program should ensure that providers furnish care in the best interests of their patients, and, restrictions on physician self-referrals are an imperative program safeguard to ensure that clinical decisions are determined solely on the basis of quality and medical necessity. The proposed changes do not impact the availability or delivery of pathology services and are designed only to remove the financial conflict of interest that compromises the integrity of the Medicare program.

Sincerely,

Michael A. Deck, M.D.

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

Organization : **Mary Snyder**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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Thank you for your consideration of this serious matter.

Sincerely,

Mary Snyder

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

Organization : **Teranne Williams**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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LcsV. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Teranne Williams

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

Organization : PAULINE PARKER

Category : Individual

Issue Areas/Comments

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Centers for Medicare and Medicaid Services
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PAULINE PARKER

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

Organization : **Physicians Anesthesia Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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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.

I am honored to care for our nation s seniors. This is part of my commitment to my community and our country. Though I will continue to care for my patients independent of the CMS decision, a full implementation of the RUC recommendation would begin to address the looming decline in access to anesthesia medical care.

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.

You may reach me at 410-913-3781 should you have any questions regarding my correspondence. Thank you for your consideration of this serious matter and your service to our patients.

Sincerely,
Paul D Gilmore, MD

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

Organization : Gary Williams

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Submitter : REX PAYNE **Date:** 08/31/2007

Organization : REX PAYNE

Category : Individual

Issue Areas/Comments

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REX PAYNE

factors (e.g., nutritional counseling), prescribed exercise, education, and counseling.[2] As physicians who work with patients throughout the Pritikin Program, we firmly believe that exercise alone is not sufficient to achieve significant cardiac rehabilitation results, and we are glad that Medicare now covers the other services that are essential to cardiac rehabilitation. We also support the discretion granted to Medicare's contractors by the revised NCD to extend coverage, on a case-by-case, to 72 sessions, instead of the 36 sessions that were usually covered under the former NCD.

In the Proposed Rule, CMS explains that it will "clarify the coding and payment" for cardiac rehabilitation services by creating two new Level II Healthcare Common Procedure Coding System (HCPCS) G-Codes for these services when billed under the physician fee schedule.[3] We believe that the G-codes would describe the services we provide more accurately because, unlike the current codes (93797 and 93798), they would describe one hour of service rather than an undefined "session." In our practice, patients undergo several modalities of cardiac rehabilitation in a single day. The new codes would clearly instruct physicians to report each hour of the program separately, rather than grouping different services together into a "session." This will help ensure that all providers of cardiac rehabilitation report their services consistently and will help Medicare to set accurate rates for all of the services now covered under the NCD. We strongly recommend that CMS implement the new codes in the final rule.

We are concerned, however, that the abbreviated descriptions of the new G-codes in Addendum B of the Proposed Rule could cause confusion among Medicare's contractors about the services. Although the G-codes and the Current Procedural Terminology (CPT) codes have the same descriptions, with the substitution of "per hour" for "per session," CMS has used different abbreviations for the G-codes in Addendum B. The proposed abbreviations are, "MD serv cardiac rehab wo ECG" and "MD serv cardiac rehab w ECG"[4] instead of, "Cardiac rehab" and "Cardiac rehab/monitor." Medicare's contractors could interpret these descriptions as requiring the physician to be present in the room during these services when they are furnished by auxiliary personnel, even though CMS has not changed the supervision requirements for these services. Like other services furnished by auxiliary personnel incident to a physician's service, Medicare requires the physician to be present in the office suite and immediately available to provide assistance and direction during cardiac rehabilitation, but not necessarily to be in the same room as the auxiliary personnel.[5] We ask CMS to modify the descriptions of the new codes in Addendum B of the Proposed Rule to match the abbreviated descriptions used for 93797 and 93798, respectively: "Cardiac rehab" and "Cardiac rehab/monitor." This change would help to prevent confusion about the level of physician supervision required for cardiac rehabilitation services that are provided incident to a physician's services.

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2 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10.

3 72 Fed. Reg. at 38,149. The new codes would be: Gxxx1, Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour), and Gxxx2, Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour)

4 Id. at 38,361.

5 See Medicare Benefit Policy Manual, ch. 15, § 60.1.

The proposed G-codes are an important first step toward protecting and promoting access to these life-changing services, but the NCD's potential to expand access to these services and prevent future hospitalizations could be frustrated if CMS does not take these additional steps. We make the following recommendations to further support Medicare beneficiaries' use of effective cardiac rehabilitation programs, such as the Pritikin Program. First, we ask CMS to clarify in the final rule that multiple sessions of cardiac rehabilitation can be covered on the same day. As we said above, our patients participate in several modalities of cardiac rehabilitation, such as a medical evaluation, prescribed exercise, education, and counseling, in a single day. In order to be reimbursed appropriately for each modality, we need to be able to bill multiple units of the G-codes on one day. Including a statement in the final rule that modifier 59 may be used with the G-codes would allow us to bill for each "distinct and independent" procedure performed on the same day.[6] We ask CMS to provide this instruction in the final rule.

Second, CMS must set payment for the G-codes at a level that will allow physicians to provide all of the services required for an effective cardiac rehabilitation program. CMS proposes to set payment for the Gxxx1 and Gxxx2 equal to payment for 93797 and 93798, respectively. We are concerned that the current rates for 93797 are not adequate for all of the cardiac rehabilitation services we provide in the Pritikin Program, and we recommend that both G-codes be paid at the rate for 93798. When CMS set the current payment rates for 93797 and 93798, it considered only the resources necessary to provide supervised exercise. Now that medical evaluation, education, and counseling also are covered, CMS will need to calculate new rates that include the resources involved in providing those services. While CMS collects data using the new G-codes, it should set the payment for both new G-codes equal to the current rate for 93798 to protect beneficiary access to these services in the physician office setting.

Third, to ensure that beneficiaries can receive a sufficient number of sessions of cardiac rehabilitation, CMS should explain in the final rule that it is likely to be reasonable and necessary to cover 72 cardiac rehabilitation sessions when multiple sessions are provided in one day. Under the old NCD, which covered only exercise, a cardiac rehabilitation program consisted of 36 sessions of supervised exercise, typically provided in two to three sessions per week. The new NCD recognizes not only that medical evaluation, education, and counseling are necessary, but also that up to 72 sessions of cardiac rehabilitation may be necessary to achieve the full benefits of cardiac rehabilitation, and it gives contractors the discretion to cover the additional 36 sessions.[7] These additional sessions are necessary for our patients because they typically participate in multiple sessions per day, and for each session of exercise, they participate in at least one session of another modality. In this kind of program, patients are likely to need the full 72 sessions to provide enough hours of each modality for the patient to receive the full benefit of the program. We ask CMS to advise its contractors that 72 sessions are likely to be reasonable and necessary for programs providing multiple sessions per day. CMS should remind contractors of their discretion to cover up to 72 sessions and to explain that 72 sessions are likely to be reasonable and necessary where beneficiaries receive cardiac rehabilitation from programs that provide several one-hour sessions per day of the various modalities that are included in the cardiac rehabilitation NCD.

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6 American Medical Association, CPT 2007, at 438.

7 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(D).

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

Organization : Dayna Williams

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognizcd the gross undervaluation of anesthesia serviees, 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 othcr physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from arcas with disproportionately high Medicare populations.

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

To 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.
Dayna Williams

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

Organization : KAY PAYNE

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
KAYE PAYNE

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

Organization : Massachusetts General Physicians Organization

Category : Physician

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

see attached

CMS-1385-P-14605-Attach-1.DOC

Geographic Practice Cost Indices (GPCIs); Section 102 of MIEA-TRHCA and Section 1848 (e) (1) (A) (iii)

The physicians of the Massachusetts General Physicians Organization (MGPO) would like to comment on the removal of the floor of 1.000 from the work Geographic Practice Cost Indices (GPCI) calculation as of January 1, 2008, in accordance with section 102 of MIEA-TRHCA. There are two issues that we wish to address: (1) support of the removal of the GPCI floor and (2) a comment concerning the full application of the work GPCI adjustment.

Removal of the work GPCI floor: The use of an artificial floor of 1.000 for the work GPCI ignores the economic realities across geographic regions. While the implementation of a floor would on its surface appear to benefit some regions without negatively impacting others, it actually creates an inter-region transfer. Real cost differentials experienced throughout the economy are not reflected in the Medicare payment system to physicians. As a result of the floor, the relative cost differential across geographic regions is substantially narrowed compared to other cost differential measures. For example, the GPCI for Urban Massachusetts is 1.030. Establishing a work GPCI floor at 1.000 results in a national average that is greater than 1.000, so that the Urban Massachusetts differential is less than 3 percent. By comparison, the CMS Part A wage adjuster for the Boston area is 1.1843, recognizing that wages in the Boston area are much higher than the national average. The 3 percent work differential currently allowed by the work GPCI only recognizes about 16 percent of the difference between Boston and the national average. Because of the substantial influence of Medicare payments in the marketplace, this contributes to a disadvantage in recruiting and retaining physicians in the Boston area. This disadvantage has been documented in the report of the Massachusetts Medical Society, *2007 Physician Workforce Study: Executive Report.* The study identifies at least nine specialties that have critical or severe shortages of physicians, and further states:

> Based on our experience in analyzing studies of the behavior of other labor markets, this is most uncharacteristic. This leads us to conclude that unless Massachusetts labor markets become more flexible and respond this supply-demand gap will continue for some time to come. (*2007 Physician Workforce Study: Executive Summary,* p. 8.)

Full application of the work GPCI adjustment: As noted in the proposed rule, "section 1848 (e) (1) (A) (iii) of the Act requires that the physician work GPCIs reflect only one-quarter of the relative cost differences." Applying only one-quarter of calculated adjustment for work ignores the economic realities of costs incurred by physicians to locate and work in higher-cost regions. Since about 52 percent of the overall payment is attributed to the work RVU and 75 percent of that payment is not adjusted, the result is that 39 percent of payments are not adjusted for area cost differences. Physicians working in such regions incur costs of living that are similar to other persons living in the same region; often the cost of housing is the principle driver of the cost difference. Failure to apply the full impact of the geographic cost differential adds to the burden of recruiting and retaining physicians in high-cost areas. The application of only a portion of the calculated difference in the costs by geography is not consistent with the application of similar geographic cost differential formulas in other government programs. For example,

the wage differential for Federal employee programs and the wage adjustment in Part A payment programs are not subject to such a reduction.

Summary: We agree with the proposal to allow the expiration of the floor as of January 1, 2008, and would support any effort that would recognize the full impact of the work GPCI cost differences.

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

Organization : AUDREY PERIMAN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.
KAYE PAYNE

Submitter : Dr. keith schrader **Date:** 08/31/2007

Organization : brevard anesthesia services

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

It is certianly time that medicare adjust this gross inequity. It is absurd that anesthesiologists work for little more than a pumbers hourly rate when taking care of medicare patients who are oftcn the sickest and most challenging patients we care for.

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

Organization : FRANK PERIMAN

Category : Individual

Issue Areas/Comments

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FRANK PERIMAN

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

Organization : **Beulah Winter**

Category : **Individual**

Issue Areas/Comments

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Beulah Winter

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

Organization : MERLENE PERIMAN

Category : Individual

Issue Areas/Comments

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Centers for Medicare and Medicaid Services
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MERLENE PERIMAN

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

Organization : **Chip Winter**

Category : **Individual**

Issue Areas/Comments

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Chip Winter

Submitter : Dr. Joanna Pease **Date:** 08/31/2007

Organization : American College of Osteopathic Internists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1385-P-14612-Attach-1.PDF

14012

AMERICAN COLLEGE OF OSTEOPATHIC INTERNISTS

3 Bethesda Metro Center, Suite 508, Bethesda, MD 20814 (301) 656-8877 (800) 327-5183 Fax (301) 656-7133
www.acoi.org

August 31, 2007

Mr. Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule. *72 Fed. Reg. 38,122 et seq.* (July 12, 2007)(CMS-1385-P)

Dear Mr. Kuhn:

The American College of Osteopathic Internists appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for calendar year 2008.

The American College of Osteopathic Internists (ACOI), which represents the nation's osteopathic internists, medical subspecialists, residents and fellows, is dedicated to the advancement of osteopathic internal medicine through excellence in education, advocacy, research and the opportunity for service. Further, the ACOI is committed to assisting its members' efforts to provide the highest level of care possible to their patients. Adoption of the proposed rule published in the *Federal Register* on July 12, 2007 without amendment would jeopardize the future ability of physicians to provide needed care to Medicare beneficiaries.

Impact

Under the proposed rule, physicians are facing an estimated 9.9 percent reduction in reimbursements under the Medicare program for calendar year 2008. Further, as a result of the Sustainable Growth Rate (SGR) formula, physicians are facing additional reductions totaling an estimated 40 percent in Medicare reimbursements over the next eight years. These reductions will be on top of projected practice cost increases of 20 percent over the same time period. The effect will be an even greater disparity between the cost of providing care to Medicare beneficiaries and the reimbursements received from the Centers for Medicare and Medicaid Services (CMS).

Application of basic economic principles suggests that the future projected reductions for physician reimbursements under the Medicare program, coupled with increasing practice expenses, is simply unsustainable. In fact, the Medicare Payment Advisory Committee (MedPAC) acknowledged this in its *2007 March Report to Congress: Medicare Payment Policy*

stating that the "Commission is concerned that such future consecutive annual cuts would threaten beneficiary access to physician services, particularly those provided by primary care physicians." The ACOI believes that it is incumbent upon CMS to utilize its full regulatory authority to curb the negative impact of the SGR formula on physicians, and to protect access to care for millions of Medicare beneficiaries.

One such step that can be taken by CMS is to adjust the conversion factor to achieve budget neutrality. CMS is required to ensure that expenditures will not differ more than $20 million from what expenditures would have been absent changes in work RVUs for any given year. The proposed changes in work RVUs for certain services will increase expenditures and thus require a budget offset. Under the proposed rule, CMS would reduce work RVUs by 11.9 percent to achieve the necessary savings. The ACOI is opposed to this approach in light of past experiences with this mechanism. In fact, in 1999 CMS itself recognized the inherent problems with this approach and stated that it "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).

The ACOI believes the proper way to achieve budget neutrality is to apply an adjustment to the conversion factor. Budget neutrality is a fiscal issue and not one of relativity. To this end, applying an 11.9 percent reduction to work RVUs inappropriately ignores the fiscal rationale for the mandatory adjustments. Therefore, the ACOI recommends that CMS reconsider its proposed approach to achieve budget neutrality and apply an adjustment to the conversion factor.

Geographic Practice Cost Indices (GPCIs)

The ACOI recognizes the difficulties faced by CMS to ensure that Medicare payments to providers are adequately adjusted to reflect regional variations in resource costs. Further, we commend your acknowledgement of potential pitfalls and your interest in proceeding with care. However, we are concerned with the three potential recommendations put forth in the proposed rule.

Specifically, the ACOI is concerned that the three mechanisms put forth by CMS will result in resources being shifted from one region to another without addressing the fundamental issue of increasing cost of providing care. Should CMS pursue these efforts and expand them in the future, we are concerned that due to the need to maintain budget neutrality the end result would be a shifting of resources from one geographic area to another. This may help physicians who practice in certain geographic areas, but it will come at a cost to others. In turn, these proposals have the potential to cause access to care problems for Medicare beneficiaries in the regions from where resources are pulled due to economic barriers for physicians who want to provide care in these areas, but will be unable to do so. The ACOI does not believe that geographic location should be a determinant as to whether a physician can provide care to a Medicare beneficiary. Therefore, the ACOI recommends that CMS abandon these considerations and reexamine efforts to adjust GPCIs.

Physician Self-Referral Provisions

Physicians continually find themselves confronted with a staggering array of regulations and rules that impact their ability to provide care to their patients. The self-referral provisions of this proposed rule do little to lesson this burden, and in some instances, actually expand the regulatory maze physicians must navigate each day in order to provide the highest level of care possible to their patients.

The ACOI appreciates and supports CMS' efforts to ensure that services provided under the Medicare program are not over-utilized. We caution CMS, however, not to pursue initiatives so aggressively that they ultimately prevent timely access to appropriate health care services or prevent access to care altogether. Further, we appreciate CMS' recognition that the self-referral rule is so complicated that inadvertent failures to comply with all prescribed criteria could result in severe penalties. The ACOI is concerned, however, that many components of the proposal actually expand the murky waters known as the Stark law and ultimately would increase the likelihood of unintentional violations. In light of these concerns and the release of the Stark II, phase III final regulations on August 27, 2007, we encourage CMS to withdraw the self-referral provisions of this proposed rule. Greater attention must be given to the simplification of the existing self-referral regulations.

MEI

The Medicare Economic Index (MEI) measures the weighted-average annual price change for various inputs needed to produce physicians' services. The proposed rule estimates the MEI for calendar year 2008 to be 1.9 percent with a productivity offset of 1.5 percent. The ACOI strongly encourages CMS to revisit the productivity offset which appears to be nearly double that of the .65 percent recommended for other Medicare providers such as outpatient and inpatient hospital services and ambulance services, among others.

In light of the ever-increasing burdens placed on physicians to provide care, the 1.5 percent offset suggested in the proposed rule is too high and does not accurately reflect the realities of providing care within the current health care delivery system. As a result, the ACOI recommends that CMS apply a .65 percent productivity offset. We believe this more accurately reflects the increase in efficiencies and would be consistent with other Medicare providers.

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Section 101 of the Medicare Modernization Act (MMA) (Pub.L 108-173) provided for the adoption of voluntary electronic prescription standards. The E-Prescribing and the Prescription Drug Program final rule published on November 7, 2005 established the NCPDP SCRIPT Standard, Implementation Guide, Version 5, Release 0 (Version 5.0) (NCPDP SCRIPT) as the standard required for the exchange of certain prescription information. Appropriately, the final rule provided an exemption for entities that transmit prescriptions through computer-generated facsimiles. The proposed rule would repeal this important exemption. The ACOI is concerned that repeal of the exemption for computer-generated facsimiles will stifle continued adoption of electronic prescribing tools and other electronic health record systems.

CMS itself recognized the need for this exemption when adopting it by stating, "requiring prescribers/dispensers who already use electronic media to e-prescribe to modify or change their software and hardware products to be compliant with the foundation standards would likely result in their simply reverting to paper prescribing and would be counterproductive...." Further, CMS acknowledged that any costs of the transition to NCPDP SCRIPT will be borne by physicians. Therefore, the ACOI believes the justifications for the exemption in the past remains pertinent today.

The ACOI and its members are committed to the adoption and utilization of technologies that facilitate increased efficiency and safety. The realities of this proposal, however, are that CMS will be effectively increasing the barriers to the adoption of new technologies that could be used

to increase both efficiency and quality within the Medicare program. Physicians, faced with increased regulatory burdens and decreased reimbursements may have little choice but to revert back to paper prescriptions because of economic realities well beyond their control. We strongly encourage CMS to delay removal of this exemption for a sufficient period of time to allow the adoption that is taking place to continue. Without doing so, the "tipping point" referenced in the proposed rule could tip the other way, back to paper prescriptions. We believe the timeline put forth in the proposed rule is unrealistic for such major changes. Therefore, the ACOI strongly encourages a delay in the repeal of the exemption for computer-generated facsimiles.

TRHCA—Section 101(d): PAQI

Section 101(d) of the "Tax Relief and Health Care Act of 2006" (TRHCA)(Pub. L. 109-432) requires the Secretary of the U.S. Department of Health and Human Services to establish a Physician Assistance and Quality Initiative Fund (PAQI). The $1.35 billion fund was made available for physician payment and quality improvement initiatives. This includes the ability of CMS to utilize the funds to update the physician fee schedule conversion factor. The ACOI is disappointed that CMS is proposing using the full $1.35 billion for quality initiatives without addressing the reductions in physician Medicare reimbursements. The ACOI recommends that CMS apply the $1.35 billion made available under the PAQI Fund to the physician fee schedule conversion factor.

Application of the $1.35 billion made available under the PAQI Fund to the physician fee schedule conversion factor would help minimize the projected impact of the SGR formula. Fair and adequate compensation would allow physicians the opportunity to reinvest in their practices and support efforts to adopt health information technology and other tools that would support efficiency and quality initiatives. Without this assistance, physicians may not be able to obtain the necessary tools to support the quality initiatives to which CMS proposes applying the full $1.35 billion PQRI Fund. Application of the full $1.35 billion by CMS to quality initiatives would be a failure by CMS to utilize its full regulatory authority to improve the overall quality and efficiency of the health care delivery system and efforts to ensure beneficiary access to health care services.

The ACOI appreciates the opportunity to provide these comments. We look forward to working with CMS in the future on these and other issues of importance impacting the nation's health care delivery system.

Sincerely,

Joanna R. Pease, DO, FACOI
President

Cc: ACOI Board of Trustees
ACOI Clinical Practice Committee
ACOI Government Affairs Committee
ACOI Task on Information Technology

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

Organization : Ms.

Category : Individual

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Aug. 31, 2007

Re: Docket ID CMS-1385-P

Dear Sir or Madam:

I live in Plano, Texas, and while I am concerned that the therapy standards proposed by CMS in the Physician Fee Schedule will harm the patients of athletic trainers and create access problems, I am also concerned because both my parents, who live in New York, are Medicare patients. There is a strong possibility that these rules will, in fact, decrease the quality of services provided to my mother and father and other Medicare beneficiaries. These CMS proposed rules are not supported by any objective reports or other rationale that has been made public.

As a 50-year-old female, I personally used the services of an athletic trainer when I injured my rotator cuff. The athletic trainer was fully qualified to assess, treat and rehabilitate my injury. I was pleased that I that I received a home rehab program, which reduced my cost and inconvenience.

I believe these rules will harm non-Medicare patients. Anytime Medicare makes a rule it eventually gets adopted in the private sector. Millions of secondary school and college students will lose access to services. Millions of seniors recovering from hip replacement and other orthopedic surgeries and conditions will lose access. Is this what Medicare intends?

These are unnecessary and unreasonable rules. I want to choose the best provider for me especially now that I have a Health Spending Account and that flexibility.

These whole therapy standards rules make no sense. I respectfully request that all rules past and present that restrict the ability of athletic trainers to lawfully practice their profession be reversed by CMS. Further, I recommend that the broadest possible panel including sports medicine consumers of physical medicine and rehabilitation services providers be established to review future therapy rules prior to such efforts to insert them into the Federal Register.

Sincerely,

Ellen Satlof
7816 Aqua Vista Drive
Plano, TX 75025

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

Organization : WAYNE PETTIT

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
WAYNE PETTIT

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

Organization : **Lisa Winter**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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Thank you for your consideration of this serious matter.
Lisa Winter

Submitter : Dr. Michael Poon **Date:** 08/31/2007

Organization : Society for Cardiovascular Comptued Tomography

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14616-Attach-1.DOC

1410160

Society of Cardiovascular Computed Tomography

2400 N STREET, NW WASHINGTON, DC 20037
TEL: 202-375-6190 TOLL-FREE: 800-876-4195 FAX: 202-375-6818
EMAIL: INFO@SCCT.ORG WEBSITE: WWW.SCCT.ORG

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C5-01-14
Room 313 HHH
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1385-P

ELECTRONICALLY SUBMITTED

Dear Mr. Kuhn:

The Society for Cardiovascular Computed Tomography (SCCT) is a professional medical membership organization with over 4,000 members that addresses all issues pertaining to the field of cardiovascular computed tomography. SCCT works to foster optimal clinical effectiveness of cardiovascular CT (CCT) through professional education, establishment of standards for quality assurance and professional training, and the development of evidence-based guidelines to enhance patient care and improve the quality of cardiovascular medical practice.

SCCT has reviewed the notice of proposed rulemaking 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)** web posted on July 2, 2007.

Being a subspecialty to the cardiovascular and radiology community, SCCT strives to support the efforts of the American College of Cardiology and the American College of Radiology. In a decision to reinforce the concerns of computed tomographic imagers, the SCCT is in full support of the proposed comments submitted by the American College of Cardiology. With so many issues to address including coding—additional codes from the 5 year review, independent diagnostic testing facilities, physician self referral provisions and PQRI; SCCT believes that the American College of Cardiology has appropriately presented the concerns of the cardiovascular CT community and has provided thoughtful recommendations to CMS to ensure that the 2008 Medicare Physician Fee Schedule

SCCT would like to echo the largest concern to our members regarding the flawed Sustainable Growth Rate formula used by the Centers for Medicare and Medicaid Services (CMS) to calculate annual physician payment updates. Physicians now face drastic Medicare payment cuts totaling almost 40% over the next eight years. The continued cuts and reductions are preventing medical practices and physicians from providing quality care to Medicare beneficiaries. Physicians cannot continue to absorb these drastic cuts. The SCCT urges CMS to work with Congress to avert the proposed 10% cut for 2008 and ensure that physician payment updates for 2008 and subsequent years accurately reflect increases in medical practice costs.

SCCT supports rational and fair physician payment policies and appreciates the opportunity to share our comments. If you have any questions for SCCT please feel free to contact Mia Rosenberg at (202) 375-6418.

Sincerely,

Michael Poon, MD
President, Society of Cardiovascular Computed Tomography

Submitter : Mr. Walter R. Wilkins III **Date:** 08/31/2007

Organization : Mr. Walter R. Wilkins III

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 since 1994 and have worked in a variety of settings. Presently, I am the coordinator of the sports medicine program for the largest non-for-profit hospital in the United States. We are considered a community outreach program that offers free athletic training services to area rural high schools.

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,
Walter R. Wilkins III, ATC

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

Organization : ALICE PETTIT

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

Thank you for your consideration of this serious matter.
ALICE PETTIT

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

Organization : **Elisabeth Winter**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

Re: CMS-1385-P
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Elisabeth Winter

Submitter :

Date: 08/31/2007

Organization :

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14620-Attach-1.DOC

14620

39202

August 30, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare & Medicaid Services
U.S. Dept of Health & Human Services
Attn: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

Subject: Medicare Program: Proposed Revision to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY2008; Proposed Rule

Dear Mr. Weems:

I am contacting you regarding the Physician Self-Referral Issues, specifically the July 12, 2008 physician fee schedule rules regarding self-referral and "in-office ancillary services."

I believe that physicians who own Physical Therapy practices are inherently incentivized (if not coerced) to refer excessively to their own physical therapy practice.

My partner and I have operated a private physical therapy practice in the Mid-Mississippi area since 1985. We have worked and marketed the Mid- Mississippi area for over 20 years, often calling on physicians who traditionally do not utilize physical therapy. They become regular P.T. referrers once they invest in a P.T. practice.

A large orthopaedic practice has been our main referral source during these 22 years. In 2006 they opened their own P.T. practice in a building addition designed to fit the Stark II "loopholes". We refused to become their employees and offered to lease their P.T. space for fair market value. (We are located next door to them).

Their ownership of a P.T. practice was not required to provide patient convenience or any supervision on their part. As we were their initial choice for employees, obviously they were satisfied with our services.

Please consider the American Physical Therapy Association's position to eliminate any abusive and for profit financial arrangements as allowed by the existing Stark Law. I strongly urge you to remove Physical Therapy as a designated health service (DHS)

permissible under the in-office ancillary exception of the federal physician self-referral laws.

Thank you very much for your consideration.

Sincerely,

Mississippi Private Practice PT 39202

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

Organization : ALAN PIATT

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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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.
ALAN PIATT

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

Organization : **Quitman Winter**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.
Quitman Winter

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

Organization : **Mack Morgan**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.
Mack Morgan

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

Organization : LARQUE PIATT

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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Thank you for your consideration of this serious matter.
LARQUE PIATT

14026

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: "TECHNICAL CORRECTIONS"

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Dr. Louis S. Crivelli II
1533 Ashburnham Drive
Crofton, MD 21114
410-721-4147

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

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See attached letter

CMS-1385-P-14627-Attach-1.DOC

14627

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, D.C. 20201

RE: CMS-1385-P, Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule (Vol. 72, No. 133), July 12, 2007 – **Physician Self-Referral Provisions**

Dear Mr. Kuhn:

The Tennessee Hospital Association (THA), on behalf of over 200 healthcare facilities, including hospitals, skilled nursing facilities, home care agencies, nursing homes, and health-related agencies and businesses, and over 2,000 employees of member healthcare institutions, such as administrators, board members, nurses and many other health professionals, appreciates the opportunity to submit comments on the proposed changes rates and policies under the Medicare physician fee schedule.

THA supports Medicare's efforts to ensure that "payment policies provide incentives to improve the quality of care." However, THA believes the proposed rules impact the hospital-physician relationship in a way that will disincentivise hospital-physician coordination of care and, thereby, jeopardize the quality of care. THA understand the agency's need to "close certain loopholes and further limit the over-utilization of services" and control the growth of costs in the Medicare program. However, THA believes laws that impact the physician-hospital relationship can and should be designed, not only to avoid conflict and reduce cost but, wherever appropriate, to encourage alignment and incentive behavior that improves the quality of care and patient safety. THA and its members are committed to improving patient safety and the quality of healthcare throughout our communities. That commitment serves as the guiding principle behind the comments expressed herein.

At this time, THA is expressing concern relative to the proposed revisions clarifying percentage-based compensation arrangements. THA also is providing comments, as requested, in the areas including the: 1) in-office ancillary services exception; 2) obstetrical malpractice insurance expansion; and 3) incorporation of a method to address innocent or de minimis violations.

THE PERCENTAGE-BASED COMPENSATION REVISION WILL LIMIT FINANCIAL ARRANGEMENTS DESIGNED TO PROMOTE THE QUALITY OF CARE AND PATIENT SAFETY.
The proposal to limit percentage-based compensation solely to "revenue directly resulting from personally performed physician services" is too limiting and fails to recognize the important role of financial incentives in achieving patient safety and quality of care goals in health care. It appears the provision would prohibit payment arrangements based on achieving quality measures and/or patient satisfaction. It treats a physician and the care provided singularly without regard for the integration and coordination of care needed to achieve patient safety goals. Achieving many of the public policy goals for patient care and the delivery system change requires more than what a hospital or a physician can do alone. To be effective, the incentives must drive individuals to work together to achieve the kind of outcomes expected by patients, payers and providers.

Some percentage-based arrangements should be permitted where the likelihood of abuse is less than the efficiencies – in savings and quality – that can be achieved. For example, arrangements that should be permitted include:

- Sharing of cost savings from efficiencies.
- Incentives that support quality indicators.
- Incentives to clinically integrate services and coordinate care across settings.
- Sharing of pay-for-performance bonuses from payers.
- Service contracts to build new service capacities.
- Management contracts.

These arrangements can improve the care provided and yield savings to the healthcare system overall. The efforts already underway among payers to incentivise integrated care will be frustrated if the only factor that may be taken into account is physician performed services.

THA SUPPORTS NARROWING THE IN-OFFICE ANCILLARY SERVICES EXCEPTION TO COVER ONLY THOSE SERVICES "NECESSARY TO THE DIAGNOSIS OR TREATMENT OF THE MEDICAL CONDITION THAT BROUGHT THE PATIENT TO THE PHYSICIAN'S OFFICE."
The Medicare Payment Advisory Commission (MedPAC) reports that the overuse of the in-office ancillary services exception has led to the duplication of services and technology, and to over-utilization, higher expenses and unnecessary procedures for patients. The overuse of the in-office ancillary exception is one of the many forces driving hospitals and physicians apart, and frustrating a hospital's ability to improve physician relations and better coordinate care in the facility.

The overuse of the in-office ancillary services exception is particularly apparent and detrimental to the delivery of health care in rural settings. In rural communities where the volume of needed services is not sufficient to support both hospital-based and physician practice-based duplicative services, it is always the hospital-based service that will suffer because physicians control where their patients go. The ultimate effect is to potentially jeopardize the viability of the local hospital and that community's around-the-clock access to needed healthcare services. It also can jeopardize access to a particular service for patients who do not have access to physician practice-based services.

THA AGREES THAT THE EXCEPTION FOR SUBSIDIZING OBSTETRICAL (OB)

MALPRACTICE INSURANCE IS TOO RESTRICTIVE.

As suggested in the rulemaking, maintaining OB services in some communities is an increasingly difficult challenge. Multiple factors contribute, including the cost of malpractice premiums in some areas. Fewer physicians are training for the specialty, and physicians with training and experience have left the field or are considering leaving that area of practice. Currently, the Stark law allows hospitals to subsidize certain obstetrical malpractice insurance costs for obstetrician/gynecologists working in a health professional shortage area (HPSA). Permitting malpractice insurance subsidies on a broader basis may help minimize the loss of OB services in some communities.

The current preconditions for subsidizing coverage – that the physician practice is in a primary care health professional shortage area (HPSA) and that 75 percent of those served live in a primary care HPSA or be medically underserved – are too limiting. Non-HPSA areas may have a high indigent population, and an increase in primary care physicians may take an area out of the primary care HPSA designation without any increase in physicians providing OB services. The combination of the relatively low payment for OB services and the high cost of insurance premiums works against a physician agreeing to maintain 75 percent of his or her OB practice for the underserved.

Additionally, communities other than underserved ones are experiencing the shortages of OB services due to insurance premiums and other practice expenses with relatively low payments for OB services. As such, a broad exception for subsidies in such communities may similarly help minimize the loss of OB services. THA recommends that this exception be allowed in any area where there is a shortage of physician OB services.

THA SUPPROTS THE INCORPORATION OF ALTERNATIVE METHODS FOR ADDRESSING INNOCENT VIOLATIONS.

Current Stark law has a narrow exception for temporary noncompliance. Because it is so narrow, however, the exception is often unavailable when needed to address purely technical noncompliance that poses no risk of program abuse. THA supports adding a complement to the current exception that would permit self-disclosure and other reasonable determinations as to the nature of the violation. However, THA is concerned that the proposed revision is so burdened by cautions and reservations that it may be less viable than it could be. THA encourages CMS to take another look at providing a reasonable common sense approach to address this exception.

Again, THA appreciates the opportunity to submit these comments. If you have any further questions or need any additional information on how the revisions to the Medicare Physician Fee Schedule will impact the hospital community, please do not hesitate to contact THA.

Sincerely,

Craig A. Becker, FACHE
President

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

Organization : **Marcia Morgan**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

Thank you for your consideration of this serious matter.
Marcia Morgan

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

Organization : RICHARD PIATT

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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RICHARD PIATT

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

Organization : **Dan Wulf**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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LcsV. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Dan Wulf

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

Organization : Sherry Wiley

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.

Sincerely,

Sherry Wiley

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

Organization : **Sandra Wulf**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Sandra Wulf

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

Organization : **Roger Helms**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
Roger Helms

Submitter : Mr. Timothy Colbert **Date:** 08/31/2007

Organization : Delta State University

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Please see teh attached letter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

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

Organization : Mike Yancey

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. 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.
Mike Yancey

Submitter : **Mrs. Marlene Lovenguth** **Date: 08/31/2007**

Organization : **AANA**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

Dear Administrator;
I have been a CRNA since 1994 and have worked as an independent contractor in rural settings for many years. I am writing to support CMS' recent proposal to increase the value of anesthesia reimbursement by CRNAs to 32%. When approved this bill will ensure that as a Medicare Part B provider I can continue to provide Medicare patients access to my anesthesia services.

As it stands now Medicare reimburses most services at 80% of market rates but anethesia billings only receive 40%. It seems to me that this is quite an injustice to the CRNAs (Nurse anesthetists) who provide more than 27 million anesthetics per year.

I support CMS ruling to correct this disparity between health care providers. Thank you for considering my concerns as it is important for myself and the 27 million other CRNAs who provide anesthesia throughout the USA.

Sincerely,

Marlene Lovenguth CRNA, M.S.
5379 E. Evans Creek Rd.
Rogue River, Oregon 97537

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

Organization : **Darla Helms**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Darla Helms

Submitter : **Dr. Donny Chung** **Date: 08/31/2007**

Organization : **Kaiser Permanente**

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

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Thank you for your consideration of this serious matter.

Donny Chung, MD

Submitter : Dr. Samuel Goldhaber **Date:** 08/31/2007

Organization : Harvard Medical School.Brigham & Women's Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14639-Attach-1.PDF

14639

BRIGHAM AND WOMEN'S HOSPITAL

Harvard Medical School
Professor of Medicine

Samuel Z. Goldhaber, MD
Director, Venous Thromboembolism Research Group
Director, Cardiac Center's Anticoagulation Service
Department of Medicine
Cardiovascular Division

75 Francis Street
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Patient Appointments: (617) 732-4837
E-Mail: sgoldhaber@partners.org

August 31, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1533-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

FILE CODE: CMS 1385-P

RE: TRHCA-Section 101(b): PQRI

I would like to commend Medicare for taking the lead in implementing quality measures that will improve the VTE prophylaxis rate for surgical patients (SCIP VTE 1 and VTE 2) and the PQRI Measure #23 – VTE Prophylaxis for physicians. Medicare's actions to date constitute an important first official step. It is important that these accomplishments are kept in perspective and recognized as a first step in the major task of improving VTE prophylaxis and reducing VTE for all patients, in all settings.

Current measure for VTE prophylaxis

At this time, in its proposed Physician Fee Schedule rule, dated July 12, 2007, Medicare is considering measures for the PQRI program for FY 2008. Medicare proposes to continue to use the existing measure for VTE prophylaxis measure for surgical patients for FY 2008. This is appropriate; we have only begun to translate

the goal into increasing rates of VTE prophylaxis for surgical patients at high risk based on their surgical procedure at the patient level.

Future measures

In the proposed rule, Medicare recognizes its responsibility to implement measures that are "relevant to the Medicare beneficiaries, address overuse/misuse of pharmacologic therapy, and that expand the specialty applicability and patient population" (CMS, 2007a). In the past, Medicare has contracted and/or solicited quality measures from measure developers and specialty societies to address specific clinical issues that were considered important to the Medicare population.

Critical questions for developing quality measures are whether a clinical problem exists, whether there are evidence-based guidelines for effective intervention, and whether there is evidence of a gap in care now being provided.

Studies demonstrate that there is an important gap in care for VTE prophylaxis for hospitalized and ambulatory patients. Physician quality measures that address inpatient prophylaxis and outpatient prophylaxis will be an important next step to minimize the rate of VTE. This gap is particularly wide in medical (nonsurgical) patients.

VTE prophylaxis in hospitalized inpatients (especially medical [nonsurgical] patients

VTE is a significant medical problem

The statistics on VTE events are well known: VTE is a major and often unrecognized cause of morbidity and mortality in hospitalized patients.

It is estimated that as many as 2 million people are affected by VTE each year. DVT is associated with silent PE in 40-50% of the patients (Weill-Engerer 2004). Approximately 600,000 developed PE each year. Heit reported on a study in Olmsted County that identified an average annual incidence rate of VTE of117 per 100,000. He notes that it is "virtually equivalent to the incidence of stroke" (Heit, 2002).

VTE is most often considered to be associated with surgery or trauma; however, Geerts states that "50-70% of symptomatic thromboembolic events and 70-80% of fatal PEs occur in nonsurgical patients"(Geerts, 2004). It is estimated that massive PE is responsible for 4-8% of hospital mortality in Medical Service wards (Nicolaides,

2006). PE can have a 3-month mortality rate as high as 17% (Goldhaber 2004). In our International Cooperative Pulmonary Embolism Registry, we found an all-cause mortality rate of 11.4% during the first 2 weeks after diagnosis and 15.3% at 3 months. The data "demonstrate, that in the 'real world,' the death rate from PE exceeds that from acute myocardial infarction"(Goldhaber, 2003).

Presence of effective interventions
Wein et al (2007) confirm findings of King et al (2007) and Dentali et al (2007). The appropriate prophylaxis of medical patients, the right medication at the right time for the proper duration reduces the frequency of DVTs and PEs. Dentali et al found a 57% reduction in fatal or nonfatal PE, a 62% reduction in fatal PE, and a 53% reduction in DVT.

Gap in current treatment
The low rate of prophylaxis of medical patients is now well documented. In 2004, we reported on 5,451 patients with confirmed DVT (Goldhaber, 2004). Of those patients, 71% had not received prophylaxis before they developed DVT; 40% were medical. In 2005, we reported on a study of prophylaxis among medical patients (Goldhaber, 2005). We found a combination of omitted and ineffective prophylaxis among patients admitted to the MICU (Medical Intensive Care Unit) and later in an audit of patients admitted to the hospital. Fifty-two percent had received ineffective prophylaxis and 48% had received no prophylaxis. Of those who received no prophylaxis, 60% were medical patients.

More recently, Spencer et al have demonstrated that prophylaxis rates have not improved significantly (Spencer, 2007). For outpatients who developed VTE within 3 months of a hospital stay, they found that only 60% of patients had received any form of VTE prophylaxis during a preceding hospitalization.

A role for quality measures for physicians
Prompt identification of patients at risk is important to initiate prophylactic measures (Goldhaber 2005). By raising physician awareness of the issue and the patients to whom the measure applies, quality measures can play an important role in educating physicians and achieving early identification of patients.

The Joint Commission (TJC) has developed hospitals measures for medical (nonsurgical) patients. These measures are expected to be reviewed and referred to NQF for endorsement (TJC, 2007). This will address the hospital component. It is important that quality measures for physicians also address the topic.

Care of hospitalized patients is increasingly provided by hospitalists. To date, there are limited quality measures that might apply to this specialty. The prophylaxis of medical (nonsurgical) patients for VTE would be an excellent measure to address two gaps: one in underutilization and the other in measures appropriate for all specialties. CMS could play an instrumental role working with measure developers to encourage the development of measures that will address this population.

VTE in the outpatient setting

Presence of a clinical problem

VTE prophylaxis is also important in the outpatient setting. There are 3 common myths about VTE: 1) that inpatient presentation is more common than outpatient; 2) that outpatient VTE is not associated with surgery or recent hospitalization; and 3) that outpatient VTE cannot be prevented (Goldhaber, 2007).

Spencer et al demonstrated that VTE is 3-times more common than inpatient VTE (Spencer, 2007); in their Worcester, Massachusetts study, 73% of VTE patients presented from the outpatient setting. Almost half of the outpatients had been recently hospitalized: 23.1% had undergone surgery and 36.8% were medical (nonsurgical) hospitalizations. Less than half (42.8%) of those outpatients recently hospitalized had received pharmacological VTE prophylaxis during their hospital stay. The median and mean LOS for the preceding hospital stay for those developing VTE within 3 months of the hospital stay were 4.0 and 7.4 days, respectively. For those who did not have surgery, 66.9% were diagnosed with a VTE within 1 month of their hospital stay.

In another registry study, the median time from surgery to diagnosis of DVT for those diagnosed as outpatients was 21 days (Goldhaber 2004). We reported that 38% of patients had surgery within the prior 3 months. Of those, 65% were diagnosed as outpatients. The median length of hospital stay for those with a DVT diagnosis while outpatients was 5 days.

Evidence of a gap in care

While VTE does occur during the hospital stay, it is far more common in the outpatient setting. The prevalence of outpatient VTE could be a quality measure for VTE prophylaxis among hospital patients (Goldhaber, 2007). Inpatient and outpatient care can no longer be addressed in separate silos. Outpatient VTE rates will be reduced when we improve the VTE prophylaxis for inpatients, both surgical and medical patients. But that will not be sufficient.

Most pharmacological prophylaxis trials tested 7-10 days of anticoagulant therapy. The data show that hospitals stays are for fewer days than the recommended course of VTE prophylaxis. It is important that continuity of care, specifically prophylaxis, be addressed to ensure that VTE prophylaxis is continued in the post-acute care settings.

At present, we have no quality or facility level measures for post-acute care in the outpatient setting, long-term care hospital (LTCH) and inpatient rehabilitation facility (IRF)(CMS, 2007b). The measures for skilled nursing facilities (SNFs) (CMS, 2007c) and home health (CMS, 2007d) do not address VTE or rates of readmission for VTE. In the absence of other measures, it becomes important for physicians to address both the outpatient and office settings.

The creation of physician quality measures that address continued VTE prophylaxis after hospitalization will be invaluable to improving the VTE prophylaxis post-discharge and ultimately, reducing the rates of VTE.

In summary, VTE remains an important public health issue. VTE often develops in the outpatient setting, with many of the patients having undergone a recent inpatient stay. VTE developed post-discharge reflects on the quality of inpatient care and the issue of appropriate initial inpatient and predischarge VTE prophylaxis strategy. The prevalence of outpatient VTE can be reduced with better inpatient prophylaxis and the continuation of prophylaxis after discharge. This would also reduce rates of readmissions, the morbidity and mortality associated with recurrent VTE, and the development of the post-thrombotic syndrome.

CMS could again play an instrumental role working with measure developers to encourage the development of measures for physicians, as part of the PQRI, that will address the prophylaxis of medical inpatients as well as continuation of prophylaxis in post-acute care, including the office, outpatient setting, LTCH and IRF.

Thank you for considering these comments.

Best regards,

SZGoldhaber, MD

Samuel Z. Goldhaber, MD

REFERENCES

CMS 2007a. 1385P. Federal Register, Vol. 72, July 12. p. 38199.

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EDITORIAL

Outpatient Venous Thromboembolism

A Common But Often Preventable Public Health Threat

QUALITY IMPROVEMENT TEAMS FOCUS ON improving the safety of hospitalized patients. Common problems undergoing scrutiny include (1) avoiding slips and falls, (2) ensuring accurate administration of prescribed medications, and (3) recognizing the warning signs of clinical deterioration prior to full-fledged cardiopulmonary arrest. Clever strategies are under development to deal with these dangerous situations: (1) strict protocols for raising bed rails and automated bed alarms that sound when at-risk patients attempt to get out of bed unassisted, (2) electronic bar coding of prescribed medications in conjunction with bar coding of patient identification wristbands, and (3) rapid-response teams (rather than "code teams") that can be activated by the staff nurse at the first clinical sign of trouble.

See also pages 1471 and 1476

These initiatives have one element in common: they address complications of hospitalization that occur during the hospitalization itself. Slipping and falling are apparent to all. Incorrect medication administration can be discovered by careful audits. The events leading to cardiac arrest can often be reconstructed by retrospective study of the telemetry log, nursing notes, and laboratory blood test results.

Venous thromboembolism (VTE), however, poses a more complex set of challenges. Most cases are asymptomatic. When patients die of acute pulmonary embolism (PE), the cause is usually ascribed to acute myocardial infarction or cardiac arrhythmia. Few patients undergo autopsy and, therefore, the diagnosis of PE is usually missed.[1] Acute deep vein thrombosis (DVT) is often occult, too.

When VTE occurs outside the hospital setting, we tend to think of unusual situations that do not involve recent hospitalization. Vice President Dick Cheney developed acute DVT after an around-the-world diplomatic mission that required extensive long-haul air travel. In 2003, NBC News reporter David Bloom succumbed to fatal PE while embedded with an army brigade on the outskirts of Baghdad, Iraq. He had been dehydrated, was in the desert, and had been immobilized in a tank during the military assault that originated in Kuwait.

These high-profile VTE cases attract widespread media attention. They cause fear among those planning vacations or business trips in faraway places, but they do not represent the typical patient who develops acute outpatient VTE.

Three common myths about VTE abound: (1) that presentation with an inpatient VTE is far more common than presentation with an outpatient VTE; (2) that, when outpatient VTE does occur, it presents as a condition unprovoked by surgery or recent hospitalization; and (3) that outpatient VTE, unlike inpatient VTE, cannot be prevented.

Spencer and colleagues, in their landmark article that appears in this issue of the *Archives*,[2] shatter these myths. Their carefully executed and elegant study demonstrates that (1) outpatient VTE is 3-fold more common than inpatient VTE, (2) almost half of the outpatients with VTE had been recently hospitalized, and (3) less than half of the recently hospitalized patients had received VTE prophylaxis during their hospitalization.

The Spencer group unearthed additional findings of major importance. Of those who had been hospitalized and subsequently developed VTE, approximately half had had a length of stay that was less than 4 days. This suggests that many who develop VTE will not fit the stereotype of prolonged immobilization during hospitalization. With these facts in hand, we must prospectively "immunize" hospitalized patients with VTE prophylaxis because it will not be possible to determine during the short hospital stay which patients will subsequently develop acute VTE.

These demographics establish outpatient VTE as a common but often preventable public health threat. Although outpatient VTE was 3 times as common as inpatient VTE in the study by Spencer et al, many cases originated during a prior hospitalization. Among those previously hospitalized, only the minority had received VTE anticoagulant prophylaxis. These findings raise disturbing questions because evidence is plentiful to support the efficacy and safety of anticoagulant prophylaxis in hospitalized medical[3] and surgical[4] patients.

This issue of the *Archives* also features Wein et al's methodologically rigorous meta-analysis of anticoagulant VTE prophylaxis trials in hospitalized medical patients.[5] Wein and colleagues studied more than 48 000 patients from 36 randomized controlled trials. Key findings were that unfractionated heparin, 5000 U 3 times daily, was more effective than unfractionated heparin, twice daily, in preventing DVT. Thus, they confirm the meta-analysis results of King et al.[6] In addition, Wein et al[5] showed that low-molecular-weight heparin was one-third more effective than unfractionated heparin in preventing DVT.

These results indicate that inpatient prevention of VTE is not a dichotomous yes or no metric. Proper VTE prophylaxis requires evidence-based measures applied ac-

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cording to protocols used in randomized controlled trials. For pharmacological prophylaxis, this means ordering the right dose of the right medication at the right time for the proper duration (which may span the hospitalization and the early period after hospital discharge).

The findings by Wein et al[5] are similar to those of Dentali et al,[7] who performed a meta-analysis of 9 studies encompassing 19 958 patients in randomized trials comparing anticoagulant prophylaxis with no prophylaxis in hospitalized medical patients. Dentali et al[7] found, with prophylaxis, a 57% reduction in fatal or nonfatal PE, a 62% reduction in fatal PE, and a 53% reduction in DVT.

In summary, the incidence of outpatient VTE rises when inpatient VTE prophylaxis is overlooked. Therefore, the prevalence of outpatient VTE can be used as a quality measure for VTE prophylaxis among hospitalized patients. Outpatient and inpatient VTE are coupled; they should no longer be placed in separate silos.

It is unclear why some at-risk hospitalized patients do not receive VTE prophylaxis. If there is a risk of bleeding, these patients should receive mechanical preventive measures, which appear to be both effective and safe.[8] If hospitalized high-risk patients are overlooked, regardless of the reason, electronic alerts to the responsible physician can reduce the incidence of symptomatic VTE over the ensuing 3 months.[9]

The culture surrounding inpatient VTE prophylaxis is undergoing a transition from optional to mandatory. For example, in 2003, Medicare and the Centers for Disease Control and Prevention initiated the Surgical Care Improvement Project.[4] The aim is to reduce the rate of surgical complications such as infection, myocardial infarction, and VTE. Medicare has recently launched 2 official quality VTE prophylaxis process (not outcome) measures under this initiative[4]: (1) surgical patients will be expected to have recommended VTE prophylaxis ordered, and (2) surgical patients will be expected to receive appropriate VTE prophylaxis within 24 hours before surgery to 24 hours after surgery. While these measures may seem modest, they constitute an important first official step in the eventual mandating of VTE prophylaxis.

Medicare's initial mandatory process measures do not suffice. They do not cover hospitalized medical patients, who are at least as vulnerable to VTE as surgical patients are. Hospitalized medical patients receive VTE prophylaxis less often than do hospitalized surgical patients.[10] Furthermore, hospitalized medical patients with DVT tend to have more extensive VTE and more frequent concomitant PE than do hospitalized surgical patients.[11]

Most pharmacological prophylaxis trials tested 7 to 10 days of anticoagulation therapy, but most contemporary hospitalizations are shorter. How often do patients who remain at risk at the time of hospital discharge receive VTE prophylaxis? When prophylaxis is inappropriately omitted at hospital discharge, are the overlooked patients ones who also failed to receive VTE prophylaxis during hospitalization? Are these patients simply not being prescribed continued VTE prophylaxis that, objectively, is medically advisable?

I predict that preventing outpatient VTE will be the "hot button" issue in 2008. We must start collecting relevant data at the time of hospital discharge so that we can provide these vulnerable patients with proper and comprehensive VTE prophylaxis. Recognizing the public health threat of outpatient VTE and breaking down artificial barriers between outpatient and inpatient VTE prophylaxis are vital first steps.

Samuel Z. Goldhaber, MD

Correspondence: Dr Goldhaber, Cardiovascular Division, Brigham and Women's Hospital, 75 Francis St, Boston, MA 02115 (sgoldhaber@partners.org).
Financial Disclosure: None reported.

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

Organization : **Sharyl Thompson**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Sharyl Thompson

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

Organization : Cheryl Yancey

Category : Individual

Issue Areas/Comments

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Thank you for your consideration of this serious matter.
Cheryl Yancey

3. System Outages. When a pharmacy's or a prescriber's e-prescribing network is not functioning, computer-generated faxing is the most safe and efficient alternative and should be permitted during such temporary communication failures.

Finally, we urge CMS to clarify that pharmacies will not be subject to any recoupment of claims that were filled with a good faith belief that the prescription complied with the rule concerning the elimination of the computer-generated fax exemption and to specifically advise all applicable enforcement agencies that the fulfillment of a prescription transmitted in a non-compliant manner may not be deemed to be a violation of federal or state false claims statutes.

We appreciate the opportunity to comment on these important matters.

Very truly yours,

Debbie Garza

Debbie Garza, R.Ph.
Vice President, Government and Community Relations
202-624-3172
debbie.garza@walgreens.com

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

Organization : **Bart Thompson**

Category : **Individual**

Issue Areas/Comments

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Thank you for your consideration of this serious matter.
Bart Thompson

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

Organization : Gordie Crow

Category : Individual

Issue Areas/Comments

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Gordie Crow

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

Organization : **Jesse Snyder**

Category : **Individual**

Issue Areas/Comments

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Thank you for your consideration of this serious matter.

Sincerely,

Jesse Snyder

Submitter : **Mr. Philip Hensler** **Date: 08/31/2007**

Organization : **Mr. Philip Hensler**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I graduated from the Athletic Training program at Duquesne University in May 2006 with a Bachelors of Science degree in Athletic Training, Performance Enhancement Specialization, and Emergency Medical Technician. I currently hold a position with UPMC working at the CRS outpatient physical therapy clinic in Forest Hills and Steel Valley High School. At Steel Valley I work with 23 WPIAL AA teams. I have been certified since my graduation in 2006.

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,

Philip J. Hensler, B.S., ATC, PES, EMT-B.

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

Organization : **Jeanne Asher**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
Jeanne Asher

Submitter : Mr. Fredrick Oliver **Date:** 08/31/2007

Organization : Orthopaedic Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

My name is Fredrick Oliver, and I am a physical therapist in Cincinnati, Ohio. I am writing to express my discontent with the ability for physicians to manipulate the healthcare system for profitable reasons. In my opinion, a physician telling a patient to see their own therapy staff and get reimbursed again for this service seems to be a case of double-dipping. In essence, they are taking advantage of the healthcare system to make more money, and the bigger the physician group, the bigger the monopoly of rehab services. This, I believe, encroaches on my right to free enterprise. It is very hard to compete with these physician owned practices when they corner their patients out of free choice of treatment location. Although the advent of direct access has allowed patients to sidestep the need for physician referrals, the doctor's office remains the springboard for referrals. Eliminating the ability for doctors to profit from their own referrals will allow for unbiased and better quality care for the patients. In my opinion, the ability to allow PT services under the in-office ancillary exception is both wrong and unethical. You may as well let them produce and prescribe their own expensive medications too.

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

Organization : Gina Snyder

Category : Individual

Issue Areas/Comments

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Sincerely,

Gina Snyder

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

Organization : **Hal Brown**

Category : **Individual**

Issue Areas/Comments

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

Thank you for your consideration of this serious matter.
Hal Brown

Submitter : **Dr. Melissa Rockford** **Date: 08/31/2007**

Organization : **Dr. Melissa Rockford**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Submitter : **Mrs. Carol schrader** **Date: 08/31/2007**

Organization : **wuesthoff medical center**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Let's get real. Anesteheiologist are highly trained medical specialest. They are the back bones of any major medical center and are often the people who keep the sickest patients alive and stabalize critical situations. If anesthesiologist were to leave the field of medical practice beeause of the inadequate remembursements form medicare, I fear the ramifications of this would be far reaching and cause the quality of patient care to fall considerably.
Please, do not let this happen.

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

Organization : Kitsap Urology Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14657-Attach-1.DOC

14057

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Re: Physician Self-Referral Provisions

Dear Sir or Madam,

We are writing to express our concerns regarding certain proposals in the recently released 2008 proposed physician fee schedule. As Urologists practicing in Bremerton, Kitsap County, Washington, we fear that several of the proposed changes to the physician self-referral rules will needlessly and unjustifiably harm Medicare patients and providers. Although we understand and support the efforts by CMS to prevent abusive practices, we believe the current proposals will extend beyond this worthy goal to hamper valuable and legitimate joint venture agreements. We believe that CMS could address its concerns in a much less intrusive manner.

As Urologists, we have seen firsthand the beneficial effects that joint ventures have had for the healthcare system. We have been involved with providing our patient's lithotripsy both ESWL and laser endoscopic technologies as well as emerging technologies for both benign and neoplastic prostatic diseases that would not have been widely available to our patients, including Medicare beneficiaries, unless physician joint ventures had provided these services. By accepting the risk of providing these costly services when hospitals refused to do so, urology joint ventures have greatly expanded patient access to worthwhile and effective treatment. Yet the proposals in your 2008 physician professional fee schedule attack the substance of the very joint ventures that by all accounts have saved Medicare millions of dollars and increased beneficiary access to effective treatments.

Prior to organizing a joint venture partnership to provide lithotripsy services, no lithotripsy services were provided or available at the only hospital in Kitsap County which serves a population of almost 240,000 people. Patients had to commute one hour by ferry or 1 1/2 hours by car to Seattle or one hour by car to Tacoma. These services are now provided at the local hospital or ambulatory surgery center approximately every two weeks. This joint venture has allowed for the continuous upgrading of lithotripsy equipment as new and improved technologies emerge. I have seen firsthand that lithotripsy services provided by nonphysician owners where this is their sole source of income, do not invest in new technologies as readily as do physician joint venture partnerships. We have upgraded and or replaced lithotripters on four occasions and laser and microwave systems for prostate disease on four occasions as well because this would result in better urologic treatment. These were not prudent financial decisions but were made because we are physicians and truly care about improving patient care. Conversely, our local hospital has refused to purchase in-house holmium laser endoscopic technology for treatment of ureteral calculi or cryotherapy equipment for prostate cancer.

Hospitals are generally unwilling to take risks and are often operating on razor-thin margins. They are averse to bearing the risk of low volume usage for new and innovative technologies and services. When physician joint ventures bring these beneficial technologies to hospitals, the hospitals may require per click arrangements to protect themselves from the risk of low volume. Physicians who invest in these joint ventures however, are willing to take the risk of failure. With us, per click arrangements are essential to bringing new, improved treatments to many places in the United States, by allowing cash-strapped hospitals to pay risk taking joint ventures to bring new treatments and technologies to them, without the hospitals having any financial risk for less than projected use or adoption. By banning per click lease arrangements, CMS may inadvertently preclude beneficiary access to innovative treatments as outlined above.

Further, per click arrangements are vital to the provision of certain services such as lithotripsy and laser prostatectomy. Not infrequently, patients scheduled for these services will require unexpected additional or separate services. These services may include insertion or removal of indwelling ureteral stents, ureteroscopy, resection of unexpected bladder tumors, bladder stones, or cystoscopy. The hospital and the company that provides the service are unable to determine in advance how often a procedure will be needed or which procedures will be required. Per click fees are the most accurate and fair way to determine compensation.

We have significant concerns regarding the goal of the proposed changes to the Stark regulations regarding services furnished under agreements as this appears to prohibit physician joint ventures from contracting with hospitals to provide legitimate diagnostic designated health services. Unfortunately, the proposals are so broad they would ban legitimate, non-abusive arrangements for therapeutic services that are not otherwise designated health services except for the fact that they are performed in a hospital setting. The therapeutic services that will be affected from a urologic standpoint include a variety of laser procedures for benign prostatic disease and cryotherapy for cancer of the prostate. Based on the commentary in the proposed rule, CMS seems to view physicians who invest in these joint ventures do so at the expense of good patient care. Our group has quite the opposite experience. One of our urologists undertook cryotherapy training in 2000; no other Urologist in the Northwest i.e. Washington, Alaska, Idaho, Montana and Oregon was trained or was performing this procedure that at time. As you can imagine our local hospital would not invest in this new and expensive technology. Only by using cryotherapy equipment provided by a joint venture out of California were we able to provide this new and emerging technology that has now become an accepted curative treatment for carcinoma of the prostate. In spite of its acceptance as a standard curative treatment for carcinoma of the prostate, the volume of patients treated with cryotherapy is still limited and the sharing of technology via a mobile service on a rotating basis is still required. The healthcare system, including CMS, benefits from these arrangements because otherwise unavailable technology is brought to both urban and rural settings, and the cost is spread among several providers, reducing overall capital costs.

It appears to us that the reason CMS wants to ban services under arrangements where there is physician ownership is because it has heard of questionable diagnostic imaging arrangements. CMS does not identify any overuse or improper referrals for therapeutic services such as laser services or other urological procedures. Fairness would dictate that under arrangements should not be prohibited for services that would not otherwise be designated health services but for being furnished in a hospital. Incentive to over utilize present in diagnostic imaging services, is not present for most other services furnished under agreements where the referring physician also performs a professional portion of the referred procedure. Where urologists perform therapeutic procedures, the referring physician receives a professional fee and the professional fee is greater than the distributions for any particular referred procedure that the physician will earn from his

investment interest in the joint venture. The portion of the technical fee that he will earn in distributions from his investment in the venture is not likely to create an inducement to refer for the procedure. CMS should not prohibit services under agreements where the investor physician performs the professional portion of the procedure.

We asked CMS to separate those beneficial therapeutic joint ventures which are not of themselves designated health services from the abusive and questionable diagnostic ventures that physicians and hospitals may have propagated. Without a doubt, it should be clear to CMS that the urology community's therapeutic joint ventures have broadened access to new technology for Medicare patients, brought needed efficiency to the market and simultaneously saved CMS hundreds of millions of dollars. As CMS tries to stop abusive arrangements it would be a great mistake to jeopardize such time tested and proven arrangements.

Sincerely,
John C. Hedges M.D.
Keith A. Schulze M.D.
Scott A Bildsten D.O.

14661

William A. Conway, MD
Senior Vice President &
Chief Quality Officer, Henry Ford Health System
Chief Medical Officer, Henry Ford Hospital
Breech Chair for Health Care
Quality Improvement

Henry Ford Hospital
2799 W. Grand Blvd.
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(313) 916-8096 Fax
Email: wconway@hfhs.org

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Center for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue
Washington D.C, 20201

RE: CMS-1385-P, Medicare Program; Proposed Revisions to the Medicare Physician Fee Schedule for CY2008

TRHCA—SECTION 101(b): PQRI

Dear Mr. Kuhn,

It was very encouraging to see that the proposed changes to the PQRI reflect many of the concerns expressed to you and Dr. Valuck by myself and other representatives of the American Group Practice Association when we met on February 12. On behalf of the Henry Ford Medical Group, I'd like to express appreciation for the CMS efforts in the daunting task of developing a nationally coordinated quality improvement initiative. We welcome the opportunity to provide the perspective of a large medical group that is dedicated to improving the quality of care we provide to our patients.

The Henry Ford Medical Group thoroughly evaluated the feasibility of comprehensive reporting under PQRI in 2007 and determined it would have negligible impact on the quality of care provided to our patients. This was due, in large part, to the fact we had existing initiatives to encourage best practices that overlapped with the objectives of PQRI. In addition, the value of the bonus and uncertainty of future funding were considered. And, while some small pockets of our group are participating in the 2007 PQRI initiative, it was determined that, for the most part, we could not justify the expense and administrative burden that comprehensive reporting entailed. The biggest barrier was the requirement that the quality measures be reported on the same claim as the billed services.

It was encouraging that the NPRM proposes testing more efficient methods of collecting quality data and alternative means of reporting the data in 2008. We were disappointed to see, however, that the issue of bonuses for organizations pursuing alternative reporting methodologies was not addressed. Given the resources and effort required to pursue such

Submitter : **Ms. Jeanne Hendricks** **Date: 08/31/2007**

Organization : **AANA**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

I am writing to ask you to support CMS-1385-P (Background Impact) Anesthesia Services. Presently Medicare reimburses for anesthesia services at a 40% rate and 80% for other medical services. The proposal would boost value of anesthesia work by %32. Under the proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

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

Organization : **American Academy of Audiology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Submission of comments for CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008;
Coding-additional codes from 5-year review

CMS-1385-P-14664-Attach-1.PDF

14664

AMERICAN ACADEMY OF AUDIOLOGY

August 31, 2007

Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue
Washington, DC 20201

Subject: CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Coding-additional codes from 5-year review

Dear Mr. Kuhn:

On behalf of the American Academy of Audiology, I appreciate the opportunity to provide comments regarding the proposed revisions to payment policies under the physician fee schedule and other part B payment policies for 2008. The American Academy of Audiology, with an active membership of more than 10,000 audiologists, is the world's largest professional organization of, by and for audiologists.

The Academy appreciates CMS' recognition that audiology services, which previously were included under the nonphysician work pool, are considered professional services and should be assigned work values. Because audiologists are health care professionals who enroll as providers independently under the Medicare program and directly bill Medicare for their services, clearly these services should have work values.

However, we are deeply concerned with the work values recommended by the American Medical Association Specialty Society RVS Update Committee (RUC) and proposed in the rule for CPT codes 92557 and 92579, which would significantly undervalue these services. CMS indicates in the proposed rule that changes to the work values and the practice expense values combined would result in a 17% decrease in payment for audiology services when fully implemented in 2010. When combined with the projected decreases that would occur due to the sustainable growth rate, audiologists would receive

a cut of approximately 37% in their reimbursement in 2010. Such a dramatic cut is disproportionate to reductions proposed for other specialties and creates an undue burden on audiologists.

The decrease in rates is compounded by the fact that as a specialty, the audiology services described above represent the majority of services billed. Unlike other specialties who bill a mix of services—including some services whose rates decrease and some whose rates increase—audiologists experience a disproportionately greater decrease in reimbursement as a specialty compared to others.

The Academy appreciates the importance of establishing codes that properly reflect the costs and resources associated with providing services and CMS's important role in this process. We believe it is especially important that CMS use its resources to ensure that the value inputs assigned to individual codes reflect the true resources and costs of furnishing the services. We strongly recommend the following:

1) **CMS should recognize that the work values for two audiology codes (CPT codes 92557 and 92579) recommended by the RUC in the 2008 final rule and times proposed significantly undervalue these services.**
2) **CMS and the RUC should revisit the work values for CPT codes 92557 and 92579 in order to determine appropriate values for these services. As CMS and the RUC reconsider values for these services, there should be an opportunity to obtain additional data and further input from all affected groups regarding the resources needed to furnish these services. As these values are revisited, the American Academy of Audiology, as well as other stakeholders, should be given a meaningful opportunity to participate in the process.**

I. CMS Payment Policies Should Permit Access to Audiology Services

Audiologists provide services to people who have hearing, balance, and related ear problems. They examine individuals of all ages and identify those with hearing loss and other auditory, balance, and related sensory and neural problems. Audiologists assess the nature and extent of the problems and help the individuals manage them. Audiologists utilize audiometers, computers, and other devices to diagnose hearing and balance dysfunction, and the impact of hearing loss on an individual's daily life. Audiologists share the results of their testing with physicians, who use this information to determine appropriate medical or surgical treatment of a hearing or balance deficit.

It is a well-known fact that hearing loss is strongly associated with aging and therefore audiology services are of critical importance to Medicare beneficiaries. Undiagnosed and untreated hearing loss will result in social isolation and depression, and may hasten dementia. In the near future, as the baby boomer generation approaches their sixties and will be prone to medical conditions that result in hearing problems, there will be an even

greater demand for the services of audiologists. The demand for these services is also increasing due to medical advances that are improving the survival rate of individuals who have had a stroke or other neurological disorder.

Audiologists are highly trained professionals, who have received a master's or doctoral degree from an accredited university graduate program. By combining a complete history with a variety of specialized auditory and vestibular assessments, audiologists determine appropriate patient treatment of hearing and balance problems. The services of an audiologist result in significant improvements in the quality of life for their patients. Thus, the Centers for Medicare and Medicaid Services must ensure that Medicare beneficiaries are able to access these important services.

II. The Values Proposed in This Rule Threaten Access to Audiology Services

On the individual CPT code level, the cuts are severe. For example, payment for CPT code 92557 (Comprehensive audiometry threshold evaluation and speech recognition) would drop from approximately $50.40 in 2007 to $35.96 in 2010 (a 29% reduction) if payment is calculated in 2010 using the 2007 conversion factor ($37.8975). These cuts will be far greater if the forecasted reductions in the conversion factor due to the flawed "sustainable growth rate" (SGR) formula become effective. For example, if the projected 9.9%, 5%, and 5% reductions to the conversion factor occur in 2008, 2009, and 2010, respectively, CPT code 92557 would be paid at approximately $29.26 compared to $50.40 in 2007. These cuts will occur while the practice costs faced by audiologists will continue to rise.

The work values proposed in this rule, combined with an anticipated cut in the SGR, and the fully implemented practice expense values, severely undervalue certain audiology services. According to estimates prepared by The Moran Company, audiologists will experience a decrease in reimbursement of 27% by 2010 -- jeopardizing access to these essential services for seniors. Table 1 below summarizes the percent change in reimbursement experienced by audiologists compared to other specialties; it holds 2006 volume constant across years and incorporates changes to work values over time, changes to practice expense values over time, and includes the proposed change in the conversion factor for 2008-2010.

Table 1. Percent Change in Reimbursement from 2006 for Audiology and Selected Specialties

Specialty	% Δ (2006 to 2007)	% Δ (2006 to 2008)	% Δ (2006 to 2009)	% Δ (2006 to 2010)
Audiologist	-1%	-7%	-17%	-27%
Optometry	-4%	-13%	-15%	-17%
Dieticians	42%	12%	-2%	-16%
Otolaryngology	-1%	-10%	-11%	-11%
Internal Medicine	4%	-6%	-6%	-5%

Source: The Moran Company
Uses 2006 "Utilization File", 2006 RVU file, 2007 RVU file, and 2008 Proposed Rule Appendix B

The Academy is alarmed by these cuts. The resources necessary to provide the services will be greater than the payment amount. These cuts will undermine the goal of Congress and CMS to create a Medicare payment system that preserves patient access and achieves greater quality care. If audiologists experience significant cuts in payment at a time of rising practice costs, access to care for the elderly and disabled will be jeopardized.

III. CMS and the RUC should reconsider the work values for CPT codes 92557 and 92579

The Academy strongly disagrees with the RUC determination regarding values for CPT codes 92557 and 92579, which would significantly undervalue these services. CMS and the RUC should revisit the work values for CPT codes 92557 and 92579. To determine appropriate values it is necessary to obtain further information regarding the resources and time necessary to provide these services.

There are several factors that show the values assigned by the RUC would undervalue these services. First, recent surveys conducted jointly by the Academy and the American Speech-Language-Hearing Association (ASHA) showed significantly higher values for these audiology services than the values recommended by the RUC. Specifically, in 2007, the Academy and ASHA conducted surveys to determine appropriate work values for the audiology CPT codes in order to transition these services from practice expense values to work values. These surveys yielded a high number of responses for CPT codes (i.e., 92557, 92567, 92568) billed frequently by audiologists. For example, there were 147 respondents to the survey of CPT code 92557 (comprehensive audiometry threshold evaluation and speech recognition), resulting in an Academy/ASHA recommended work value of 1.40.

Table 2 below shows the number of responses to the surveys and the recommended work RVUs that were based on these surveys. We believe that these services accurately reflect current clinical practice. These values are compared in the Table to the work values recommended by the RUC. The large discrepancy in these values indicates these codes were undervalued.

Table 2: Academy/ASHA recommended work values compared to RUC recommended work values

HCPCS Code	Descriptor	Academy/ASHA recommended work RVU based on survey data	RUC recommended work RVU	Academy/ ASHA survey respondents
92557	Comprehensive audiometry threshold evaluation and speech recognition	1.40	.60	147
92579	Visual reinforcement audiometry (VRA)	1.70	.70	91

The Academy/ASHA surveys conducted in 2007 showed times for furnishing these services that were significantly higher than the times recommended by the RUC. Table 3 below includes the results of the survey conducted in 2007 by the Academy and ASHA in comparison to the RUC recommended time. Clearly, there is a large difference between these recommendations, pointing to the fact that the work values proposed in this rule for these codes do not accurately reflect the audiologist time and therefore undervalue these services

Table 3: Comparison of Assigned Time

HCPCS Code	Descriptor	Academy/ASHA 2007 survey time (pre, intra, and post)	RUC recommended time (total)
92557	Comprehensive audiometry threshold evaluation and speech recognition	55 minutes	28 minutes
92579	Visual reinforcement audiometry (VRA)	55 minutes	34 minutes

As CMS is aware, the existing times adopted by the PEAC, RUC, and CMS in 2002 and 2004 would be removed from the clinical labor time used in valuing the practice expense component of these services and replaced with the new work values. Because this time will be removed from the practice expense component, it is critical that the correct amount of audiologist time be used to determine values for these services.

A comparison of the work values recommended for these audiology CPT codes with work values assigned to CPT codes for other services that could be considered comparable supports our contention that these CPT codes were undervalued. There are a number of instances when CMS and the RUC have relied on the Intra Work Per Unit of Time (IWPUT) in making determinations of whether a code is undervalued. In addition, the RUC has also used the IWPUT for comparable services to derive work values for codes that do not have values assigned to them. Although no particular service is entirely the same as audiology services, the Bureau of Labor Statistics has identified occupational therapy, physical therapy, optometry, and psychology as related occupations.

The Academy determined the IWPUT for certain services furnished by physical therapists, occupational therapists and psychologists, and physicians. Using the time survey data from the Academy/ASHA survey conducted in 2007, the Academy derived work values for these services. For instance, a physical therapy evaluation (CPT code 97001) has an IWPUT of .031. For CPT code 92557, the Academy/ASHA survey resulted in median times of 5 pre-service minutes, 35 intra-service minutes, and 15 post-service minutes. Applying the IWPUT to these survey times would result in a work value of 1.533 for CPT code 92557. This work value is significantly higher than the RUC recommended value of .60 and is close to the work value of 1.40 recommended based on the Academy/ASHA survey.

In another example, the code for psychological testing, interpretation and reporting, per hour by a psychologist (CPT code 96101) has an IWPUT of .028. As referenced above, for CPT code 92557, the Academy/ASHA survey resulted in median times of 5 pre-service minutes, 35 intra-service minutes, and 15 post-service minutes. Using the IWPUT of .028, the work value for CPT code 92557 would be 1.428, which is close to the work values recommended from the Academy/ASHA survey. By comparing these values to other comparable services, it is clear that these services would be undervalued.

IV. Assigning Work Values for Audiology Services Presents Unique Challenges

Over the years, the RUC has developed sophisticated rules and processes for recommending relative values. Because audiology services were previously included as part of the practice expense values, developing work values for audiology services presented unique challenges. One major challenge to developing work RVUs is that there is no well-established set of reference codes. Without a reference code that the

audiologists are familiar with performing, it is difficult for the audiologists to evaluate and value their services relative to others.

Another challenge is that there are different views among specialties regarding the pre-service, post-service and intra-service work involved in providing this service. When treating a patient, an independent audiologist assumes a comprehensive and global role, including history-taking, administering the procedures, interpreting the findings, counseling the patient, and coordinating care. An independent audiologist typically schedules approximately one hour for each patient who is scheduled to receive a comprehensive hearing test (CPT code 92557). Some physician specialties are of the opinion that the audiologist only administers the procedure with limited patient interaction because the physician in the practice manages the patient encounter. These differences of opinion are indicated by the descriptions of pre-service, intra-service and post-service work that were included in surveys conducted by the Academy/ASHA as compared to surveys conducted by a physician specialty during the RUC process.

Table 4 (below) shows a comparison of the descriptions of work included in two different surveys of CPT code 92557. It clearly shows that there is a difference of opinion and confusion over the work involved in providing this service. As a result, the amount of time and values recommended for services, such as 92557, were significantly different. When the results of these surveys were combined, the result was a work value for CPT code 92557 that is too low.

Table 4: Comparison of Description of Work included in surveys for CPT code 92557

CPT Descriptor: Comprehensive audiometry threshold evaluation and speech recognition (92557)

Clinical Vignette: A 49-year old female was referred for an audiologic evaluation with chief complaint of progressive tinnitus in her right ear. No episodes of vertigo or imbalance were reported.

Survey	ASHA/AAA Survey	Physician specialty survey
Description of Pre-Service Work	Review any prior records and referral documentation. Prepare the room for the patient. Enter demographics in computer.	The test is explained to the patient. The patient is then seated in a booth, headphones placed, computer set up and patient information entered.
Description of Intra-Service Work	The audiologist greets the patient and accompanies her to the audiometric test area. The audiologist confirms elements of the referring history and makes further inquiries regarding other medications and aspirin	The patient is presented sounds (different frequencies and sound levels). The patient indicates whether heard or not by pressing/not pressing a button. This is done with air/bone and

	ingestion earlier that same day. An otoscopic examination is performed and the patient is then seated in the audiometric test booth. The audiologist instructs the patient regarding what to listen for in establishing pure tone thresholds for air conduction stimulation. Earphones are then placed over her ears and appropriate comfort is ensured. The audiologist then moves to the control side of the audiometric test booth and presents an initial series of pulsed 1000 Hz tones at a level that is clearly audible to the patient. Based on the patient's responses, the audiologist decreases the intensity of each pulsed tone series by 10 dB until the patient no longer responds. He then increases the intensity in 5 dB steps until the patient indicates that the tones are once again audible. This minimum level is verified to ensure accuracy through a repeated presentation. Threshold is defined as the lowest intensity at which the patient consistently responds to a pulsed tone stimulus. This procedure is repeated for the frequencies 250 Hz, 500 Hz, 2000 Hz, 4000 Hz, and 8000 Hz for each ear. After the air conduction thresholds are completed, the audiologist enters into the patient side of the audiometric booth, removes the earphones, and places a bone conduction oscillator on the patient's right mastoid, securing the appropriate position with a head band. The patient is then instructed to listen for another series of pulsed tones and to respond in the same manner as before. She is also	masking if needed. Patient is then given words to repeat to test their discrimination.

	instructed that if she should hear a "noise" (e.g., 1/3 octave band masking noise) in the opposite ear, she should ignore the noise and respond only to the pulsed tones. An earphone is then placed over the ear contralateral to the bone conduction oscillator and secured in place with the earphone headband. The audiologist then proceeds to the control side of the audiometric test booth and begins the bone conduction threshold measurements by presenting a pulsed tone that is clearly audible to the patient. Thresholds are determined in the same manner as described above for the frequencies 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz. If a difference between the bone conduction threshold and the air conduction threshold exceeds 10 dB, masking noise is introduced into the earphone to remove the contralateral ear from possible participation in the test. The bone conduction threshold is then verified by increasing the masking noise levels and checking for shifts in the bone conduction threshold. After the bone conduction testing is completed, a speech reception threshold is then established by presenting bisyllabic words through the earphones and having the patient repeat them. Again, the audiologist begins the test by presenting the words at a level that is clearly audible. Upon a correct response from the patient, the audiologist decreases the intensity in 10 dB steps until the patient's responses are no longer accurate. At that intensity, the audiologist begins	

	to increase the intensity in 5 dB steps until the patient once again achieves accuracy. Speech reception threshold is defined as at least 50% accuracy in repeating the bisyllabic words at the lowest possible intensity. After the speech reception threshold has been established, the audiologist presents monosyllabic words to evaluate speech recognition. The patient is instructed for this new task, the audiologist then presents a recorded word list at a level approximately 40 dB louder than the speech reception threshold. The audiologist records errors and establishes a percent correct score for each ear.	
Description of Post-Service Work	The audiologist reviews, synthesizes and interprets the results of the functional diagnostic tests and discusses the results of the test outcomes with the patient. The audiologist summarizes the results and answers questions from the patient/family. A report is then written for the referring professional.	The results are recorded or saved in computer and/or printed out.
Median Pre-Service Time	5 minutes	1 minute
Median Intra-Service Time	35 minutes	15 minutes
Median Post-Service Time	15 minutes	3 minutes
Total Time	55 minutes	19 minutes
Surveys completed	147	21

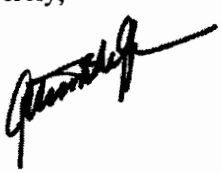
The Academy along with ASHA had an informal discussion with the RUC about our concerns and was advised that we could request a review of the values assigned to CPT codes 92557 and 92579. We intend to request this review and plan to resurvey these two codes with our colleagues at ASHA assuming we are given that opportunity by the RUC.

We hope to work with the RUC and CMS in the future to address this unique situation and determine a methodology that will appropriately value these services.

Conclusion

We appreciate the opportunity to submit comments and look forward to working with CMS to address our concerns. The Academy understands the important role of the RUC in assisting CMS with the valuation of codes; however, there are times when it is appropriate for the Agency to address issues that may have been overlooked in the RUC process. If you have further questions, please contact Phil Bongiorno at (703-226-1032), email pbongiorno@audiology.org.

Sincerely,



Alison M. Grimes, AuD
President

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

Organization : Galeda Jones

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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Thank you for your consideration of this serious matter.
Galeda Jones

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

Organization : GEORGE RANDOLPH

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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GEORGE RANDOLPH

Submitter : **Dr. Vernon Ross** **Date: 08/31/2007**

Organization : **Wake Forest University Baptist Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

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

Organization : **Debbie Crow**

Category : **Individual**

Issue Areas/Comments

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Thank you for your consideration of this serious matter.
Debbie Crow

Submitter : Dr. Kenneth McNeil **Date:** 08/31/2007

Organization : Anesthesia Associates of West Virginia

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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

RE: CMS-1385-P
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I have served as the anesthesia representative for the Medicare Carriers Advisory Committee for West Virginia since 1990 and have always been supportive of the hard work that goes into these types of decisions. This increase will truely impact improved patient care and access for our nations seniors. West Virginia has one of the highest Medicare populations in the nation, and this increase will ensure expert anesthesiology medical care to them in the future.
Thank you for your consideration in this matter.

Kenneth F McNeil MD
Carrier Advisory Committee Member Anesthesia--West Virginia

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

Organization : BETSY RANDOLPH

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
BETSY RANDOLPH

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

Organization : Mary Clay

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
Mary Clay

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

Organization : SHELLEY RAPPE

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
SHELLY RAPPE

obstructing benign prostatic hyperplasia or other therapeutic needs. I believe that there is a marked difference in this venue from diagnostic procedures, which could be done in search of possible pathology. At this particular point, many urologists who have joined together to bring technology, largely at their own financial risk to their patients, should not be prohibited by rules that are totally unfair for compensation should these technologies prove beneficial I would urge you to differentiate between diagnostic ventures and therapeutic ventures, the latter of which are what we in the urological community have provided and should be able to continue to provide to our patients and to your Medicare beneficiaries, of which I am about to become one.

Respectfully yours,

H. Alan Bigley, Jr., M.D., F.A.C.S.

HAB/smc

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

Organization : **Eleanor Cowley**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
Eleanor Cowley

Submitter : **Dr. Kelly Myers** **Date: 08/31/2007**

Organization : **Anesthesiologist**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
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Thank you for your consideration of this serious matter.

Kelly Myers M.D.

Submitter : **Mrs. Kimberly Hickman** **Date: 08/31/2007**

Organization : **University Suburban Sports Medicine**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a 29 year old certified athletic trainer working for University Sports Medicine Center in South Euclid, OH and am contracted out to Cleveland Heights High School. In order to apply for this or any other cretified athletic training position I had to graduate from an accredited university and sit for a nationally recognized crctification as well as a statc licensure test. I completed two bachelors and one masters in five ycars at The University of Akron in Akron, OH.

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 facilitics proposed in 1385-P.

Whilc I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that thesc proposcd 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 profcssionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes relatcd to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Kimberly M. Hickman, MS, ATC

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

Organization : TONY RAPPE

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
TONY RAPPE

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

Organization : **Virginia Denton**

Category : **Individual**

Issue Areas/Comments

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Virginia Denton

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

Organization : **Misty Segarra**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Misty Segarra

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

Organization : **Virginia Denton**

Category : **Individual**

Issue Areas/Comments

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Virginia Denton

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

Organization : JOETTA RAPPE

Category : Individual

Issue Areas/Comments

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JOETTA RAPPE

Submitter : **Mr. Stephen McCoy** **Date: 08/31/2007**

Organization : **Williams Mullen**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See attachment.

CMS-1385-P-14682-Attach-1.PDF

14682

WILLIAMS MULLEN

Direct Dial: 804.783-6469
smccoy@williamsmullen.com

August 31, 2007

Via Electronic Mail to http://www.cms.hhs.gov/eRulemaking

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

Re: Comments Regarding the Centers for Medicare & Medicaid Services ("CMS") Proposed Revisions to Payment Policies under the Physician Fee Schedule; Physician Self-Referral Issues

Ladies and Gentlemen:

Enclosed you will please find comments on CMS' Proposed Revisions to Payment Policies under the Physician Fee Schedule, published as a proposed rule on July 12, 2007 as Federal Register Volume 72, pp. 38122-38395 (the "Proposed Rule"). The following comments focus specifically on those portions of the Proposed Rule that address physician self-referral issues and appear at 72 Fed. Reg. pp. 38179 *et seq.* Consistent with instructions set out in the Proposed Rule, these comments are being submitted no later than 5 p.m. on August 31, 2007.

PHYSICIAN SELF-REFERRAL PROHIBITIONS

1. Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Mark-up Provision)

Under existing Medicare rules, a physician is prohibited from marking up the technical component of certain diagnostic tests that are performed by outside suppliers. Instead, a physician or group that purchases the technical component of a diagnostic test must accept as payment from Medicare the lowest of (i) the Medicare allowable charge, (ii) the physician or group's actual charge, or (iii) the net amount charged by the party performing the technical component of the test.

The anti-mark-up provision does not currently apply to the professional component of diagnostic tests. However, in order to bill for the technical component of a diagnostic test, the

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billing physician or group must perform the professional component of the test and may not purchase it from an outside supplier. In addition, physician and medical group billing of the purchased professional component of a test is limited by the purchased interpretation rules.

Under the Proposed Rule, CMS would modify §414.50 of the Medicare rules to provide that "an outside supplier is someone other than a fulltime employee of the billing physician or medical group."

Adoption of the foregoing definition of "outside supplier" would have a substantial and harmful effect on physician practices that employ physicians to provide services on a part-time basis. The proposed definition suggests that any physician practice that employs part-time physicians would need to restrict the physicians' services to ensure that they do not interpret diagnostic tests that are subject to the rule. In the alternative, such physician practices would be required to determine the per test compensation paid to their part-time employees for purposes of submitting the appropriate charge to Medicare. Such a requirement ignores the fundamental truth that the large majority of physician groups pay their physician employees on a salaried or hourly basis, rather than on a per-service basis. In short, it would be difficult or impossible for physician practices to determine the per test compensation paid to their hourly or salaried part-time employees.

The proposed definition of "outside supplier" also ignores the substantial protections that already exist against the excessive use of part-time physician employees who have multiple employers. Most, if not all, physician groups must qualify as a "group practice" under 411.352 of the Stark regulations in order to receive payment from Medicare for diagnostic tests performed by their physician employees (whether under the physician services or the in-office ancillary services exceptions that appear at §411.355(a) and (b), respectively). A physician practice will not qualify as a "group practice" under Stark unless at least 75% of the total patient care services of its physician members (including both full- and part-time employees) are provided through the group. Any physician practice that provides a high percentage of its services through part-time employees who "moonlight" elsewhere risks violation of this 75% test and loss of its ability to submit claims for diagnostic health services ("DHS") to Medicare.

Finally, the proposed regulation does not define the term "full-time". As a result, it appears clear that the regulation would discourage employment of physicians who work for a single employer on a reduced time schedule. The employment of physicians on a part-time basis has become common in the industry as primary, specialty and urgent care physician practices adapt their business models to provide extended hours of service, flexible and no-appointment scheduling for patients, and employment opportunities for female physicians who are working

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mothers. This firm represents a large number of physician practices that successfully employ female physicians on a part-time basis. Adoption of the proposed definition of "outside supplier" would threaten those practices' business models and directly impact their female physician employees who, whether by choice or otherwise, work on a part-time basis.

We appreciate the opportunity to comment on the Proposed Rule and bring to your attention the unintended consequences of the proposed definition of "outside supplier". Please feel free to call us with any questions you may have about these comments, or if we may be able to provide you with information useful in your analysis. Thank you.

Sincerely,

Stephen C. McCoy

1495692v1

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

Organization : **Jim Cunningham**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Jim Cunningham

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

Organization : Steve Segarra

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Steve Segarra

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

Organization : JERRY ROBERTS

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
JERRY ROBERTS

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

Organization : **The Endocrine Society**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Thank you for the opportunity to comment. Please see our attached comments for your review.

CMS-1385-P-14686-Attach-1.DOC

THE ENDOCRINE SOCIETY

8401 CONNECTICUT AVENUE, SUITE 900 + CHEVY CHASE, MARYLAND + 20815-5817 + TELEPHONE 301.941.0200 + FAX 301.941.0259 + www.endo-society.org

14686

August 31, 2007

Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue
Washington, D.C. 20201

RE: CMS-1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008

Dear Mr. Kuhn:

On behalf of The Endocrine Society (Society), representing more than 14,000 physicians and scientists in the field of endocrinology, we appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed revisions to the payment policies under the Physician Fee Schedule for calendar year 2008. The Society looks forward to working closely with the Agency as this proposed rule moves toward implementation.

Founded in 1916, our Society represents physicians and scientists engaged in the treatment and research of endocrine disorders, such as osteoporosis, diabetes, infertility, obesity, and thyroid disease. The following comments focus on three areas of particular importance to our members:

1) Physician Fee Schedule Across-the-Board Cuts
2) Physician Quality Reporting Initiative
3) Thyroid Ultrasound Cuts
4) Cuts to Dual X-Ray Absorptiometry (DXA)

Physician Fee Schedule Across-the-Board Cuts

The Endocrine Society would like to state its opposition to the proposed 9.9 percent across-the-board physician payment cuts as a result of the flawed Medicare sustainable growth rate (SGR) formula. As you are no doubt aware, the SGR does not accurately reflect the cost of caring for Medicare patients and must be replaced. We urge CMS to take administrative action to increase funding for physicians' services and facilitate enactment of legislation to replace the SGR with payment updates based on physicians' practice cost increases. Further, we ask that CMS continue to work diligently with Congress and physician groups to avert the proposed cut for 2008, and to find a long-term solution to the flawed payment formula.

Physician Quality Reporting Initiative

Second, we believe that the $1.35 billion fund established to provide bonus payments to physicians for their participation in the Physician Quality Reporting Initiative (PQRI) should instead be applied to the conversion factor in order to reduce the amount of the 9.9 percent proposed payment cuts. The average internal medicine physician is expected to receive approximately $1400 under the 2007 PQRI bonus payment, a figure that likely does not strongly entice physicians to join the reporting program. In addition, the PQRI is a voluntary program, and one that does not include a majority of Medicare providers. If the $1.35 billion was instead applied toward the conversion factor to reduce the physician payment cut, a greater number of physicians would benefit in a more direct way.

Thyroid Ultrasound Cuts

Our third major concern under the 2008 physician fee schedule relates to thyroid ultrasound. Under the Deficit Reduction Act of 2005 (DRA), thyroid ultrasound codes 76942 (Echo Guide for Biopsy) and 76536 (US exam of head and neck) had payments capped at the level of the Hospital Outpatient Prospective Payment System (OPPS). This has had a negative affect on physician reimbursements for these important services. In addition, CMS has proposed a reduction in the practice expense value for code 10022 (Fine Needle Aspiration with Image), a code not affected by the DRA, from 2.41 in 2007 to 2.32 in 2008. We expect that the reduction in the practice expense for this code will cause the payment for this service to decrease from $137.57 in 2007 to approximately $120.16 in 2008, a change we believe to be unwarranted. As a result, the Society respectfully requests that CMS:

1) Re-examine practice expense values, including equipment and utilization costs, assigned to CPT code 10022.

Cuts to Dual X-Ray Absorptiometry

Finally, another significant area of concern within the Physician Fee Schedule proposed rule relates to procedures used to help diagnose and treat osteoporosis. We continue to be concerned with the affects of the Deficit Reduction Act of 2005 (DRA) that has drastically cut payment for Dual Energy X-Ray Absorptiometry (DXA) & Vertebral Fracture Assessment (VFA). We believe that this policy will continue to have negative and unintended consequences for the more than 10 million Americans with osteoporosis and the 34 million at risk for fractures due to low bone mass (osteopenia). The Society's comments address the following areas:

1) Osteoporosis Patient Care and Access to DXA & VFA
2) Methodology Used to Calculate Practice Expense for DXA & VFA

Osteoporosis is a major health care issue in the United States costing more than $18 billion annually. DXA and VFA are crucial for the detection of osteoporosis and identification of those at highest fracture risk before a fracture occurs. Federal initiatives to identify patients with osteoporosis have led to the increased utilization of DXA and VFA; however, the vast majority of affected individuals continue to remain undiagnosed and untreated.

The Society is concerned that the proposed changes in the physician fee schedule, combined with the DRA cuts would reduce DXA reimbursement from approximately $140 to $40 and VFA from $40 to $25 by 2010. These reductions will force physicians to discontinue offering these vital services, resulting in a severe limitation of patient access to quality bone densitometry and vertebral fracture assessment. While we applaud CMS' agreement with the American Medical Association's Resource-Based Relative Value Scale (RUC) Committee to increase the physician practice expense for DXA services, there still appears to be flaws in data input including inappropriate application of equipment cost, and inappropriate utilization rates. Even combined with an increased physician practice expense, these calculations will significantly contribute to severe cuts in DXA and VFA reimbursement. In fact, a study (methodology and findings attached) funded in part by The Endocrine Society and conducted by The Lewin Group in July 2007 found that only 5 percent of study respondents stated that their costs to perform DXA were equal to or less than the $82 payment rate for 2007. The study details that costs to perform DXA ranged from the 25th percentile cost of $95.07, to the 75th percentile cost of $195.02. The median cost associated with performing DXA services was $134.13, a figure that is over 60 percent higher than the 2007 payment of $82. For these reasons, the Society respectfully requests that CMS:

1) Reassess utilization rates and equipment costs for DXA (CPT codes 77080 and 77081) and VFA (CPT code 77082) and the effects that the DRA has had on these services.

Patient Access to Care Compromised

The cuts contained in the DRA, compounded with the 9.9% physician payment cut included in the CMS Proposed Rule, would profoundly impact patient access to this and other types of imaging procedures. DXA and VFA are low cost procedures that have been directly linked to improvements in patient outcomes; furthermore, both diagnostic options are readily available to primary care physicians and other medical specialties. Reduced access to outpatient DXA scanning resulting from these cuts would also directly conflict with federal initiatives such as the Surgeon General's Report on Osteoporosis from 2005, which supports increasing bone density screening for at-risk groups including patients with fractures, women aged 65 and older, patients on glucocorticoids, and other high risk groups. Finally, these policies would make it even more difficult for primary care physicians to adhere to future "pay-for-performance" measures that may recommend DXA screening and testing for these high risk groups.

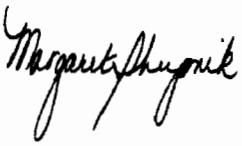
Flawed Methodology Used to Calculate Practice Expense Component for Procedures

The Society is also concerned about the methodology used to calculate Practice Expense for these procedures. The utilization rate of 50 percent was applied across-the-board to all procedures. Imaging procedures utilized in single-disease states, such as DXA and VFA for osteoporosis, have substantially lower relative rates of utilization. The 2002 Medicare data reflect the fact that 70 percent of DXA studies are performed in an office setting (versus only 30 percent in a hospital setting), and 60 percent of studies are performed by non-radiologists. These data indicate that primary care physicians perform DXA on patients as part of routine medical care in their practice, versus the high volume imaging centers that may exhibit significantly higher utilization rates. We believe that a more appropriate utilization rate for DXA and VFA services to be 21 or 22 percent. The Endocrine Society, along with other provider groups, brought this particular issue before the RUC in 2007. The RUC expressed the opinion that they were not the appropriate body to debate issues of utilization and we strongly encourage CMS to consider this issue in its final rule.

Equipment costs given for VFA are based on software additions to current fan beam densitometers (cost approximately $85,000). However, the cost for DXA, which is based on pencil beam instrumentation, is $41,000 in the 2008 proposed rule, even after CMS agreed with our 2007 proposed rule comments and increased the equipment cost for DXA in 2007 to $85,000. Fan beam densitometers comprise the majority of densitometers currently available in practice because one of two largest United States manufacturers of DXA devices no longer produces pencil beam densitometers. Pencil beam densitometers comprise less than 20 percent of sales for the other US manufacturer. Thus, the equipment cost for DXA should remain at the 2007 rate of $85,000.

In conclusion, the Society appreciates the opportunity to submit these brief comments regarding CMS' 2008 Physician Fee Schedule. As always, the Society is grateful to CMS staff for the hard work that went into drafting this proposed rule. Please do not hesitate to contact Janet Kreizman, Senior Director of Government & Professional Affairs, at jkreizman@endo-society.org, if we may provide any additional information or assistance as CMS moves forward in developing this rule.

Sincerely,



Margaret Shupnik, Ph.D.
President
The Endocrine Society

Appendix A

I. Methods

We discuss the methodology for each component below:

b. Practice Expense and Malpractice Expense

1. Survey Administration

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

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

2. Generating Practice Expense and Malpractice Expense Cost Components

The Lewin survey collects expenses for entire individual practices[1]. The analysis consists of first estimating total aggregate DXA costs and then generating a practice expense and malpractice cost per DXA procedure for each practice. We report the median cost, 25th percentile and 75th percentile statistics. Lewin also investigated the range of expenses for different cost categories and the effect procedure volume has on per DXA procedure costs. Consistent with CMS methodology, Lewin used the median as our metric of central tendency to reduce the effect of data outliers.

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

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

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

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

Equipment costs

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

Space allocated to DXA

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

Allocation of overhead expenses attributed to DXA

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

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

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

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

c. *Physician Work*

1. *Survey Administration*

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

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

2. *Generating Labor Costs Attributed to Providing DXA*

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

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

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

d. Generating a per Procedure DXA cost

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

e. Utilization Rate

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

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

II. Sample characteristics

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

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

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

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

Appendix B

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

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

Instructions

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

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

To submit this paper survey:

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

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

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

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

Information about You

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

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

	responses to Ted Kirby at 703-269-5501.

Information about Your Practice

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

	_____ professional component only (-26)
B-8	What is the average number of hours per week that your office is open for business? _____ hours per week
B-9	How many days of the week is your office open for business? _____ days of the week
B-10	How many weeks of the year is your office open for business? _____ weeks of the year
B-11	What is the average number of hours per week that DXA is available/offered in your office? _____ hours per week
B-12	How many central DXA procedures are performed in an average month per machine? _____ procedures

Information about VFA

C-1	Do you have VFA capability? ____ Yes ____ No
C-2	Do you read VFA? ___ Yes ___ No* *Skip to next section*
C-3	How many VFA procedures are performed in an average month per machine? _____ procedures
C-4	How many machines are used for VFA? _____ machines
C-5	What percent of central DXA patients receive VFA?

	_____%

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

Information about Your Equipment Costs

	Total number of DXA machines in your practice: _____
	Please fill out one row in the following table for each DXA machine in your practice.
	Please specify if the manufacturer is: • Hologic, • Norland/Cooper, or • GE/Lunar

D-1

Machine Number	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
1					
2					
3					
4					

D-2	Cost per year of interest on loan(s) used to purchase your DXA machine(s): $_____ per year
D-3	Cost per year of any service contract(s) for your DXA machine(s): $_____ per year
D-4	Cost per year of software upgrade(s) for your DXA machine(s): $_____ per year
D-5	Cost of the last PAC/DICOM upgrade(s) (ability to transmit radiographic images electronically): $_____

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

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

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

Do include:

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

Do not include:

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

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

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

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

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

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

Do you have any additional comments?

Congratulations, you have finished the survey!
Thank you for your responses.

To submit your complete survey, please fax it to
Audrey El-Gamil at the Lewin Group, 703-269-5501

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

Organization : **Karen Peterson**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 31, 2007

Docket ID CMS-1385-P

The therapy standards proposed by CMS in the Physician Fee Schedule will harm the patients of athletic trainers and create access problems.

I believe these rules will decrease the quality of services provided to Medicare beneficiaries. These CMS proposed rules are not supported by any objective reports or other rationale that has been made public.

Athletic trainers are fully qualified to evaluate, treat and rehabilitate injuries. I am 51 years old and worried about access to medical services as I get older. I believe these rules will harm Medicare AND non-Medicare patients. The private sector follows Medicare's lead. If that happens, millions of secondary school and college students will lose access to services. Millions of seniors recovering from hip replacement and other orthopedic surgeries and conditions will lose access. This is unacceptable and cannot be what Medicare intends.

These are unnecessary and unreasonable rules. I have a Health Spending Account and I want to exercise that flexibility and choose the best provider for me.

I respectfully request that all rules past and present that restrict the ability of athletic trainers to lawfully practice their profession be reversed by CMS.

Further, I recommend that the broadest possible panel including sports medicine consumers of physical medicine and rehabilitation services providers be established to review future therapy rules prior to such efforts to insert them into the Federal Register.

Sincerely,
Karen Peterson

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

Organization : SHERRY ROBERTS

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
SHERRY ROBERTS

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

Organization : **Kathy Cunningham**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Kathy Cunningham

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

Organization : **Keith Schuessler**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Thank you for your consideration of this serious matter.
Keith Schuessler

Submitter : **Dr. Alexandru Georgescu** **Date: 08/31/2007**

Organization : **UAB**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14691-Attach-1.DOC

CMS-1385-P-14691-Attach-2.DOC

14691

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

Organization : TOM RYE

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Thank you for your consideration of this serious matter.
TOM RYE

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

Organization : **Shari Schuessler**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Shari Schuessler

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

Organization : **Kellis Cunningham**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Kellis Cunningham

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

Organization : DONAS RYE

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
DONAS RYE

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

Organization : **Joy Cunningham**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. 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.
Joy Cunningham

1-1700

PhotoMedex

August 31, 2007

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

Ladies and gentlemen:

We are writing to you to support the efforts of CMS to improve competition and reduce costs in health care through the Tax Relief and Health Care Act of 2006.

Our company provides medical equipment to healthcare providers on a "fee per case" model. We also provide a clinical support technician to operate the equipment. We are independent of the hospitals and physicians whom we serve. We are not owned by any group of physicians. All of our pricing decisions are made at arm's length.

The same cannot be said of other providers of medical equipment to health care institutions and professionals. We have seen an increase in the number of equipment providers which are owned by a group of physicians. There are typically enough physicians in the group that no one physician owns more than 5% of the entity providing the equipment. Not surprisingly, the physicians owing the entity practice in the medical field in which the entity provides equipment, and less surprisingly, the physician-owners refer their cases to the entity.

Such physician-owned groups are anti-competitive, restrain trade and undermine a hospital's independence. Physician-owners steer their cases to their groups. With the power to control the cases, the physician-owners will attempt to charge more for cases than other, non-physician-owned providers will charge.

Here is how such a group handles competition: a group of physicians, having no equipment but controlling the referral of cases, can simply say to the incumbent, arm's-length equipment provider: "Be our subcontractor and take a cut on the fee per case; otherwise, we will deal with another provider, or procure our own equipment, and you will be frozen out of the market." Even if the incumbent provider succumbs to the pressure, do not expect that the reduced, subcontracted rate translates into lower charges to the hospital; the physician group can reap the discount from its subcontractor and also charge a premium to the hospital.

We know this first-hand: a physician was acting as promoter to assemble a group of urologists to join a physician-owned entity that would provide equipment and technicians for urological procedures. We regarded this promoter as something of a charlatan, for at the same time he was lining up his group and entity, he was also lining up a subcontractor for the entity. He came to us, avowedly with a gift, but strangely the gift made a ticking noise: "Join and cut your fee, or the group will not use you, and it is no business of yours that I will increase the charges to the hospital."

Here is how such a group handles the hospital: if a hospital demands that such services should be awarded to the lowest bidder of equivalent services, such groups will test their muscle on the hospital, threatening to move the cases which their physician-owners control to another hospital, presumably a hospital that will be glad for the increased case-loads and will overlook the costs charged for such cases. If the first hospital stands its ground, it must be ready for a palace revolt.

We know of several instances of this first-hand: in one instance, a physician-owned entity was charging more than our company, dealing at arm's length, was offering to charge. When the hospital changed over to our company, much – but not all – of the business went over to other hospitals, where the physician-owners could continue to use their own entity. This shows that such entities are much like cartels, with all the strengths and weaknesses of cartels. But who wants an OPEC in our health system?

Not every physician willingly ignores his or her conscience and joins such a group. But those who resist face considerable peer pressure to join derision if they do not join. If the regulations are clear on their purpose and intent, then the regulations help such people of conscience decline to abet groups built on legalistic loopholes.

We applaud the changes CMS has proposed to current regulations dealing with physician self-referral.

Sincerely,

/s/ Davis Woodward

Davis Woodward
Corporate Counsel

Submitter : Lea Ann Patterson **Date:** 08/31/2007

Organization : Lea Ann Patterson

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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Thank you for your consideration of this serious matter.
Lea Ann Patterson

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

Organization : DIANNE SAMMONS

Category : Individual

Issue Areas/Comments

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

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

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

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

Thank you for your consideration of this serious matter.
DIANNE SAMMONS

Submitter : Mrs. BRIDGET COLLINS **Date:** 08/31/2007

Organization : COUNCIL ON PROFESSIONAL STANDARDS-KINESIOTHERAPY

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

RE: Docket #1385-P Therapy Standards and Requirements, Physician Self-Referral Provisions

My name is Bridget Collins and I am a Kinesiotherapist at Hines Veterans Hospital in the Suburbs of Chicago. For over 60 years, Kinesiotherapy has been an integral team member within many Veterans Affairs Hospitals Physical Medicine and Rehabilitative Departments. Personally, I have served our veteran population for over 23 years as a Kinesiotherapist. I also serve as Director of Continuing Competency for the Council on Professional Standards-Kinesiotherapy. In this capacity, I fully understand the importance of demonstrated professional competency.

I am writing today to voice my opposition to the proposed therapy standards and requirements regarding the staffing provisions for rehabilitation in hospitals and other facilities(proposed in Federal Register issue #1385-P. I am concerned that these proposed rules will create additional lack of access to quality health care for patients. I also believe that the proposed changes to Hospital Conditions of Participation, have not been thoroughly reviewed and studied. I have to believe that a governing body such as CMS would remain open minded yet steadfast to the values so crucial to governing safe/effective health care. As professionals it is crucial that we are not consumed by turf issues, but rather by the means to which we can provide the most effective and fiscally responsible quality of care. Let s work together rather than create more division.

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. This ruling would make sweeping changes that very well need not be. I would personally be willing to work on a task force that would review problems/concerns specific to Therapy Standards and Requirements, Physician Self-Referral Provisions.

Sincerely,

Bridget Collins, MS., RKT
Director, Council on Professional
Standards-Kinesiotherapy

Sincerely,
Name, RKT

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

Organization : **Anesthesia Medical Consultants**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Thank you for your consideration of this serious matter.
John Huntington MD

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

Organization : Steve Stulce

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Steve Stulce

14706

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Raymond A. Foxworth **Date:** 08/31/2007

Organization : Foxworth Chiropractic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

Submitter : MORRIS S'RENCO **Date: 08/31/2007**

Organization : MORRIS S'RENCO

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
MORRIS S RENCO

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

Organization : **Glenda Maxwell**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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Thank you for your consideration of this serious matter.
Glenda Maxwell

Submitter : **Mrs. Ashley Hanson** **Date: 08/31/2007**

Organization : **Archdiosese of Baltimore**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dcar Sir or Madam:

My namc is Ashlcy Hanson and I am a certified athletic trainer and certified high school teacher. I work in a private high school in Baltimore, providing health carc to studcnt-athlctcs at my school. I rcccivcd my undergraduate education at Salisbury Univcrsity in Maryland and did my graduate degrcc at UNC-Chapel Hill, providing athletic training services for the highly successful women's soccer and track and field teams.

I am writing today to voicc my opposition to the therapy standards and requirements in regards to thc staffing provisions for rehabilitation in hospitals and facilitics 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 thesc 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.

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

Sincerely,

Ashley Hanson, MA, ATC

Submitter : Mr. Mark Medvitz **Date:** 08/31/2007

Organization : MedImmune, Inc.

Category : Drug Industry

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Summary

I am writing in response to the proposed rule released on June 29, 2007 that would eliminate the exemption for computer-generated faxes from e-prescribing standards. In my view, this elimination is premature and should be delayed until the SCRIPT ePrescribing standards, or another subsequent ePrescribing standard, contains provisions that enable the transmission of prior authorization information along with electronic prescriptions or, that certain classes of specialty pharmaceutical and biologic products maintain the exemption while broader e- prior authorization standards are developed.

Discussion

Many prescription drugs are not filled by retail pharmacies, but are instead dispensed by specialty pharmacy providers. These drugs may require special handling, may be administered to patients by a health care provider or may be costly enough to require prior authorization or approval from payers before the drug can be dispensed. The current SCRIPT standard is well suited for drugs that can be dispensed by a retail pharmacy directly to patients, but it is not sufficient for those cases where drugs, due special handling requirement, clinical oversight, method of administration or cost, must be pre-approved by payers prior to fulfilling the prescription and dosing patients.

Specifically, there is no provision in the current SCRIPT standard for the transmission of detailed patient information, insurance carrier information, medical history or medical criteria necessary for approval of a high dollar value drug. A 2006 CMS sponsored study, 'Pilot Testing of Initial Electronic Prescribing Standards Cooperative Agreements Required Under Section 1860D-(4) (e) of the Social Security Act as Amended by the Medicare Prescription Drug, Improvement, and Modernization Action (MMA) of 2003 ' reached just this conclusion. This study states that, while the existing standards are suitable for many purposes, existing prior authorization standards are, '...technically unable to convey the information needed to support this function...'¹ until such time as a workable standard exists, prior authorization information can be transmitted to specialty pharmacy providers via a computer-generated fax that contains a prescription request as well as any additional information necessary for a payer to approve payment for a particular drug.

Eliminating the faxing of documents that provide both pre-authorization information along with a viable prescription would create a two-step process (submitting pre-authorization data, waiting for clearance, then providing the prescription, as opposed to submitting both at once) requiring more work from physician staff and possibly delaying time to therapy or treatment. Although I fully support increased automation and its goals of clarity and speed, until such time that e-prescribing standards are developed fully to capture insurance and patient medicinal information, the fax option must be maintained for those products, typically those dispensed by specialty pharmacies, in order to ensure timely and appropriate access.

Thank you for your consideration of these comments.

Mark S. Medvitz
Sr. Director of Reimbursement
MedImmune, Inc.
One MedImmune Way
Gaithersburg MD 20878
Phone 301.398.4238
Fax 301.398.9238
medvitzm@medimmune.com

1. 'Pilot Testing of Initial Electronic Prescribing Standards - Cooperative Agreements Required Under Section 1860D-(4) (e) of the Social Security Act as Amended by the Medicare Prescription Drug, Improvement, and Modernization Action (MMA) of 2003' available at the following web address: <a href='http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_3882_227312_0_0_18/eRxReport_041607.pdf
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CMS-1385-P-14710-Attach-1.DOC

14710

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

Organization : **Amanda Stulce**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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Thank you for your consideration of this serious matter.
Amanda Stulce

Submitter : CHARLENE S'RENCO **Date: 08/31/2007**

Organization : CHARLENE S'RENCO

Category : Health Care Professional or Association

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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CHARLENE S RENCO

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

Organization : Kerry Guinn

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Kerry Guinn

Submitter : **Dr. Aimee Walsh** **Date: 08/31/2007**

Organization : **University of Alabama at Birmingham**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Aimee Walsh, M.D.

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

Organization : **Jason Stulce**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Jason Stulce

14717

Consumer-Purchaser
DISCLOSURE
PROJECT Improving Health Care Quality through Public Reporting of Performance

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., NW
Washington, DC 20201

File Code: CMS-1385-P (Proposed Revisions to Payment Policies Under the Physician Fee Schedule)

RE: TRHCA—SECTION 101(b): PQRI

Dear Mr. Kuhn:

The 30 undersigned organizations representing consumer, labor, and purchaser interests believe strongly that the system of payment for services provided or controlled by physicians, for both Medicare and commercial payers, is in need of a major overhaul. Physicians are central to the delivery of health care and many seek to provide the best care possible. Unfortunately, rather than promoting better quality, coordination, greater efficiency and more effective delivery of care, most payments reward quantity, errors, rework and unnecessary care. Medicare can, and should, lead the way in reforming these dysfunctional payment policies.

Overall, we believe that the path that you are proceeding down under the Physician Quality Reporting Initiative (PQRI) must be one part of wide-ranging efforts to reform how providers are paid and held accountable. The PQRI program is a step in the right direction to aligning payment with performance, and in particular we support the following elements:

- We agree that the intention should be to use measures that have been endorsed by the National Quality Forum. At the same time, we are deeply concerned that there remain few measures that can be easily collected and that would provide physicians with a clear picture of their practice. Because of this, we support – as an interim process – allowing for the use of AQA approved measures in circumstances where no NQF-endorsed measures exist.

- We agree with and affirm the CMS interpretation that endorsing organizations are not limited to considering measures submitted by physician specialty organizations. While some specialty societies have risen to the challenge of developing robust measures – in too many cases the measures developed are weak and do not provide consumers,

C/O National Partnership for Women & Families
1875 Connecticut Avenue, NW Suite 650
Washington, DC 20009

purchasers or physicians themselves with anything close to a fair picture of performance. Additionally, it can be argued that single physician specialty submissions may result in confusion and redundancy since it is not uncommon for multiple specialties to provide the same procedures or care.

- We support CMS' having participation in the STS registry meet the incentive requirements – but believe that, as with all PQRI measures, the results be made public.

- We agree that CMS should explore additional data submission methods, including the submission of data from EHRs and the generation of performance results from administrative data that requires no submission or additional coding beyond the normal claims submission done by physicians.

While we agree with some core components of the program, we view it as an initial step and significantly more needs to be done to meet the goal of aligning payment with performance. What follows are suggestions we urge you to consider to improve the PQRI program:

The Federal Government must support the development and endorsement of a robust set of physician (and other provider) performance measures. There needs to be a greater focus on measures that assess high levels of performance rather than adherence to minimum standards of competence. Additionally, measures need to address all of the IOM's six aims (safe, timely, effective, efficient, equitable, patient-centered), and in particular there is a need for physician-specific measures on patient-centeredness (including family-centered care), equity/disparities, and episodes of care based quality and efficiency. While we affirm the use of both structural and process measures, there is currently too much reliance on process measures that have not been directly linked to outcomes. Outcome measures are desperately needed and we are concerned that over-reliance on process measures that are not linked to outcomes and reflect only minimum standards of competence will "clog" the system and divert from resources that should be allocated to measures that are far more meaningful to consumers and purchasers.

Additionally, measures should be prioritized for development and/or use that do not require additional coding and that can be generated from existing administrative data (including claims and Medicare Part D/pharmacy data). We must move forward with the administrative data now so that we can meet the needs of employees, patients, and other consumers who need information to make informed decisions. With administrative data (that does not rely on voluntary coding), Medicare can evaluate the performance of each health care provider that bills Medicare, using nationally-endorsed, scientifically-valid, risk-adjusted, and regularly-updated measures. We also must continue to proactively pursue the submission of data via other electronic means, including electronic health records.

<u>Recommended Actions</u>

- HHS or CMS should provide substantial and ongoing funding to support development of consumer-relevant measures that fill existing gaps (especially episode based quality and efficiency, patient-centered/continuum of care, and equity). Developing measures is a public good that requires significant financing from the public sector. Because of the lack of well-specified and endorsed measures that meet consumers' and purchasers' needs, the federal government should specifically support the rapid development of measures that are:
  - Reasonably scientifically acceptable. Consumers and purchasers want measures to be scientifically sound and evidence-based, but do not want the pursuit of perfection to delay the availability of good and useful information.

  - Feasible to implement. Rapid reporting necessitates measures are constructed and specified so that the data needed are currently available or can be collected with limited reporting burden.
  - Relevant to consumers and purchasers. The needs of consumers and purchasers for important and actionable information must drive the development of measures.
  - Reflect the continuum of care/care coordination from a patient's perspective. Measures should address the extent to which comprehensive, patient-centered care is delivered, often by multiple providers and across multiple settings.
- HHS or CMS should provide core ongoing operating support for the National Quality Forum (NQF) to ensure an ongoing, independent consensus process reviews, endorses, and updates measures to enable the availability of comparative information and the reduction of provider reporting burden.
- CMS should strongly consider and explore use of specialty boards' Maintenance of Certification (MOC) programs as a means to meet PQRI where the underlying clinical and patient experience performance information that will be provided meets or exceeds the requirements as both programs evolve
- CMS should produce reports based on existing administrative data (that does not require voluntary coding) for all physicians that bill Medicare.
- CMS should strengthen the link between the PQRI and Better Quality Information (BQI) for Medicare Beneficiaries by allowing performance measures collected by BQIs that are either parallel or are more robust than those being required under the PQRI to be used for providing credit (e.g., financial reward) consistent with what would have occurred had they submitted their measures through PQRI processes.
- CMS should consider using NCQA's Physician Practice Connections and Back Pain Recognition Programs as measures in 2008, provided they meet other requirements of the PQRI, such as NQF or AQA endorsement.
- CMS should launch (or at least pilot) Clinician/Group CAHPS and make patient experience a core element of any reward system. In California, over 3,000 primary and specialty care physicians are being assessed based on patient-level standardized surveys. Massachusetts has also demonstrated in the commercial and Medicaid populations that it is possible to obtain reliable and valid measures of patient experience on primary care physicians.

CMS should ensure that measures are reported publicly to foster improvement, accountability and consumers' ability to make better informed decisions. The PQRI results must be made public. Medicare should provide the public with the information on the aspects of provider performance described above. Doing so will: 1) allow consumers to make informed decisions about their health care; 2) support insurers and purchasers in making value-based contracting decisions and using differential payments as incentives; and 3) spur providers to increase the pace of their improvement efforts.

Recommended Actions

- CMS should develop and implement a strategy for making public the results of the PQRI reporting data, including all the components of what are considered structural or composite measures.
- CMS should immediately make available physician-identifiable Medicare claims data (fully protecting patient privacy), to allow for better quality and efficiency performance reporting.

CMS should differentially pay providers who deliver higher quality, evidence-based care more efficiently and not just "pay for reporting". Incentives should support the evolution of the health care system into one that delivers appropriate, high-quality, efficient, equitable, and patient-centered care. In addition to moving from pay for reporting to pay for performance, changes need to foster a reimbursement system that:

- Encourages care coordination and supports the integration and delivery of services for those with chronic illnesses, such as a medical home.
- Drives rapid re-engineering of care delivery, such as those that are IT-enabled.
- Reduces health care disparities and encourages the provision of quality care for at-risk populations.
- Supports the inclusion of improving physician performance as a part of the measurement process, such as through medical specialty board's Maintenance of Certification programs, medical home initiatives, and Better Quality Information pilots.

One way that even the current payment reforms could drive toward a health care system that accomplishes the above goals is to have a disproportionate share of incentives made available for care delivery that promotes these goals (rather than having all types of care have the same potential rewards for "better" performance).

We also concur with the Institute of Medicine's (IOM) *Rewarding Provider Performance* report that recommends that incentives should be based on a combination of improvement and meeting performance thresholds. As Medicare moves to institutionalize performance-based payment, it should consider how to use baseline thresholds of performance and the potential of relative comparisons to encourage and foster action by all physicians to make improvements appropriate to their current level of performance. We also support the IOM's recommendation to initially focus on efficiency, effectiveness and patient-centeredness.

Recommended Actions

- Over time, the share of payment tied to performance should be substantial. The overall proportion of CMS payments to physicians that are directly linked to performance should increase.
- CMS should set and revise the appropriate level using the information that continues to develop from its implementation of performance-based payments for eligible professionals, hospitals, demonstration projects, and from private sector efforts.
- We also strongly support performance incentives being budget neutral. Providing additional funding to finance performance incentives is an unrealistic option given the current economic and cost pressures faced by CMS.

CMS should increase the number of measures required for reporting and provide more guidance on how measures are selected. CMS should expand the number of required measures and be more directive in the criteria that providers use for the selection of measures to be reported. Instead of allowing "self-selection of 3 measures", PQRI should include as many measures as possible that can be generated from administrative data without new and additional coding for the eligible provider.

Performance reports should be produced on all physicians for whom this is possible based on existing administrative and pharmacy data (allowing for "opt-out" rather than "opt-in"). If this is not possible nationally, it should be done in those six geographic areas for which Better Quality Information pilots can generate performance measures.

Recommended Actions

- CMS should increase the number of measures required for reporting.
- CMS should develop guidelines for the selection of measures so those that are chosen are most relevant to the provider's population and reflect the most robust measures available, such as requiring a minimum number of outcomes measures.

Thank you for the opportunity to comment on the Physician Quality Reporting Initiative and your leadership in this important area. If you have any questions, please contact either of the Disclosure Project's co-chairs, Peter Lee, CEO of the Pacific Business Group on Health, or Debra Ness, President of the National Partnership for Women & Families.

Sincerely,

AARP
American Hospice Foundation
Business Health Care Group
Center for Medical Consumers
Childbirth Connection
Consumers Union
Dallas-Fort Worth Business Group on Health
Employer Health Care Alliance
Employer Health Care Alliance Cooperative
Employers' Health Coalition
Florida Health Care Coalition
Fond du Lac Businesses on Health
General Electric
General Motors
Health Policy Corporation of Iowa
HR Policy Association
Iowa Health Buyers Alliance
The Leapfrog Group
Midwest Business Group on Health
National Business Coalition on Health
National Family Caregivers Association
National Partnership for Women & Families
National Retail Federation
New Jersey Health Care Quality Initiative
New York Business Group on Health
Labor/Management Health Care Coalition, Upper Midwest
Pacific Business Group on Health
Piedmont Health Coalition, Inc.
St. Louis Area Business Health Coalition
Wisconsin Purchasers for Healthcare Quality

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

Organization : Ms.

Category : Individual

Issue Areas/Comments

Background

Background

August 20, 2007
Office of thc Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dcar Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Mcdicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to providc Mcdicare beneficiaries with access to anesthesia services.
This increase in Mcdicarc payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia serviccs, putting at risk the availability of anesthesia and other healthcare services for Mcdicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstratcd that Medicare Part B reimburses for most services at approximately 80% of privatc market rates, but reimburses for anesthesia services at approximately 40% of privatc markct rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia scrvices which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicarc payment, an average 12-unit anesthesia service in 2008 will bc reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved Amcrica. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthcsia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
_debra jellison, crna_____
Namc & Credential
45260 N littlc pine rd__perham, mn 56573_____
Addrcss

_____
City, Statc ZIP

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

Organization : **Tony Tabor**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Tony Tabor

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

Organization : MICHELE SCHEFFE

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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

Thank you for your consideration of this serious matter.
MICHELE SCHEFFE

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

Organization : Wickens, Herzer, Panza, Cook

Category : Attorney/Law Firm

Issue Areas/Comments

IDTF Issues

IDTF Issues

I am writing this comment as a legal representative of several health care providers who utilize and/or have ownership interests in IDTFs. I object to the restrictions which are being proposed as part of new IDTF performance standard (410.33(g)(15)) which, if enacted, would prohibit IDTFs from continuing to participate in block-leasing of their space and/or equipment.

It has become a common practice throughout the IDTF industry to have block-lease arrangements between healthcare practitioners which also have ownership interests in the IDTF. Provided that these relationships are structured to satisfy the requirements of the in-office ancillary services exception and federal and state anti-kickback laws, they have been widely accepted as being legally permissible.

Continuing to allow IDTFs to enter into these types of block-leasing arrangements will advance a number of important public policies. Most state of the art imaging equipment utilized at IDTFs today are cost prohibitive for smaller or independent facilities to purchase. Allowing block-leasing of the equipment and space at IDTFs allows the IDTF to defray the cost of the equipment amongst the lessees. Thus more readily allowing underserved communities and independent facilities to have access to state of the art equipment, which would otherwise have been economically prohibitive. This in turn increases the overall quality of imaging care which is accessible to individuals in a number of rural and suburban locations. In summary, block-leasing at IDTFs increases the accessibility and quality of medical imaging care afforded to a greater number of individuals in our communities.

Once more the current restrictions imposed by the stark and anti-kickback laws are more than sufficient to curtail any potential abusive schemes. Continuing to mandate that rents be set in advance and be consistent with fair market will provide appropriate checks and balances.

For these reasons I am respectfully objecting to the proposed enactment of the IDTF performance standard which would make any type of block-leasing of space and/or equipment at IDTFs impermissible.

Submitter : **Dr. Ona Kareiva** **Date: 08/31/2007**

Organization : **Tidewater Anesthesiologists Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. Brent Smith **Date:** 08/31/2007

Organization : Champion EMS

Category : Other Health Care Professional

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

see attachment

14724

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Plea.. note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

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

Organization : **Teresa Tabor**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

Rc: CMS-1385-P
Anesthesia Coding (Part of 5-Ycar Review)

Dear Ms. Norwalk:

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

Whcn thc RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician serviccs. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthcsia 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 undcrvaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To cnsurc 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 scrious matter.
Tcresa Tabor

Submitter : Dr. WILLIAM PANZA **Date:** 08/31/2007

Organization : NEW BERN ANESTHESIA ASSOCIATES

Category : Physician

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

William S. Panza, MD
New Bern Anesthesia Associates
2719B Neuse Blvd
New Bern, NC 28562

August 31, 2007

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

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

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am a practicing anesthesiologist in New Bern, NC. 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. Current Medicare underpayment for anesthesia services forces my practice to set a high unit value for commercial insurers in order to offset the losses from inadequate Medicare payment. Though Medicare patients account for 55% of our charges, payment only generates shy of 9% of collections. We are in essence acting like the tax man buy taxing insured patients to subsidize government patients care. Your correcting this situation would allow us to not raise our commercial rates, thus making insurance affordable for others and reducing the roles of the uninsured.

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

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

Thank you for your consideration of this serious matter.

Sincerely,

William S. Panza, MD
Anesthesiologist

Submitter : Dr. John A. Gans **Date:** 08/31/2007

Organization : American Pharmacists Association (APhA)

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14727-Attach-1.PDF

14727

American Pharmacists Association

Improving medication use. Advancing patient care.

APhA

August 30, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8015
Baltimore, MD 21244-8015

RE: Docket No. CMS-1385-P. 42 CFR Parts 423.160. Medicare Program; Proposed Elimination of Exemption for Computer-Generated Facsimiles.

[Submitted electronically to: www.cms.hhs.gov/eRulemaking]

Dear Sir/Madam:

Thank you for the opportunity to comment on the proposed elimination of the exemption for computer-generated facsimiles, published in the *Federal Register* notice on July 12, 2007 (72 FR 38122, Docket No. CMS-1385-P). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 60,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice settings, and the military.

APhA is supportive of CMS' efforts to facilitate e-prescribing and the previous adoption of the NCPDP SCRIPT standards for physicians and suppliers using e-prescribing for Medicare Part D prescriptions. Within the E-Prescribing and the Prescription Drug Program Final Rule published November 7, 2005 (70 FR 6256), CMS appropriately recognized the need to provide an exemption from the NCPDP SCRIPT standard for entities that transmit prescriptions and prescription related information via computer-generated faxes as a way to prevent such prescriptions from being reverted back to paper prescription. However, the proposed entire elimination of this computer-generated fax exemption, as described in the proposed rule, and the January 1, 2009 deadline may be too aggressive and adversely impact the health care system.

In the proposed rule discussion, CMS distinguished two different types of computer-generated faxes: those generated by prescriber's/dispenser's software that has the ability to generate e-prescribing transactions using the NCPDP SCRIPT standard, but the specific software feature has not been activated; and those generated by prescriber's/dispenser's software (such as a word processing program) that do not have e-prescribing capabilities to meet the NCPDP SCRIPT standard and thus generates a paper prescription as a fax printout. APhA recommends that the

1100 15th Street, NW, Suite 400 • Washington, DC 20005-1707 • 202 628 4410 • Fax 202 783 2351
www.aphanet.org • www.pharmacist.com

distinction between these two types of computer-generated faxes remain as the impact of the proposed rule could be dramatically different depending on the systems that prescribers and pharmacies use.

APhA supports the proposal to eliminate the computer-generated fax exemption in circumstances where the software is already in place and simply needs to be activated, or needs a minimal upgrade to meet the NCPDP SCRIPT standard. However, we are concerned with the impact such exemption elimination would have on prescribers and pharmacies whose system capabilities do not meet the NCPDP SCRIPT standard, and recommend that the exemption continue to apply for these prescribers and pharmacies. Rather than eliminating the entire exemption, we recommend that the Agency consider implementing a more gradual, step-wise approach, thus allowing more time for the health care system to implement the technology needed for true e-prescribing.

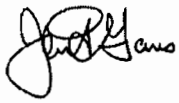
Additionally, APhA recommends that the Agency consider the following:

- Impact on workflow for prescribers and pharmacies who send/process a significant number of faxed prescriptions within their practice settings;
- Exemption of controlled substances per the Drug Enforcement Agency's regulation that does not allow e-prescribing of controlled substances;
- Situations in which faxed prescriptions may be the preferred alternate method for transmitting a prescription electronically, such as computer system and software problems, technology failures, maintenance operations, etc.;
- Potential unintended outcome that may limit adoption of true e-prescribing if computer-generated faxes are not allowed and prescribers revert to paper prescriptions; some entities use computer-generated faxes as an intermediate step towards true e-prescribing;
- Impact on faxed prescribing practices within the long-term care industry;
- Impact on pharmacy practice and prescriber practice in States that include faxed prescriptions within the definition of e-prescribing;
- Impact of the increasing number of systematic errors that are unique to e-prescribing and the resolution of those errors on pharmacists and prescribers workflow and time; gradual implementation will help the industry address systematic error issues to reach the ultimate goal of improved patient safety reducing errors through true e-prescribing;
- Need for two-way electronic communications between prescribers sending and pharmacies receiving e-prescriptions using the NCPDP SCRIPT standard;
- Potential impact on patient choice and access to pharmacies if prescribers are limited to sending e-prescriptions only to pharmacies that are capable of accepting NCPDP SCRIPT messages;
- Investment costs to upgrade prescriber and pharmacy software applications; the January 1, 2009 may be too aggressive;
- Pharmacy e-prescribing transaction costs associated with receiving and sending messages and additional time needed to potentially renegotiate contracts with third-party payers to cover these costs;
- Inability of pharmacies receiving computer-generated faxes to know if the fax was sent from a prescriber that had the ability to send the prescription electronically via NCPDP SCRIPT standard but failed to do so.

In conclusion, APhA recognizes that pharmacy systems and prescribing processes have had substantial growth in electronic information exchange and we supports the Agencies commitment to further advance the exchange of electronic information within the health care system.

Thank you for the opportunity to provide comments on this important issue. We look forward to continuing to work with the Agency. If you have any questions or require any additional information, please contact Marcie Bough, Director of Federal Regulatory Affairs at (202)429-7538 or at MBough@APhAnet.org.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Catherine M. Polley, RPh, Chief Policy Officer, Senior Vice President, Government and Professional Affairs
Marcie A. Bough, PharmD, Director, Federal Regulatory Affairs

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

Organization : South Carolina State University

Category : Other Health Care Professional

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam:
My name is George Harkness. I am Certified Athletic Trainer (ATC) practicing at the collegiate level and have practiced at the clinical level as well. I provide physical medicine and rehabilitation services to elite athletes on a daily basis. I obtained a Masters degree in healthcare administration, and am certified by the National Athletic Trainers Association Board of Certification. I am licensed to provide the above services in the state of South Carolina.

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,
George Harkness, MHA, ATC

Submitter : **Ms. Tracy Baroni Allmon** **Date: 08/31/2007**

Organization : **CVS Caremark**

Category : **Other Health Care Provider**

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

See attached WORD document

CMS-1385-P-14729-Attach-1.DOC

CVS CAREMARK

August 31, 2007

Herb B. Kuhn
Acting Deputy
Centers for Medicaid Medicare Services
Department of Health & Human Services
Attn: CMS-1385-P
PO Box 8018
Baltimore, MD 21244
www.cms.hhs.gov/erulemaking

Re: Comments on "Proposed Elimination of Exemption for Computer-Generated Facsimiles" – CMS-1385-P

Dear Mr. Kuhn:

I am pleased to submit the following comments on behalf of CVS Caremark. CVS Caremark is the No. 1 provider of prescriptions and related healthcare services in the nation. The Company fills or manages more than 1 billion prescriptions annually. Through its unmatched breadth of service offerings, CVS Caremark is transforming the delivery of healthcare services in the U.S. The Company is uniquely positioned to effectively manage costs and improve healthcare outcomes through its 6,200 CVS/pharmacy stores; its pharmacy benefit management, mail order and specialty pharmacy division, Caremark Pharmacy Services; its retail-based health clinic subsidiary, MinuteClinic; and its online pharmacy, CVS.com.

CVS Pharmacy is one of the founders of SureScripts, and, through Caremark, one of the founders of RxHub. CVS Caremark is proud to be the first national chain pharmacy to have all of our retail pharmacies – 6,200 in 44 states and the District of Columbia - e-enabled. CVS Pharmacies fill 17% of prescriptions nationwide, yet 39% of all e-prescriptions filled are filled at a CVS Pharmacy, making us by far the leader in the e-Rx market. As such, we believe it is important not only to increase the number of providers adopting e-prescribing, but also to support and strengthen those providers currently utilizing e-prescribing.

Executive Summary

CVS Caremark supports efforts to increase electronic prescribing, but believes that a more targeted approach that focuses on only those prescribers and pharmacies that have e-prescribing capability will be more effective, and avoid the unintended consequence of driving other prescription transactions back to paper. CVS Caremark has closely reviewed CMS' proposed rule change to eliminate the e-fax exemption and would like to make three observations pertaining to the breadth of the current proposal:

1. CMS' rationale for creating an exemption for e- faxes remains valid for most prescribers and pharmacies, and in most situations.
2. Eliminating the exemption entirely would have a significant negative effect on pharmacies and prescribers, even those capable of using the SCRIPT standard. For example, CVS sends 150,000 refill renewal requests by e-fax per day to prescribers that are not e-enabled. The proposed change would force pharmacies to discontinue these efficient transactions and instead revert to manual faxes or telephone calls, which raise quality and patient service concerns.
3. The information necessary for a specialty pharmacy to process, bill and dispense a prescription for a specialty drug cannot be transmitted via current electronic prescribing standards because there are insufficient "fields" available for the level of back up information that must be transmitted. Thus, e-faxes are a vital component of specialty pharmacy practice.

Based on these observations, CVS Caremark appreciates the opportunity to make the following general recommendations aimed at creating a more targeted approach to removing the e-fax exemption:

1. Eliminate the exemption for only transmissions from prescribers who utilize software that has e-prescribing capability but that has not been activated or upgraded to send true NCPDP SCRIPT standard compliant transactions. This change will drive significant adoption and avoid significant unintended consequences of the proposal, some of which were mentioned above and others that will be discussed in greater detail later.
2. CMS should continue to allow e-faxes from a prescriber or dispenser in all situations where that fax transmission is sent for reasons unrelated to the prescriber's e-prescribing capability. This would include, for example, additional attempts to send refill requests (e.g. due to prescriber non-response), pharmacies that are unable to accept SCRIPT transmissions, emergency situations, or temporary connectivity failures.
3. As it relates to specialty pharmacy operations, we believe that the unique nature of specialty drugs and the necessary prescribing processes related to the complex conditions being treated require that the fax exemption remain in place for prescribers ordering specialty drugs until such time as the SCRIPT standard evolves to better capture the complexities of this area of pharmacy practice.

Specific Comments

I. CMS' Rationale for Creating an Exemption for E- Faxes Remains Valid for Most Prescribers and Pharmacies.

Both Congress in the Medicare Modernization Act (MMA) and CMS have recognized the value of e-prescribing. In adopting foundation e-prescribing standards in November 2005, CMS determined that e-faxes warranted separate consideration from other forms of electronic transmission. Specifically, CMS recognized that unless it created an exemption for e-faxes, those prescribers without the necessary software to do full electronic prescribing would simply revert to faxing paper, losing the other benefits of e-prescribing. CMS stated:

Consequently, requiring these entities to comply with the NCPDP SCRIPT Standard would force the vast majority of them to revert to paper faxes, and, thus, it would impose a significant burden on those entities presently using computer-generated faxing, and would be counterproductive to achieving standardized use of non-fax electronic data interchange for prescribing. Moreover, we believe prescribers using computer fax capabilities will migrate to e-prescribing in time, possibly at the same time as they implement electronic health record systems.[1]

CMS acknowledged that physicians are likely to migrate to full e-prescribing when they implement electronic health record (EHR) systems. However, most physicians have not yet implemented EHR systems, and there is still much work to be done on a national level to encourage and facilitate the development and implementation of EHR systems. In addition, in some cases prescribers are reluctant to adopt e-prescribing until it can be used for all prescriptions, including those for controlled substances. For example, currently the Drug Enforcement Agency prohibits the use of e-prescriptions for controlled substances. In order for e-prescribing to enjoy widespread adoption, it must be easy and universal. Thus, it seems premature for CMS to eliminate the exemption for e-faxes when the reason for the exemption still holds.

CMS has recognized in the proposed rule and in the final e-prescribing regulation that there are two very distinct groups of prescribers using e-faxes. The first group consists of those prescribers whose software can generate SCRIPT transactions, "but the ability is 'turned off' because electronic communication with the pharmacy has not been established," whereas the second group consists of those prescribers using "software (such as a word processing program) that creates and faxes the prescription document, but does not have true e-prescribing capabilities."[2] Regarding this second group, CMS states:

However, the prescriber in the second case is not actually capable of conducting e-prescribing using the [SCRIPT standard]. The prescriber is merely using word processing software and the computer's fax capabilities in lieu of faxing paper.

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[1] 70 Fed. Reg. at 67571.
[2] 70 Fed. Reg. at 67571.

Requiring these prescribers to convert to e-prescribing using the foundation standards would likely result in their simply reverting to faxing paper.

We concur with this conclusion, and believe it would be extremely detrimental to not only these prescribers, but to the dispensers that transact with them, to eliminate the e-fax exemption for their transactions. For the reasons stated by CMS, namely, that these prescribers lack true e-prescribing capability, we have little doubt that most of these prescribers would revert to paper if the e-fax exemption is eliminated. This would impose a significant burden on them and the dispensers with which they interact, restoring the huge inefficiencies and increased administrative costs involved in manual paper faxes, and potentially resurrecting the problems associated with illegible hand-writing, including the constant phone calls from dispensers to prescribers' offices for clarification.

In contrast, for those prescribers who have true e-prescribing capability and simply need to have it activated or upgraded, we believe that the proposed rule will likely move them to simply activate that capability by turning the switch or upgrading their software. As CMS points out, for many of these prescribers, the cost to do so would already be included in their annual maintenance fees paid to their software vendors, or would otherwise be a small cost of doing business. Indeed, for many of these prescribers, they may not even realize that their scripts are being received as e-faxes rather than e-prescriptions.

Recommendation: Eliminate the e-fax exemption for only (i) those prescribers who utilize software that has e-prescribing capability, but that have not activated or upgraded it to send true e-scripts, (ii) in connection with only those transactions sent by such a prescriber where there are otherwise no temporary connectivity issues, *and* (iii) where the receiving pharmacy is able to accept an e-prescription.

II. Eliminating the exemption would negatively impact pharmacies, and thus patient care, even for those pharmacies capable of using the SCRIPT standard.

The current exemption not only permits the prescriber to *send* an e-fax, and pharmacies to *accept* an e-fax, but also allows the dispensing pharmacy to send out refill requests to prescribers by e-fax. This allows the pharmacy to communicate effectively and efficiently with prescribers who have no or limited e-prescribing capabilities. As mentioned in the Executive Summary, CVS Pharmacy retail sites, which are fully e-enabled, send out 150,000 e-fax refill requests *daily.* This is a majority of the refill requests for each store, and the elimination of the e-fax exemption would –perhaps unintentionally – result in thousands of additional phone calls daily from pharmacies to prescribers.

Additionally, an e-fax serves as a critical back-up communication method to electronic prescribing. For example, when the prescriber's e-prescribing software is no longer activated, if the prescriber does not respond to repeated electronic refill requests, or if there are software or connectivity issues at any point in the transaction flow from prescriber to pharmacy, in addition to use in emergency situations.

Even assuming that the elimination of the e-fax exemption prompted more prescribers to fully adopt updated e-prescribing technologies, there is no credible reason to believe that restricting the ability of the prescriber to *receive* a refill request from a pharmacy via e-fax will have any impact on future e-prescribing of that prescriber or any other prescriber. E-fax pharmacy communications with prescribers are vastly more efficient, more reliable, and quicker than their paper fax counterparts or oral communications, and result in patients receiving the medications they need with the minimum disruption and delay, improving patient care and outcomes. Depriving pharmacies of this technology would have a major negative impact on pharmacy operations and communications, not only increasing costs and imposing a huge administrative burden on them, but jeopardizing patient care and degrading pharmacy-prescriber communications.

Recommendation: Recognize and retain the exemption for all pharmacy-initiated transactions, including (i) those sent by pharmacies that do not have e-prescribing capability; (ii) those sent to prescribers that do not have e-prescribing capability; and (iii) those sent for reasons unrelated to e-prescribing capability (e.g. additional attempts to send refill requests, emergency situations or temporary connectivity failures).

III. The information necessary for a specialty pharmacy to safely and accurately process and dispense a prescription cannot be transmitted via current electronic prescribing standards, and thus e-faxes are a vital component of specialty pharmacy practice.

Specialty pharmacies dispense drugs that are typically very high cost and that frequently require special storage and handling (e.g. refrigeration, reconstitution, use of an administration device). These drugs, often biopharmaceuticals, are provided to individuals who have serious chronic illnesses and who often require additional non-specialty drugs and ancillary services in conjunction with administration of the specialty drug. The complexity of these therapies means that when a prescriber writes a prescription for a specialty drug, there is frequently back up documentation required in order for the pharmacy to safely dispense the prescription. This information might include diagnosis codes, lab values, ancillary services needed, patient-specific clinical information, route of administration/type of administrative device, and concurrent diseases and non-specialty medications. This type and amount of information cannot be transmitted using the SCRIPT standard.

As a result, physicians who prescribe specialty therapies as well as pharmacies that dispense specialty therapies have developed systems and workflows that rely on e-faxes, because the prescription as well as the supporting documentation can be sent using this medium. The proposed removal of the fax exemption will restrict these prescribers and pharmacies to manual fax, paper or verbal prescriptions and back up documentation in order to ensure that appropriate documentation is received by the pharmacy at the time the specialty drug prescription is received. As previously mentioned, it is common for non-specialty drugs to be dispensed and administered concurrently with specialty drugs. Eliminating the e-fax exemption could result in a separation of these orders, as the specialty drug portion would now have to be sent via manual fax, paper or verbally, and

the non-specialty drug portion could be sent via e-prescription for e-enabled prescribes and pharmacies. Separation of the specialty drug from the non-specialty drugs will result in uncoordinated and decreased quality of care, and may ultimately result in loss of valuable time from a clinical perspective and a waste of expensive drugs. Alternatively, the entire order would have to revert back to a manual fax, paper or verbal order, eliminating the important clinical benefits of e-prescribing for these sensitive patients.

Recommendation: The e-fax exemption should remain in place for prescribers ordering therapies that require supporting documentation that cannot be accommodated by the SCRIPT standard. This exemption would need to apply to all accompanying prescriptions written for the same patient, not just those prescriptions that require supporting documentation. This is important because the systems and workflows in specialty pharmacies have been designed to accommodate and coordinate drug therapy utilizing e-faxes, and splitting drug orders will result in uncoordinated dispensing and potentially sub-standard care.

In summary, CVS Caremark supports a more targeted approach to the removal of the current e-fax exemption. We believe that retaining the current exemption except in limited cases is the best way to encourage the use of e-prescribing without the unintended negative impact on transmissions outside the scope of CMS' intent. CVS Caremark appreciates this opportunity to comment on this important issue. Please feel free to contact me at (202) 772-3501 if you have questions or concern.

Sincerely,

Russell C. Ring
Sr. Vice President
Government Relations

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

Organization : Vic Grissom

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Vic Grissom

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

Organization : **Buzz Thomas**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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LesV. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Buzz Thomas

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

Organization : **Jayne Grissom**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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Thank you for your consideration of this serious matter.
Jayne Grissom

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

Organization : **Vera Thomas**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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

Rc: CMS-1385-P
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Thank you for your consideration of this serious matter.
Vera Thomas

Submitter : **Miss. Brandilyn Jacob** **Date: 08/31/2007**

Organization : **Miss. Brandilyn Jacob**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-1385-P-14734-Attach-1.RTF

14734

Dear Sir or Madam:

My name is Brandilyn Jacob and I am currently an Athletic Training Student. I will be graduating this spring with a bachelor's degree in Sports Medicine with the intention of taking my NATA Board of Certification test in June. I have worked very hard to get to this point. By the time I graduate I will have put in over 800 hours, on top of my full load of course work, in observation and actual hands- on training. Upon the passing of my certification test, I plan to find a job either working in a high school setting or in a physical therapy clinic.

The reason I am writing this is to express my opinions in regards to Docket ID CMS-1385-P dealing with staffing provisions for rehabilitation in hospitals and other facilities.

As an athletic training student, I have will have spent 4 years and well over $100,000 to earn a degree which has qualified me to provide patients with quality health care. I have received an extensive education, undergone clinical experiences, and upon passing my national certification and state licensure exams, would very much like to be able to find work after all I have put into it. If state laws and national medical organizations deem me qualified to perform physical medical and rehabilitation services, then why would an insurance provider go against those standards?

With the shortage of health care providers in this country, I would think that there would be more concern with finding more medical professionals, rather than further limiting the personnel a patient would be able to seek help from. I would also hope that it would be taken into consideration the number of people who would be out of work, or would have spent so much time and money to prepare for a career only for there to be nowhere to work. As the future of the Athletic Training profession, I must also ask you to consider the fact that there seem to be no clinical or financial justifications behind this proposed change.

In conclusion, I must ask that the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility be withdrawn.

Sincerely,

Brandilyn M. Jacob, ATS

Submitter : Mrs. Sara Whiteside **Date:** 08/31/2007

Organization : Orange County High School, VA

Category : Other Practitioner

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer working at a public high school in rural Orange County, VA. My educational degrees include both a Bachelor and Master of Science in Health Sciences from James Madison University. I hold national certification as an athletic trainer, am CPR and AED certified and am licensed by the Virginia Board of Medicine, Department of Health Professions. Many of my colleagues who work in the high school setting are employed by clinical facilities that would be affected by the proposal discussed in this letter.

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

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

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

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

Sincerely,
Sara L. Whiteside, MS, ATC, VATL

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

Organization : **Becky Campbell**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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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.

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Thank you for your consideration of this serious matter.
Becky Campbell

Submitter : Mr. Jerome Connolly **Date: 08/31/2007**

Organization : Focus on Therapeutic Outcomes, Inc.

Category : Physical Therapist

Issue Areas/Comments

Background

Background

August 31, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
P.O. Box 8018
Baltimore, MD 21244

Re: CMS-1385-P

Dear Mr. Kuhn:

As the leading developer of quality and outcomes measures for outpatient rehabilitation therapy, Focus On Therapeutic Outcomes, Inc., (FOTO) is pleased to provide comments in response to the Notice of Proposed Rulemaking pertaining to the Medicare Physician Fee Schedule (PFS) as published in the Federal Register / Vol. 72, No. 133 / Thursday, July 12, 2007.

For over fifteen years, FOTO has been developing, improving, perfecting and providing valid and reliable methods for the assessment of function in patients receiving outpatient physical and occupational therapy services. Using data gathered from over 1500 clinical practice locations, FOTO has developed a robust database of over 1.9 million episodes of therapy and has advanced user-friendly, economical methods for collecting, analyzing and utilizing functional health measures.

In 2006, FOTO completed a CMS-directed project for the agency that analyzed the feasibility of implementing a pay-for-performance system in reimbursing outpatient rehabilitation therapy. (The full report of this study -- 6/1/06 Pay-for-Performance Grant #18-P-93066/9-01 2 -- is available at: http://www.cms.hhs.gov/TherapyServices/downloads/P4PFinalReport06-01-06.pdf)

These comments are submitted on behalf of FOTO which is based in Knoxville, TN

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Chiropractic Services Demonstration
In the proposed rule, CMS makes note of the 2-year chiropractic services demonstration that ended on March 31, 2007. This demonstration was authorized by section 651 of the MMA to evaluate the feasibility and advisability of covering chiropractic services under Medicare. These services extended beyond the current coverage for manipulation to care for neuromusculoskeletal conditions typical among eligible beneficiaries, and covered diagnostic and other services that a chiropractor was legally authorized to perform by the State or jurisdiction in which the treatment was provided.

FOTO notes that the demonstration was conducted in four sites, (two rural and two urban) and was required to be budget neutral. Thus the Secretary will develop a strategy for recouping funds should the demonstration result in costs higher than those that would occur in the absence of the demonstration.

FOTO would like to remind the agency that there are numerous dimensions to the analysis of effectiveness of any given service or treatment. FOTO acknowledges that the budget neutrality requirement causes the agency to focus considerably on expenditures, but such an approach misses the important dimension of the effect of care on the beneficiary. Combining claims data (such as cost, number of visits, age, comorbidities, etc.) with a measurement of functional status (effectiveness or outcome) would enable a most beneficial and useful examination of the service being demonstrated. Such an analysis has been conducted on outpatient therapy data for CMS, the report of which might be of value here (Hart DL, Connolly JB. Pay-for-Performance for Physical Therapy and Occupational Therapy: Medicare Part B Services. Final Report. Grant #18-P-93066/9-01: Health & Human Services/Centers for Medicare & Medicaid Services; 2006. http://www.cms.hhs.gov/TherapyServices/downloads/P4PFinalReport06-01-06.pdf).

It is presumed that the important construct of measuring functional capability pre- and post-treatment was not included in the chiropractic services demonstration referenced in the proposed rule. This is unfortunate as a tremendous opportunity was lost and therefore, valuable effectiveness data are not available at this time. FOTO recommends that if CMS is to undertake further examination of the effectiveness of any intervention for neuromusculoskeletal conditions that the important

dimcnsion of functional status be incorporated into the demonstration project.

GENERAL

GENERAL

8/31/07 2pm---numerous problems with web site. Repeatedly receiving the following error message:
"Thc wcb sitc you arc acccssing has cxpcricncd an unexpected error.
Plcasc contact thc website administrator.
Thc MIME type of thc uploaded file 'application/octet-stream' was not accepted by the server."

Therapy Standards and Requirements

Therapy Standards and Requirements

However, from our previous CMS funded pay-for-performance study on outpatient therapy (Hart DL, Connolly JB. Pay-for-Performance for Physical Therapy and Occupational Therapy: Medicare Part B Services. Final Report. Grant #18-P-93066/9-01: Health & Human Services/Centers for Medicare & Medicaid Services; 2006. http://www.cms.hhs.gov/TherapyServices/downloads/P4PFinalReport06-01-06.pdf.) data suggest the importance of using two measures to assess under- and over-utilization. The two measures represent a measure of efficiency (i.e., the number of treatment visits) and a measure of effectiveness (i.e., the amount of functional status change).
To assess utilization, one cannot use one measure independently of the other measure for the following reasons:
If a patient receives treatment limited in the number of visits (i.e., low number of visits represents good efficiency), one does not know if the limited visits negatively impacted the patient s possible functional improvement, although payment will be minimized.
If a patient receives treatment with a high number of visits (i.e., high number of visits represents poor efficiency), one does not know if the high number of visits positively impacted the patient s possible functional improvement, although payment was maximized.
On the other hand, if a patients receives treatment that maximized functional status regardless of number of visits (i.e., high gains in functional status represent good effectiveness but might represent maximal payment if number of visits are high), one does not know if the high functional status gains could have been attained using fewer visits, which if they could, would represent more efficient (at lower cost) attainment in functional status. Efficient (i.e., fewest visits possible) treatment that is also effective (i.e., greatest gain in functional status) should be encouraged.
Only with the coincident assessment of effectiveness and efficiency can you identify the maximal amount of gain in functional status at the most reasonable (or minimal) cost.
Under-utilization could be defined and identified as low effectiveness (i.e., poor gains in functional status) with good efficiency (i.e., limited number of treatment visits) given the patient s risk-adjustment factors.
Over-utilization could be defined and identified as poor efficiency (i.e., high number of visits) for the amount of functional status gains expected given the patient s risk-adjustment factors.
Both under- and over-utilization must be assessed using risk-adjusted data to protect patients whose functional status is not expected to change a great deal.

Submitter : **Miss. Jessica Shanks** **Date: 08/31/2007**

Organization : **Forest Park High School**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a certified athletic trainer for Forest Park High School; part of Prince William County Public Schools. Currently I provide coverage for all of the sports at Forest Park. I have been here for the past seven years. After graduating from Frostburg State University, my time was split between River Hill High School and Physiotherapy Associates. The first half of the day was spent in the PT clinic, while the second half was spent at the school. I am all to familiar with both work settings.

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

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

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

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

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

Sincerely,

Jessica Shanks, MS, ATC, VATL

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

Organization : **Grover Campbell**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Grover Campbell

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

Organization : **Ken Thomas**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. 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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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.
Ken Thomas

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

Organization : **Sage Software, Healthcare Division**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14741-Attach-1.DOC

14741

sage software

August 31, 2007

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

Re: PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

This transmits the comments of Sage Software Healthcare, Inc. ("*Sage Health*") on the proposed rule to eliminate the exemption for computer-generated facsimile transmission of prescription and prescription-related information from the standards governing electronic prescribing ("*e-prescribing*") programs for Medicare Part D eligible individuals, File Code CMS-1385-P. Sage Health welcomes the opportunity to participate in the Centers for Medicare & Medicaid Services' ("*CMS*") rule making on this important matter.

Background

Sage Health is the nation's leading provider of integrated practice management and electronic medical records software systems for physician groups. Currently serving more than 185,000 physicians nationally, Sage Health is also one of the nation's leading providers of electronic prescribing ("*e-prescribing*") systems. Today, Sage Health's e-prescribing software is deployed in 46 states and is used to transmit nearly 500,000 electronic prescription transactions each month.

Sage Health's e-prescribing software formats prescription data for electronic transmission according to the NCPDP (National Council for Prescription Drug Programs) SCRIPT Standard. Each SCRIPT-based transaction is transmitted to the pharmacy chosen by the patient via secure EDI (electronic data interchange) networks. When received by the network, the transaction is logged and routed to the pharmacy in one of two formats, based on the destination pharmacy's technological capability

If the prescription is addressed to a pharmacy capable of processing SCRIPT transactions, the network assures that the transaction is formatted in the same version of SCRIPT used by the destination pharmacy, ensures that all legally required data fields are populated and finally, transmits the transaction to that pharmacy's operating system.

If the prescription is addressed to a pharmacy not capable of processing SCRIPT transactions, the network, as above, ensures that all legally required data fields are populated, reformats the prescription content from its original SCRIPT format into a graphical image and then, using facsimile simulation software, sends the prescription in a point-to-point transmission over telephone lines to the destination pharmacy's facsimile machine.

Currently, 68 percent of the prescription transactions transmitted by Sage Health software are delivered via EDI while the remaining 32 percent must be reformatted at network level for delivery to a facsimile machine because the recipient pharmacies are incapable of processing SCRIPT transactions.

CMS should note that practitioners also use Sage Health's e-prescribing software to issue as many prescriptions on paper (500,000 each month) as electronically, in small part because the prescription is for a controlled substance but, in the vast majority of cases, because the patient has requested a paper prescription.

Comments and Concerns

Sage Health commends CMS for proposing an amendment that effectively requires prescribers, dispensers and their trading partners to comply with the SCRIPT Standard for the electronic transmission of prescription and prescription-related information for Part D eligible individuals. Sage Health also supports CMS efforts to encourage state policy makers to adopt conforming regulations so that neither prescribers nor pharmacists will be required to practice pursuant to one set of e-prescribing standards for Part D eligible individuals and another set for the rest of the population. Simply put, the requirements for issuing prescriptions must be consistent for all patients, regardless of payment source.

That being said, Sage Health would respectfully suggest that adoption of the proposed amendment could easily place at risk those prescribers who already use e-prescribing software that generates SCRIPT transactions and impose new costs on software vendors and EDI network operations. While Sage Health is convinced that the proposed amendment is well intentioned, it would submit that unintended consequences are quite possible.

As noted above, Sage Health's e-prescribing software is currently used each month to transmit approximately 500,000 electronic prescription transactions. Each electronic transaction is transmitted from the prescriber's server as a SCRIPT transaction. Given network capabilities and current law, each electronic transaction can be delivered to any pharmacy in the country, regardless of the pharmacy's technological capabilities. Because formatting takes place in the background, neither the prescriber issuing the prescription nor the patient choosing the recipient pharmacy has to be concerned about the format in which the prescription transaction is ultimately delivered. However, if the proposed amendment is adopted, what is now transparent to prescribers and patients will be held hostage by the decisions of independent community pharmacies.

SureScripts reports that 80 percent of independent pharmacies are currently incapable of sending or receiving a SCRIPT transaction. This accounts for more than 19,000 outlets, i.e. more than 31 percent of all U.S. drug stores and 32 percent of Sage Health's current e-prescribing volume. If these pharmacies fail in significant numbers to upgrade their operating systems by the effective date of the proposed amendment, e-prescribers using SCRIPT-compliant software and their trading partners will face at least two new and unwelcome challenges:

- E-prescribing software vendors cannot responsibly rely on CMS to educate prescribers and dispensers about the practical effect of the new regulation. Prior to the effective date of the proposed amendment, vendors will be compelled to alert their e-prescribers that their costs will increase and their workflow disrupted because some prescription that were electronically deliverable under prior law will have to be issued either on paper or orally.

- To make the transition as painless as possible, SCRIPT-compliant e-prescribing software vendors, in cooperation with network operators, will be compelled to re-engineer their programs/operations to generate paper prescriptions automatically whenever the patient has chosen a pharmacy that cannot process a SCRIPT transaction. The last thing for which a vendor or network operator will want to be responsible is the imposition of an unpleasant surprise on a client: e.g., an undeliverable prescription that results in a disgruntled patient (who must wait when previously the prescription would be ready for pick-up) and a pharmacist who must telephone the prescriber to request an oral prescription and defend his or her inability to process a legally uttered prescription.

Recommendations

Under current law, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the promulgation of final e-prescribing standards for Part D eligible individuals not later than April 1, 2008. Such standards are to be mandatory not later than one year after promulgation. Based on CMS' July 12, 2007 *Federal Register* notice, the effective date of the proposed amendment to eliminate the exemption for computer-generated facsimile transmissions is one year after the effective date for the 2008 rule making or, April 1, 2010.

Sage Health is of the belief, based on its understanding of CMS' July 12, 2007 *Federal Register* notice, that the vast majority of prescribers and dispensers, compelled by market forces and the regulatory environment, should be capable of generating and processing the SCRIPT transactions set for at 42 C.F.R. § 423.160(b)(1)(i) through (xii) by the effective date of the proposed amendment. Nonetheless, Sage Health remains concerned that independent pharmacies who fail to upgrade their systems will force Sage Health's e-prescribing clients to issue a larger volume of paper and oral prescriptions.

To ensure that the transition to system-wide, EDI-compliant transactions is as seamless as possible, Sage Health urges CMS to undertake an aggressive education campaign in association with the National Association of Boards of Pharmacy and National Community Pharmacists Association to educate both state Boards of Pharmacy and independent community pharmacies of the advantages, professionally and economically, of adopting operating systems/interfaces that enable conformance to the SCRIPT standard. Publishing "encouragement" of the same goals in the *Federal Register* does not constitute an effective strategy.

Should CMS have any questions or desire further clarification about the matters set forth above, please do not hesitate to call me.

Very truly yours,

Michael Burger

Michael Burger, Director
Clinical Product Management

Submitter : **Dr. Raymond Foxworth** **Date: 08/31/2007**

Organization : **Foxworth Chiropractic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1385-P-14742-Attach-1.DOC

14742

DR. R. A. FOXWORTH

PRACTICE OF CHIROPRACTIC

August 28, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: CMS-1385-P "TECHNICAL CORRECTIONS"

To Whom It May Concern:

I am writing concerning the proposed repeal of reimbursement for radiographs for Medicare patients taken by a radiologist or ordered by non-treating physicians when subsequently used by a doctor of chiropractic. I have been in practice long enough to recall when the Centers for Medicare Services required doctors of chiropractic to obtain x-rays to document the existence of a subluxation prior to initiating treatment. It is ironic at this point in time that CMS is considering repealing reimbursement of the x-rays only because they may be used by a doctor of chiropractic, regardless of whether the films are medically necessary. This sends the message that medical necessity is irrelevant but it is relevant if they are to be utilized by a doctor of chiropractic to determine if treatment is indicated or contraindicated. Many of the very conditions that CMS states are contraindications to manipulative therapy can only be diagnosed by radiographs or other advanced imaging. I would challenge CMS to identify any other group of patients that are targeted and discriminated against by CMS's policies based on the type of provider that they choose.

This issue is even more concerning to me as a practitioner who practices in a multi-disciplinary setting. While my clinic is not directly affiliated with any other practitioners, I routinely work with neurosurgeons, physical medicine & rehab specialists, family practitioners, orthopedics, and a number of other professionals in the co-management of our patients. I also happen to have referral privileges to our local hospital and I am on staff at the G. V. Sonny Montgomery VA Medical Center in Jackson. I work daily with medical staff and have imaging ordered by any number of providers who are considering referring their patients for chiropractic services. I do not understand the rationale behind limiting reimbursement for films I may ultimately use because of who might have ordered them.

1 Layfair Drive, Suite 210
Flowood, MS 39232
Phone: 601-932-9201 Fax: 601-932-4962

I would think in the year 2007 that there would be an interest in making sure that there is continuity of care among professionals and that it would be the desire of CMS to see costs controlled by having not one, but two providers agree that the films are medically necessary. I would also think that for patients typically on a fixed income, that it would not be in their best interest to have to pay out of pocket for x-rays, simply because they choose to see a doctor of chiropractic and may have had films ordered by another physician.

There is also an even more important reason to encourage collaboration. I recently evaluated a Medicare beneficiary and determined she had sacroiliac pain. She had this problem for over 10 years and had spent literally thousands of dollars trying to find relief. There is no telling how much was spent by Medicare on behalf of this lady. I did have her return to her medical doctor who had been managing this problem for a number of years to have her imaging performed. Unfortunately, a tumor was found on her films and she required medical attention for this problem. She was ultimately cleared by her physician and returned to the clinic for treatment. She initiated treatment and in a few weeks was experiencing relief she had not found for over 10 years. She continued to improve to the point she was practically pain free and was released from our care to an as needed basis. She will be happy to tell this story herself if requested. This is just one example of the importance of not placing barriers to co-management of patients. It ultimately benefits the patient and the Medicare system.

We are opposing this based on the grounds that it is clearly not in the best interest of our patients. We have no financial interests since Medicare does not presently reimburse us for imaging. I respectfully encourage you to reconsider this proposal. This policy only creates more cost if films are denied by CMS and the patient has to pay for what would otherwise be considered a medically necessary service if ordered by the "right doctor".

Sincerely,

Ray Foxworth, D.C.

1 Layfair Drive, Suite 210
Flowood, MS 39232
Phone: 601-932-9201 Fax: 601-932-4962

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

Organization : **Paul Crow**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Paul Crow

Submitter : Dr. Andrew Kirsteins **Date:** 08/31/2007

Organization : Moses Cone Health System

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14744-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,

Andrew E. Kirsteins MD
510 N. Elam , Suite 302
Greensboro, NC 27403

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

Organization : **Joe Tippins**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has rccognized 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 undcrvaluation of ancsthesia scrvices. 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 immcdiately implementing thc anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Joc Tippins

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

Organization : American College of Radiation Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachmcnt

CMS-1385-P-14746-Attach-1.PDF

14746

American College of Radiation Oncology
5272 River Road • Suite 630 • Bethesda, MD 20816
(301) 718-6515 • FAX (301) 656-0989 • EMAIL acro@paimgmt.com

August 31, 2007

Mr. Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Room 455-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington D.C. 20201

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

Dear Mr. Kuhn:

The American College of Radiation Oncology ("ACRO") is pleased to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule (CMS-1385-P).[1] With a current membership of approximately 1000, ACRO is a dedicated organization that represents radiation oncologists in the socioeconomic and political arenas. ACRO's mission is to promote the education and science of radiation oncology, to improve oncologic service to patients, to study the socioeconomic aspects of the practice of radiation oncology, and to encourage education in radiation oncology.

ACRO would like to extend its appreciation for the opportunity to comment on the proposed regulations. This letter will comment on the following sections:

- Sustainable Growth Factor, Budget Neutrality and Work RVUs & Resulting Cuts in Reimbursement
- Malpractice RVU Assignment Methodology
- Imaging Provisions in the Deficit Reduction Act
- Equipment Usage Percentage & Equipment Interest Rate
- Independent Diagnostic Treatment Facility Issues
- Physician Self-referral Provisions
- PQRI: Timetable & Commentary on Specific Measures

[1] Proposed Rule: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule (CMS-1385-P). *Federal Register*, Volume 72, No. 133, July 12, 2007, p. 38121.

A. **IMPACT: Sustainable Growth Factor, Budget Neutrality and Work RVUs & Resulting Cuts in Reimbursement**

The sustainable growth calculation (SGR) methodology continues to be a flawed system for compensating physicians. In order to preserve beneficiary access to care, physicians must receive annual updates that reflect practice expense increases. Inflation affects us each year as we must pay more for office space rent, professional liability insurance and staff salaries. Managed Medicare plans often require preauthorizations that were not previously required for Medicare patients; adding an additional staffing burden that physicians have incurred over the last few years. ACRO continues to support alternative solutions to the budget neutrality provisions. Medicare must develop a system that fairly compensates physicians and accounts for the actual cost of caring for our patients. **ACRO believes that the SGR should be repealed and replaced with an updated system that reflects increases in costs.**

For 2007, both the Relative Value Update Committee (RUC) and CMS have found compelling evidence to increase many evaluation and management (E & M) codes. Further increases are proposed for 2008 on additional evaluation and management codes. ACRO recognizes the need to fairly value all codes. However, we continue to be concerned that the appropriate changes to selected E & M codes trigger the need to implement an additional budget neutrality provision – in 2008, there will be a further decrease to all work RVUs.

While applying the reduction across all work RVUs maintains the relative relationship between codes, it undermines the provision of fair compensation for services. Furthermore, the now almost 12% reduction to all work RVUs disproportionately disadvantages those physicians that practice in a facility setting, where most income is derived from the work component of compensation. ACRO is concerned that this solution (triggered by the budget neutrality provision) penalizes many physicians instead of otherwise correcting undervalued codes. ACRO would support a more appropriate action to provide CMS with adequate funding for correct valuation of codes without reducing valid and necessary compensation for other codes.

B. **MALPRACTICE: Malpractice RVU Assignment Methodology**

CMS has expressed a willingness to examine the issues that arise when the technical component (TC) malpractice RVU assignment is greater than the professional component (PC) malpractice RVU. The proposed rule requests input on possible actions that can be taken when this situation occurs. ACRO would consider supporting a recommendation to make the TC and PC RVUs equivalent where the PC RVU is less than the TC RVU. This would appropriately compensate for the professional liability insurance that is required. **ACRO opposes any policy that would make the TC malpractice value zero, since there are clearly identifiable malpractice expenditures associated with allied health professionals working in radiation oncology.** Specifically, medical physicists carry liability insurance and are included in the TC RVU valuation. ACRO is willing to evaluate other proposed methodologies that address the current inequities and methodological problems.

C. **Imaging Provisions in the Deficit Reduction Act**

ACRO continues to oppose provisions of the Deficit Reduction Act (DRA) as it is broadly interpreted to include critical components of radiation therapy – the process by which clinicians assure that radiation delivery is targeted to the tumor specifically. The discipline of radiation oncology provides several DRA-subject services only when radiation therapy is delivered and believes that such services should not be considered comparable to traditional diagnostic imaging services. For example, CPT code 76873 - prostate volume ultrasound for brachytherapy planning is only used when planning the treatment for radioactive seed implantation. It is not a diagnostic imaging code, but rather a critical component of cancer treatment. **ACRO continues to object to the broad interpretation of the Deficit Reduction Act as it now includes visualization techniques that are critical components of treatment delivery, not diagnosis.**

As DRA issues are addressed, CMS should reiterate how it intends to handle DRA listed codes when there is now no hospital outpatient payment to be compared against. ACRO understands that, absent any established hospital outpatient payment for a specific code, the comparison of technical component reimbursement with the hospital outpatient reimbursement will not be performed.

D. **RESOURCE-BASED PE RVUS: Equipment Usage Percentage & Equipment Interest Rate**

CMS has postponed the development of equipment use rates at this time, citing the need for additional empirical evidence before proceeding. ACRO appreciates the challenges faced by CMS in developing mutually exclusive categories in order to establish category specific equipment use rates. We support the use of a sound methodology in developing specific equipment use rates. ACRO encourages the consideration of methodologies that would capture differences in patient access based on whether the community served in rural, suburban or urban. Specifically, radiation oncology treatment delivery requires that patients receive care five days a week for many weeks. The treatment itself can be debilitating and excessive drive times should be avoided. ACRO believes that ready patient access, without major inconvenience, is critical to maintaining patient compliance with this life saving treatment. Cancer patients should not be forced to drive an inordinate distance in order for access to appropriate radiation therapy.

Furthermore, radiation therapy differs significantly from diagnostic imaging in the need for ongoing, continuous care. It may be acceptable to Medicare that a one time, diagnostic test requires considerable patient travel. However, ACRO believes that considerable travel for ongoing daily treatment should be avoided, not only due to patient access but quality care and cost efficiency. A patient that does not complete his or her treatment regime due to burdensome travel requirements will likely increase Medicare expenditures and lower quality of care. CMS should consider developing equipment use rates that vary with population density to be sure that all Medicare patients have reasonable access to equipment. **Until such time, ACRO agrees that no action should be taken to change the equipment utilization percentage until data is collected and the full impact is evaluated.**

ACRO also supports the continued use of eleven percent as an appropriate equipment interest rate.

E. RESOURCE-BASED PE RVUS: Continued Decline in CPT 77366

The "bottom up" practice expense methodology is currently in its second year of implementation. The CPT code 77336 continues to decline dramatically. ACRO is concerned that this decline could be a result of incorrect practice expense inputs for this continuing medical physics consult code. As the complexity of radiation therapy has grown over the last five years, the work effort of the medical physicist has also increased. **ACRO encourages CMS to review the practice expense inputs for this code to ensure that adequate reimbursement is established.**

F. IDTF ISSUES

CMS has expanded the independent diagnostic testing facilities performance standards. **The additional IDTF standards support the provision of good patient care and are supported by ACRO.**

G. PHYSICIAN SELF-REFERRAL PROVISIONS:

ACRO shares CMS' concerns that the breadth of the Stark Law "in-office ancillary services exception" ("IOAE") has permitted the exception to be used in a manner that extends well beyond Congress' original intent, and that it has led to abuse. We appreciate the opportunity to echo those concerns as CMS considers possible modifications to the IOAE designed to prevent abuse and restore application of the IOAE to the proper circumstances intended by Congress.

CMS has noted in particular that "services furnished today purportedly under the in-office ancillary services exception are often not as closely connected to the physician practice" as was contemplated originally by Congress in enacting the IOAE.[2] According to CMS, for example, Stark Law designated health services ("DHS") may be provided by staff that have virtually no relationship to the group practice, particularly when such services are furnished in a "centralized building" remote from the group practice location, but potentially even when provided in the same building. CMS also notes the proliferation of "turn-key" arrangements marketed to "nonspecialist" physicians under which such physicians purchase specialized equipment and acquire the right to bill for the lucrative technical component simply by hiring a specialist as an independent contractor to provide the professional service. ACRO shares CMS' concern that such arrangements extend beyond the original purpose of the IOAE and instead "appear to be nothing more than enterprises established for the self-referral of DHS."

As noted in the August 20, 2007 comment letter submitted to CMS by the American Society for Therapeutic Radiology and Oncology, Inc. ("ASTRO"), a particularly egregious form of IOAE abuse has emerged in the form of for-profit companies that market turn-key Intensity Modulated Radiation Therapy ("IMRT") operations to urologists. These arrangements typically involve the following features:

- A for-profit company will target the premier urology group in a community and offer to provide a "turnkey radiation oncology service" offering only IMRT services for prostate cancer patients. While a typical comprehensive radiation treatment center may offer its prostate patients a full range of radiation therapy treatment options, including low and high dose brachytherapy or seed implantation, radionuclide therapy, and stereotactic radiosurgery, this turn-key model results in the urologist offering only IMRT for his or her patients.

[2] 72 Fed. Reg. at 38181.

- The for-profit "pitch" will emphasize the increase in revenues the urology group will attain by capturing these referrals within the group's business structure. The pitch may also include an opportunity for the physicians to joint venture in an equipment leasing company which will lease the IMRT equipment "to" the group.

- The company will "recruit" a radiation oncologist – usually from an existing radiation oncology center – to provide the radiation therapy services for the urology group. Radiation oncologists from local/regional facilities in danger of volume reductions secondary to the new site development may be coerced into employment arrangements that would otherwise not have been considered.

- The radiation therapy services typically will be set up in a "centralized building" location remote from the urology practice. The radiation oncologist and his/her technical staff will function separate and apart from the group on a day-to-day basis with little or no integration of the physicians, staff, or services.

- The urology group benefits from the revenue flowing from its referrals. The for-profit company may share in those revenues directly and/or through its share of equipment leasing fees, as well as through a management fee.

As noted by ASTRO, such arrangements can lead to over-utilization, higher costs, reduced patient choice, and the potential for lower quality care. There is anecdotal evidence to suggest that mega-urology groups are being formed for the express purpose of aggregating sufficient IMRT referral volume to justify the acquisition of IMRT equipment.

While these concerns already appear well-placed and warrant prompt corrective action, ACRO understands that CMS does not yet propose specific changes to the IOAE. Instead, CMS has asked for input on, among other things, whether certain DHS should qualify for coverage under the IOAE, and whether certain non-specialists should be able to use the exception to refer patients for specialized services provided by specialists and involving the use of equipment owned by the non-specialists, or whether other reforms may be in order. As providers of the specialized service of radiation oncology, ACRO's members are pleased to respond to these inquiries.

ACRO supports CMS' consideration of rule amendments designed to curb abuses of the IOAE that extend beyond its intended purpose and scope. ACRO looks forward to working closely with CMS to develop targeted reforms that eliminate abusive arrangements like that described in this letter without creating unintended consequences that may adversely affect legitimate and beneficial arrangements. **In particular, ACRO believes it is important to address the identified abuses in a manner that preserves the following salutary arrangements (potentially among others):**

- **The ability of radiation oncologists to furnish radiation therapy services to patients who "self-refer" to radiation oncologists;[3].**

[3] CMS previously has recognized that patients from time to time will "refer" themselves to radiation oncologists. To the extent radiation oncologists are unable to take advantage of the "consultation" exception to the Stark Law definition of "referral," they need to rely on the IOAE in order to furnish radiation therapy services to such self-referred patients. See 69 Fed. Reg. 16054, 16066 (March 26, 2004).

- **The ability of medical and radiation oncologists to refer to each other as is medically appropriate within a bona fide group practice offering comprehensive oncology services in an integrated oncology care setting.**

Again, ACRO appreciates the opportunity to comment on the current state of the Stark Law IOAE and to participate in the development of appropriate and targeted IOAE modifications that will eliminate abuses while preserving legitimate IOAE protections.

H. PQRI: Timetable

ACRO has been an active member of the Oncology Work Group. This Group has developed proposed measures through the open, consensus driven, AMA Consortium process. The proposed measures are in the public comment period today and can be viewed at: http://www.ama-ssn.org/ama/noindex/ category/4397.html. ACRO believes that the Oncology Workgroup indicators currently being finalized contain improved measures applicable to radiation oncology and other oncology care practices. ACRO believes that the establishment of these indicators is important to the further support of quality oncology care. ACRO is concerned that the deadlines established in the proposed rule allow little leeway for indicators currently under development. **ACRO strongly supports a dynamic review process that allows measures currently in the public comment period to be adopted for 2008.**

ACRO urges the Administration to access the $1.35 billion Physician Assistance and Quality Initiative Fund to help offset the negative 2008 payment update. Financing for quality reporting should come from a distinct, separate financing mechanism that is outside of the budget neutrality provision and focused solely on the improvement of health care quality.

I. PQRI: Commentary on Specific Measures

ACRO supports modifications should CMS wish to continue using the existing indicator 74 – Radiation Therapy Recommended for Invasive Breast Cancer Patients Who Have Undergone Breast Conserving Surgery. We have sent a separate letter to the AMA Consortium outlining these same concerns. At this time, ACRO wishes to take this opportunity to share its observations with CMS regarding the existing indicator 74. The current definition of CPT codes requires that the breast cancer patient be seen by the radiation oncologist as a consult – a referral from one physician to another. ACRO supports expanding the CPT code definition to include those patients that self-refer to a radiation oncologist. As CMS is aware, oncology patients are increasingly active participants in their own medical decision-making and care. This self-advocacy often leads to patients seeking additional input from physicians, outside of the physician immediately managing the clinical care especially in circumstances where a variety of treatment choices exist and patients seek opinions (and management) from a variety of specialists. ACRO supports patient self-advocacy and encourages patients to seek appropriate care and second opinions where needed. Physicians providing this care should be able to participate in the PQRI program as well. Therefore, **both physician directed consultations and patient sought "consultations" should be included in the PQRI data capture.**

ACRO recommends a second change to indicator 74 – Radiation Therapy Recommended for Invasive Breast Cancer Patients Who Have Undergone Breast Conserving Surgery. Currently, many patients are receiving their radiation oncologist consultation **in advance** of undergoing breast surgery (other than core or fine needle aspiration biopsy for the establishment of a diagnosis). This allows the patients to make a more educated decision not only about the surgical options but also about the follow up care offered post surgery. As indicator 74 is currently configured, those patients seeing a radiation oncologist in advance of definitive breast surgery fall

in the generic category of G8378 – Clinician documented that the patient was not an eligible candidate for radiation therapy measure. **ACRO encourages the development of a fourth G code to be used when radiation therapy is recommended in advance of definitive surgery.** This change would better reflect the advanced clinical care being provided across the country.

Conclusion

ACRO's comments on the Physician Fee Schedule regulations seek to ensure ongoing access to radiation oncology services. Maintaining patient access is crucial since our patients often require services five days a week for many weeks of life saving therapy. Patient accessibility and continuity are key components of service quality. ACRO appreciates the opportunity to comment on the regulations. We hope that our comments highlight our sincere interest in making radiation oncology services cost effective, properly reimbursed and readily accessible to cancer patients. We look forward to meeting with CMS in the near future.

Sincerely,

Louis Munoz M.D./AW

Louis Munoz, M.D., FACRO
President
American College of Radiation Oncology
5272 River Road
Suite 630
Bethesda, Maryland 20816

Sincerely,

Paul E Wallner, DO

Paul Wallner, D.O., FAOCR
Chair, Socioeconomics Committee
American College of Radiation Oncology
5272 River Road
Suite 630
Bethesda, Maryland 20816

cc: Rick Ensor, Centers for Medicare and Medicaid Services
Edith Hambrick, M.D., Centers for Medicare and Medicaid Services
Ken Marsalek, Centers for Medicare and Medicaid Services
Pam Ohrin, Centers for Medicare and Medicaid Services
Liz Richter, Centers for Medicare and Medicaid Services
Ken Simon, M.D., Centers for Medicare and Medicaid Services
Pam West, Centers for Medicare and Medicaid Services

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

Organization : Dr.

Category : Physician

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

I HAVE TRIED TO ATTACHE THIS LETTER SEVERAL TIMES BUT YOUR SITE WILL NOT ACCEPT IT, BUT I SUPPORT THE INCREASE IN THE ANESTHESIA CONVERSION FACTOR.

CMS-1385-P-14747-Attach-1.DOC

CMS-1385-P-14747-Attach-2.DOC

CMS-1385-P-14747-Attach-3.DOC

1747

William S. Panza, MD
New Bern Anesthesia Associates
2719B Neuse Blvd
New Bern, NC 28562

August 31, 2007

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

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

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am a practicing anesthesiologist in New Bern, NC. 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. Current Medicare underpayment for anesthesia services forces my practice to set a high unit value for commercial insurers in order to offset the losses from inadequate Medicare payment. Though Medicare patients account for 55% of our charges, payment only generates shy of 9% of collections. We are in essence acting like the tax man buy taxing insured patients to subsidize government patients' care. Your correcting this situation would allow us to not raise our commercial rates, thus making insurance affordable for others and reducing the roles of the uninsured.

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

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

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

Thank you for your consideration of this serious matter.

Sincerely,

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Sincerely,

William S. Panza, MD
Anesthesiologist

Submitter : P.J. Crow **Date:** 08/31/2007

Organization : P.J. Crow

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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P.J. Crow

Submitter : Dr. Richard Zaruba, PT, DPT, PhD **Date:** 08/31/2007

Organization : Dr. Richard Zaruba, PT, DPT, PhD

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

The loophole in the Stark Act allowing physicians to provide rehabilitation services in their office as an ancillary service is absurd. It promotes the use of unneeded therapy services by referral for profit. Evaluations and studies within your own organization has shown that this to be a constant problem. Physicians are responsible for coordinating rehabilitation services when needed. They should not provide these services as a means of increasing profit it only leads to improper use and abuse of these services.

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

Organization : Norva Tippins

Category : Individual

Issue Areas/Comments

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

Organization : **Jon Cunningham**

Category : **Individual**

Issue Areas/Comments

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

Organization : **Sheila Turner**

Category : **Individual**

Issue Areas/Comments

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

Thank you for your consideration of this serious matter.
Sheila Turner

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

Organization : **Oklahoma Christian University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam:

I have been a certified athletic trainer for 18 years. Currently, I work at Oklahoma Chrisitian University where I prevent, evaluate treat and rehabilitate athletic related injuries as well as provide immediate care to my 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 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 know 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,

Sydney G Ringer, MS, LAT, ATC

CMS-1385-P-14753-Attach-1.DOC

14753

Dear Sir or Madam:

I have been a certified athletic trainer for eighteen years. Currently, I work at Oklahoma Christian University where I prevent, evaluate, treat and rehabilitate athletic related injuries as well as provide immediate care to the athletes.

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

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

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Sincerely,

Sydney G. Ringer, MS, LAT, ATC

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

Organization : **Brenda Cunningham**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Brenda Cunningham

Submitter : Dr. Ona Kareiva **Date:** 08/31/2007

Organization : Tidewater Anesthesiology Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14755-Attach-1.DOC

14755

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

Re: CMS-1385-P
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Dr. john stratton** **Date: 08/31/2007**

Organization : **traverse anesthesia**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Sincerely,
John Stratton

Submitter : **Dr. Patrick Duey** **Date: 08/31/2007**

Organization : **Dr. Patrick Duey**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

Sincerely,

Patrick Duey, M.D.
Billings, Montana

Submitter : Mr. Edward Aube **Date:** 08/31/2007

Organization : Mr. Edward Aube

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

See attachcment

CMS-1385-P-14760-Attach-1.DOC

14760

August 31, 2007

Mr. Kerry N. Weems
Adminstrot-Designate
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention CMS 1385-P
PO Box 8018
Baltimore MD 21244-8018

Re: Physcian Self Referral Issues

Dear Mr. Weems,

As a physical therapist who has been practicing for 22 years, I feel the need to write to you regarding the July 12 prposed physician fee schedule rules surrounding the physician self-referral and the "in office ancillary services" exception.

I am writing to encourage CMS to REMOVE PHYSICIAL THERAPY FROM THE "IN-OFICE ANCILLARY SERVICES" EXCEPTION TO THE FEDERAL PHYSCIAN SELF REFERRAL LAWS.

As a physical therapist I have encountered many patients who have been done a disservice by this exception.

Several patients who had been satisfied with service they had received from our practice in the past were told by their physician to come to therapy in the physician's office so he could, "keep a close eye on them", when the physician was not present, and travel to the physician's office was inconvenient for the patient.

Other patients state they feel compelled to attend therapy in the physician's office for fear of upsetting their physician.

From a therapist's perspective I see the provision of therapy in the physician's office as a lost opportunity for a free second opinion. As a therapist working independently of a physician I am more likely than an employee of the physician to take a closer look at a patient's condition and possibly come up with an alternate, more appropriate interpretation of a patient's condition. This second look benefits both the patient and CMS by getting a more complete look at a patient's problem, and possibly saving resources in the future.

As a independent physical therapy practice owner, our practice depends on providing quality therapy to survive. As they should, physicians look to quality providers to whom to refer their patients. However, with in office physical therapy excepted from the self-referral laws, physicians' incentive to find quality physical therapy services is lost.

As taxpayer, I see the exception to the self-referral laws a waste of my tax dollars. The study performed by the inspector general showed that physical therapy utilization is significantly greater when provided in a physician office, versus a private clinic. Also, utilization rates varied widely amongst physicians, often in irrational patterns that call to question the appropriateness of the services.

Now is the time for CMS to put patients' health and tax payer dollars first. By saving money on providing services, and providing more appropriate services, our citizens and our budget will remain healthier.

Thank you for you consideration of this matter.

Sincerely,

Edward Aubé, PT, OCS
Broadview Heights, OH 44147

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

Organization : **meritcare**

Category : **Other Practitioner**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
_Adrianne Flom, CRNA_____
Name & Credential
_3234 46th Ave S_____
Address
_Fargo, ND 58104_____
City, State ZIP

Submitter : Mr. Walter Moore **Date:** 08/31/2007

Organization : Genentech

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached

14762

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : Dr. Vijay Singh **Date:** 08/31/2007

Organization : Pain Diagnostics Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14763-Attach-1.DOC

14763

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 (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 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,

Vijay Singh, MD
1601 Roosevelt Road
Niagara, WI 54151

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

Organization : **Luke Cunningham**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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

Thank you for your consideration of this serious matter.
Luke Cunningham

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

Organization : Sarah Underwood

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LcsV. 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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Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Sarah Underwood

Submitter : **Mr. roland kleeman** **Date: 08/31/2007**

Organization : **Elkhorn Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am opposed to the designation of rehabilitation services with physician ownership.

Submitter : Mrs. Jennifer Andrew **Date:** 08/31/2007

Organization : Indian River Physical

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Jennifer Andrew, I am a certified athletic trainer. I have a Master's degree from McNeese State University. I have worked in the out-patient physical therapy field for 20 years. I have lived and worked in a rural area for 12 years. In our clinic we see a large percent of medicare patients. It is sad that in the last few years our certified athletic trainers have not been able to treat medicare patients. Throughout the years patients have gotten quality care and return to our facility and asked to be treated by the certified athletic trainer. They are told they cannot see the person who gave them such great care, yet they can be treated by a PTA that does not have the same skills.

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

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

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

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

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

Sincerely,

Jennifer A. Andrew ATC, MEd

Submitter : Mr. Chad Krawiec **Date:** 08/31/2007

Organization : Harvard University Sports Medicine

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer currently employed at Harvard University with the Sports Medicine department. I am nationally board certified, licensed by the Commonwealth of Massachusetts, and possess post graduate education. I provide athletic training services to high level athletes within a network of other certified athletic trainers, dual credentialed physical therapist/certified athletic trainers, physicians, and other affiliated practitioners. My role is to provide athletic injury and illness assessment, practitioner referral, physical medicine and manual therapy treatment, and rehabilitation services. My services are invaluable in the delivery of health care to the active and athletic population.

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

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

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

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Sincerely,

Chad Krawiec, MS, ATC

Submitter : **Dr. Philip lightstone** **Date: 08/31/2007**

Organization : **Physician Anesthesia Services**

Category : **Physician**

Issue Areas/Comments

Medicare Economic Index (MEI)

Medicare Economic Index (MEI)

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Philip Lightstone MD

Submitter : **Dr. Richard Fausel** **Date: 08/31/2007**

Organization : **The Osteoporosis Center of the Desert**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Kerry Weems,Acting Administrator
CMS
Baltimore, MD 21244-1850

RE: Physician Work RVU-CPT 77080 (DXA)
Direct Practice Expense RVU for 77080 (DXA)
Indirect Practice Expense for DXA and VFA
Deficit Reduction Act.

Dear Mr. Weems:

I appreciate the opportunity to offer general comments on the proposed rule regarding changes to the Medicare physician fee schedule CMS 1385-P

As aprovider of DXA and VFA services I request CMS to re-evaluate the following:

a. The Physician Work RVU for 77080(DXA) should be increased from o.2 to 0.5, consistent with the most comprehensive survey data available.

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

The equipment type for DXA should be changed from pencil beam to fan beam with a corresponding increase in equipment cost from $41,000 to $85,000; the utilization rate for preventive health services involving equipoment designed to diagnose and treat a single disease should be calculated in a different manner than other utlization rates so as to reflect the actual utilization of that service. In the case of DXA and VFA, the 50% utilization rate should be changed to reflect the rate for DXA to 12%.

c. The inputs used to derive Indirect Practice Expense for DXA and VFA should be made available to the general public and,

d. DXA (77080) should not be considered an imaging serviee within the meaning of Section5012(b) of the Deficit Reduction AC of 2005 because the diagnosis and treatment of osteoporosis is based on a score and not on an image.

Sincerely

Richard E Fausel, DO

Submitter : Mr. Shawn Edgerly **Date:** 08/31/2007

Organization : Rockwood Clinic, P.S.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Shawn Edgerly. I am a certified athletic trainer and work in an out-patient physical therapy clinic. I also provide sports medicine coverage at a local high school and with an Arena 2 Football team.

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

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

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

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

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

Sincerely,

Shawn Edgerly,MS,ATC

Submitter : **Mrs. Sandra Thompson** **Date: 08/31/2007**

Organization : **Mrs. Sandra Thompson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Certified Athletic trainers are appropriately educated and capable of assisting with the delivery of rehabilitation of athletic populations in the clinic.

Submitter : **Miss. Julie Kruessel** **Date: 08/31/2007**

Organization : **Louisiana State University**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14773-Attach-1.DOC

14773

Dear Sir or Madam:

I am a graduate assistant athletic trainer at Louisiana State University, and currently working on my master's degree in sport management. I completed my bachelor's degree in health promotion and education with an emphasis in athletic training at the University of Cincinnati. As a certified athletic trainer, I am the insurance coordinator for LSU Sports Insurance and responsible for the healthcare of the LSU Men's Tennis team.

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

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

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Sincerely,

Julie Kruessel, ATC

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

Organization : **Dr. David Cipolla**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Sincerely,

David A. Cipolla, MD
dacdocs1@roadrunner..com

Submitter : **Dr. Michael Maves** **Date: 08/31/2007**

Organization : **American Medical Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachmcnt

CMS-1385-P-14775-Attach-1.DOC

14775

Michael D. Maves, MD, MBA, Executive Vice President, CEO

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue
Washington, DC 20201

Dear Mr. Kuhn:

The American Medical Association (AMA) appreciates the opportunity to provide our views concerning the Centers for Medicare and Medicaid Services (CMS) proposed rule on the *Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008*, 72 *Fed. Reg.* 38,122 (July 12, 2007). The AMA is especially alarmed that CMS is making a number of new regulatory proposals that would impose new hurdles on physician practices that are already struggling to comply with existing Medicare regulatory burdens. At the same time, CMS has included no proposals in this rule that would help to prevent the 10 percent reduction in Medicare physician payment rates slated to occur on January 1, 2008. We are particularly concerned that CMS has chosen to include numerous new self-referral regulations in this annual Medicare payment proposed rule. The current self-referral laws are already too complex to be understood without legal assistance and too restrictive to be fair. Adding more layers of confusion and regulation serves only to further confound physicians, shift more money to the attorneys that are required to interpret them, and discourage efficient, innovative, quality health care. Key recommendations included in this comment letter are:

- CMS should work with Congress to replace the 10 percent physician payment cut in 2008 and the series of steep consecutive pay cuts over the next decade with positive updates reflecting practice cost increases;

- CMS should reduce the productivity adjustment to the Medicare Economic Index to 0.65 percentage points from the current 1.5 percentage points, which would equal the recommended productivity adjustment for other Medicare providers that was included in the Administration's 2008 budget proposal;

American Medical Association 515 North State Street Chicago Illinois 60610
phone: 312 464 5000 fax: 312 464 4184 www.ama-assn.org

- As recommended by the Medicare Payment Advisory Commission, CMS should use the entire Physician Assistance and Quality Initiative Fund enacted in the Tax Relief and Health Care Act of 2007 to help offset the 2008 conversion factor reduction of 10 percent;

- CMS should withdraw its proposal to continue and to increase the size of the work neutrality adjustment factor established in 2007 to ensure budget neutral implementation of the changes made in the most recent five-year review and instead apply the budget neutrality adjustment for the five-year review to the conversion factor;

- CMS should withdraw and reevaluate all of the proposed changes to the physician self-referral regulations included in this Notice of Proposed Rulemaking;

- CMS should correct Physician Quality Reporting Initiative measures for accuracy in Table 17 of the proposed rule and include newly developed measures in the final rule as they are expected to be endorsed by the National Quality Forum or adopted by the AQA by November 15, 2007.

- CMS should officially add the *NCCN Drugs and Biologics Compendium* to the list of recognized compendia to determine the medical acceptability of an off-label use of a drug or biological in an anti-cancer chemotherapeutic regimen.

MEDICARE PHYSICIAN PAYMENT RATE FOR 2008

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

Payment rates for physician services today in 2007 are essentially the same as they were six years ago in 2001. Due to the Sustainable Growth Rate (SGR) formula, physicians now face drastic Medicare payment cuts totaling about 40 percent over the next nine years. Yet, during this same time period, the Medicare Economic Index (MEI), which CMS relies on to measure increases in medical practice costs, is expected to increase by 20 percent.

Physicians cannot absorb these draconian cuts. In a 2007 AMA survey, 60 percent of physicians said they will be forced to limit the number of new Medicare patients they can accept if the 10 percent cut goes into effect January 1, 2008.

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 percent cut in payment rates facing physicians is in stark contrast to Medicare Advantage (MA) plans, which are paid on average 112 percent above the cost of traditional Medicare, with a significant number of MA plans paid from 120

percent to more than 150 percent of traditional Medicare. These overpayments are shortening the life of the Medicare trust fund.

There is no rational basis for this significant disparity in the positive payment update for MA plans, in which only about 20 percent of Medicare patients are enrolled, while the steep negative updates are scheduled for the Medicare fee-for-service program, in which 80 percent of our nation's Medicare patients are enrolled. In fact, the Medicare Payment Advisory Commission (MedPAC) has pointed out that Medicare spends far more per beneficiary for seniors enrolled in MA than it does for those in original Medicare and has called for these subsidies to be eliminated.

It is not just the government that is subsidizing the extra payments to MA plans, but beneficiaries too are contributing to this lopsided playing field through their Part B premiums. In order for the health care system to effectively promote patient choice and meaningful competition, the options available to Medicare beneficiaries should be on equal footing. By favoring MA plans over Medicare fee-for-service in its budget proposals and regulatory decisions, the government has created a two-tiered system for seniors in which payment updates for managed care health plans cover more than their cost increases, whereas fee-for-service physician services face substantial funding shortfalls.

Physicians are the foundation for our nation's health care system, and thus a stable payment environment for their services is critical. But, time is running out. CMS must work with Congress to avert Medicare fee-for-service physician pay cuts by enacting positive physician payment updates that reflect increases in medical practice costs, as indicated by the MEI. In addition, CMS can and should take other steps in the final rule that will help to lessen the SGR-driven pay cuts facing physicians in 2008 and over the next decade, as follows:

MEI

The MEI measures the weighted-average annual price change for various inputs needed to produce physicians' services. In establishing the MEI each year, CMS adjusts it downward to account for assumed physician productivity increases. CMS' preliminary estimate of the MEI for calendar year 2008 is 1.9 percent, which includes a forecasted 1.5 percent productivity offset. **The AMA strongly urges CMS to reevaluate and reduce this 1.5 percent productivity adjustment to the MEI.**

The President's budget proposal for 2008 recommends that the payment update for inpatient and outpatient hospital services, hospices, and ambulance services be reduced by 0.65 percentage points each year to offset productivity increases. Unlike updates for these other providers, in measuring increases in practice costs, the MEI includes an automatic reduction for presumed increases in productivity. As stated above, in 2008, this downward adjustment in the MEI is slated to be about 1.5 percent—or more than twice as much as the proposed reduction for other services. Surely CMS does not believe that physicians' and other health professionals' productivity is increasing at twice the rate of other health care providers. In

fact, there was general agreement among economists who participated in a meeting hosted by CMS actuaries last fall that the current productivity adjustment is too large. Indeed, it would be nearly impossible for physicians to increase their productivity in treating patients in light of various Medicare initiatives that impose numerous time and paperwork burdens and increase practice costs, including provisions proposed in the rule, such as the physician self-referral provisions. All of these initiatives would tend to slow productivity, not increase it.

Use of a 1.5 percent productivity adjustment adds up to a substantial amount of dollars and a reduction in the productivity adjustment could have significant implications for physician payment rates. Over a ten-year period, the 0.85 percentage point difference between the productivity adjustment being made to the MEI and the productivity adjustment recommended for other provider groups in the President's budget is equivalent to 8.5 percent, almost the size of the rate cut physicians face in 2008.

Accordingly, the AMA urges CMS to reduce the productivity adjustment to the MEI to 0.65 percentage points, as the Administration has recommended for other Medicare providers.

We also reiterate our request that CMS address the broader problem that the MEI only measures changes in the specific types of practice costs that existed in 1973. Factors (or inputs) to the MEI are vastly different now than when the MEI was first developed in the early 1970s, and thus additional inputs may be needed to ensure that the current MEI adequately measures the costs of practicing medicine. For example, physicians must comply with an array of government-imposed regulatory requirements that did not exist in 1973, including those relating to: Medicare prescription drug plans and compliance, compliance with rules governing referrals and interactions with other providers; detailed new and modified coverage policies; advanced beneficiary notices; certificates of medical necessity; rules governing Medicare dual eligible patients; limited English proficiency rules; Medicare audits; the Health Insurance Portability and Accountability Act (HIPAA) and Clinical Laboratory Improvement Act (CLIA); billing errors; quality monitoring and improvement; and patient safety. CMS is also promoting the use of electronic medical records and other new health information technology systems that facilitate physician participation in quality improvement initiatives. To ensure compliance with these requirements, physicians often must take actions that increase their practice costs, including hiring additional types of office staff, attorneys for legal and regulatory compliance, as well as accountants and billing companies to ensure proper billing of claims to handle these additional responsibilities. These types of inputs are not currently taken into account for purposes of measuring the MEI, and therefore the MEI undervalues actual medical cost increases.

Accordingly, we urge CMS to include in the MEI any additional inputs that are needed to ensure that the MEI adequately measures the costs of practicing medicine.

remainder in 2009. If CBO anticipated that the Fund would only be used for quality purposes, as is proposed by CMS, it would have stated that CMS could use 100 percent of the Fund for quality reporting payments for services furnished in 2008.

Further, CMS states that if its estimate is too low for use of the Fund in 2008, it could leave money in the Fund and CMS would face the problem of spending the remaining funds in the future. This is not problematic since Congress stated in section 101(d) that the Fund should be used "to the maximum extent feasible" for physicians' services during 2008. Clearly, Congress anticipated that not all of the Fund would be used and the remainder could be used in 2009. CBO underscored Congress' intent by stating that "the funds will remain available until spent."

Like CBO, Congress also anticipated that CMS could use the Fund to help avert the negative payment update. Indeed, under section 101(d) of the TRHCA, Congress indicated its intent by specifically providing that the Fund "may include application of an adjustment to the update of the conversion factor." Congress further underscored its intent by directing, under section 101(d), how the conversion factor should be calculated in a subsequent year if the Fund is applied to the update: "[I]n the case that expenditures from the Fund are applied to, or otherwise affect, a conversion factor . . . the conversion factor under such subsection shall be computed for a subsequent year as if such application or effect had never occurred." We urge CMS to consider that Congress and CBO anticipated application of the Fund to help avert the negative update.

Finally, CMS states in the proposed rule that implementing the Fund through an extension of the PQRI program is the best way to ensure physicians get the greatest benefit from the Fund's resources. The AMA is committed to continuing our efforts to improve quality, but we do not believe that using the Fund solely for the PQRI provides the "greatest benefit' to physicians. As stated above, the PQRI does not provide all physicians with an opportunity to participate. Physicians within certain subspecialties treat patients with conditions for which PQRI measures do not apply and therefore these physicians cannot participate in the quality reporting program. Physicians who treat certain patient populations for which PQRI quality measures do not apply should not be disadvantaged by CMS' proposed use of the Fund. Clearly, use of the fund to "spend down" the negative update for 2008 by 2 percent (as estimated by CMS in the proposed rule) would benefit all physicians across the Board.

The Fund was intended to provide some relief and stability to the physician payment system during 2008. Yet, if CMS uses the Fund for quality improvement purposes only, relief would not be available until well after 2008 since CMS cannot begin to calculate the PQRI bonus payment until after the close of the 2008 reporting period. Neither would this aid in stability since CMS is required to meet the $1.35 billion aggregate cap. This means that CMS cannot let physicians know the amount of the reporting bonus until well after the close of the 2008 reporting period.

Accordingly, for the reasons stated above, we urge CMS to use the Fund to partially offset the negative update and allow all physicians to benefit equally from the Fund.

RESOURCE-BASED PE RVUs

CMS has proposed to adopt all of the AMA/Specialty Society Relative Value Update Committee (RUC) recommendations submitted in 2007. The direct practice expense data for nearly 300 codes were reviewed by the Practice Expense Review Committee (PERC) and the RUC at the February and April 2007 meetings. **The AMA applauds CMS for its proposal to accept all of these recommendations and appreciates all of the time and effort involved in this data review process, along with timely implementation of reliable data each year. We encourage continuation of this exemplary collaborative effort among CMS, the RUC, and specialty medical societies in this data refinement process.**

PROFESSIONAL LIABILITY INSURANCE RELATIVE VALUE UNITS (RVUs)

CMS is required by law to conduct a five-year review of the professional liability insurance (PLI) RVUs to reflect marketplace changes in the physician community's ability to acquire PLI. Yet, there are some technical services which have assigned PLI RVU values that have never been part of the 5-year review process. As a result, the PLI RVUs associated with these technical services have not been revised since their initial assignment, and, therefore, approximately 600 services have a technical component PLI RVU that is greater than the professional component PLI RVU. The RUC initially asked CMS to change the technical component PLI RVUs because if physicians have to pay the larger PLI premiums, there should be higher RVUs associated with the professional portions of these services.

CMS states in the proposed rule that it wants to address the RUC's concerns and would like to develop a resource-based methodology for the technical portion of the PLI RVUs. Yet, at this time, CMS does not have data to support such a change in methodology. Therefore, CMS has asked for comments on how to obtain the necessary data to create resource-based RVUs for these services.

The RUC PLI Workgroup was convened to respond to CMS' request for information and concluded that there are not separately identifiable costs for professional liability for technical professionals. **We understand that the RUC will discuss this issue in September 2007 and review a recommendation to reduce the PLI technical component to zero. We ask that CMS seriously consider the RUC's recommendations and ensure that the PLI relative values are indeed resource-based.**

CODING—ADDITIONAL CODES FROM 5-YEAR REVIEW

In the final physician fee schedule rule for 2007, CMS deferred decision on proposed changes to the work RVUs for a number of codes from the 5-year review that occurred for calendar year 2007 because CMS had not yet received the RUC recommendation or CMS had asked the RUC to re-evaluate the original recommendation. **The AMA appreciates**

that CMS has adopted for implementation most of the RUC recommendations. We believe these modifications better reflect the work values for these codes.

However, the AMA urges CMS to reconsider its proposal to reject the RUC recommendation to refer CPT code 93325, *Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)*, to the CPT Editorial Panel. CMS is proposing instead to bundle this service with other services provided to these patients.

The RUC has already discussed issues involved in providing the services described in 93325, 93307 (*Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete,* and 93320 *Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete)* on the same day by the same physician. Further, the RUC has recommended that this issue be referred to the CPT Editorial Panel to review whether a single code should be created to report the services currently reported in 93320, 93325, and 93307 and the cardiology community has developed a coding proposal to address this issue for *CPT 2009.* Continued RUC and cardiology review of this matter is in process during 2007.

Accordingly, the AMA agrees with the RUC's comments on the proposed rule and we urge CMS to allow this issue to be addressed within current processes and not finalize the proposal to bundle 93325 into other services provided to the same patients effective in 2008. If CMS finalizes this proposal despite our concern that to do so would preempt the RUC's review, then we urge that any savings from this proposal be redistributed within the RBRVS.

ANESTHESIA

The Medicare conversion factor payment for anesthesia services currently is $16.19 per unit—which is 29.4 percent of what private insurance typically pays for anesthesia services. In 2006, as requested by CMS, the RUC reviewed the physician work for anesthesia services to determine whether the valuations for anesthesia services are appropriate. The RUC reached unanimous agreement in recommending to CMS that anesthesia work is undervalued by 32 percent. CMS is proposing to accept this RUC recommendation and increase the work of anesthesia services by 32 percent. **We commend CMS for recognizing the undervaluation of anesthesia work, and we urge CMS to finalize and implement this RUC recommendation.**

BUNDLED CODING ISSUES

Anticoagulation Management Codes

In the final physician fee schedule rule for calendar year 2007, CMS announced its decision to bundle anticoagulation codes (99363 and 99364) into the work of the evaluation and

management codes. CMS did not offer any explanation for this decision and did not further address this matter in the proposed physician fee schedule rule for 2008. **We urge CMS to reconsider this decision in the final rule for 2008 and allow anticoagulation management services to be billed under their own separate codes.**

In previously establishing codes for these services, the Current Procedural Terminology (CPT) Editorial Panel and the RUC have been careful to ensure that work from anticoagulation management would not be included in selecting the level of evaluation and management codes. When patients receive anticoagulation therapy, extensive medical work and attention from physicians is required. If this care is not covered under a separate CPT code, physicians essentially are forced to provide this care without appropriate payment or they have to refuse to accept patients who require this therapy.

These CPT codes (99363 and 99364) recognize the important work of managing serious disease, and CMS should pay for these services under these codes without bundling them into evaluation and management services.

Education and Training for Patient Self-Management

In the final rule for 2007, CMS assigned a status indicator of "B" for education and training for patient self-management services related to CPT Codes 98960, 98961, and 98962, stating "they are bundled into another covered service under Medicare."

There is strong clinical value in providing these services to patients with conditions such as diabetes and asthma where education and training have been demonstrated as contributing to improved health outcomes and where such services have been incorporated into nationally recognized clinical practice guidelines, including some developed and disseminated by the National Institutes of Health. Coverage of CPT codes 98960–98962 will support the implementation of this benefit through the physician office and will improve access to proper medical care and prevent delayed disease complications.

Accordingly, we urge CMS to reconsider this decision and change the status of these codes from "bundled" to "active" with separate payment for these services, based on the RVUs that the RUC recommended for assignment to these codes.

IMPACT

CMS is proposing changes to work RVUs for certain codes, and these changes are required by law to be implemented on a budget neutral basis. Specifically, existing law requires that adjustments in RVUs for a year may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these adjustments. In 2007, CMS created a new "work adjuster" to ensure budget neutrality following implementation of the improved work RVUs from the 2005 five-year review of the RBRVS. In the proposed rule, CMS has announced that the five-year review work adjuster will increase from 10.1 percent to 11.8 percent. To achieve budget neutrality to

offset the increases from the five-year review, CMS will use the work adjuster to reduce all work values by this same percentage.

The AMA urges CMS to withdraw this proposal and apply the budget neutrality adjuster to the conversion factor. Applying the budget-neutrality adjuster to the work RVUs is contrary to long-held CMS policy. From 1998 to 2006, CMS implemented all work budget neutrality adjustments by adjusting the conversion factor. Prior to this time, 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 resourced-based relative value scale (RBRVS). CMS acknowledged the confusion and ineffectiveness of applying the budget neutrality adjuster to the work RVUs. In fact, constant fluctuations in the work RVUs due to budget neutrality adjustments impede the process of establishing work RVUs for new and revised services.

Adjusting the conversion factor is preferable because it does not affect the relativity of services reflected in the recommended RVUs. In contrast, adjusting the work RVUs only to achieve budget neutrality has more potential to inappropriately affect relativity. In addition, adjusting only the work RVUs will diminish the valuation improvements for the services for which the work RVUs increased due to the five-year review and the full benefit of these improvements would not be achieved.

An adjustment to the conversion factor is also preferable because it would: (i) have less impact on other payers who use the Medicare RBRVS, along with their own conversion factor; (ii) be consistent with the notion that budget neutrality is mandated for monetary reasons, and since the conversion factor is the monetary multiplier in the Medicare payment formula, this is the most appropriate place to adjust for budget neutrality; and (iii) be consistent with CMS' goal of transparency in the Medicare payment system. **Accordingly, the AMA urges CMS apply the budget neutrality adjuster to the conversion factor.**

TRHCA—SECTION 101(b): PQRI

As mandated by TRHCA section 101, CMS is implementing a system for the reporting by physicians and eligible professionals of data on quality measures, effective January 1, 2008. We have the following comments concerning the provisions in the proposed rule:

- In establishing this quality reporting program, as CMS states in the proposed rule, the statute requires that the quality measures "shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that includes measures that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures."

  In implementing this statutory requirement, CMS interprets a "consensus-based development process" to mean that in addition to the measure development, the

measure has achieved adoption or endorsement by a consensus organization. CMS offers the AQA and NQF as examples of "consensus organizations."

The AMA agrees that the statute requires that quality measures for 2008 must be those that have been adopted or endorsed by the AQA or NQF. We wish to reinforce, however, that the statute also requires that 2008 measures are those that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures. Congress' intent with this provision was to ensure that physician-level quality measures are developed by physicians through the physician medical specialties as well as a consensus-based process. The Physician Consortium for Performance Improvement (Consortium) is an organization that uses a consensus-based process in developing quality measures. The Consortium currently is comprised of over 100 national medical specialty and state medical societies; the Council of Medical Specialty Societies; American Board of Medical Specialties and its member-boards; experts in methodology and data collection; the Agency for Healthcare Research and Quality; and CMS. The Joint Commission and the National Committee for Quality Assurance (NCQA) are also liaison members. In addition, the Consortium involves purchasers and payers, and measures are released for public comment as part of the development process.

Accordingly, the Consortium truly has a consensus-based development process, which is distinct from the NQF endorsement and AQA adoption process. These organizations are not involved in measure development. **This distinction is not entirely clear in the proposed rule, and we urge CMS to clarify in the final rule that a consensus-based development process is separate and distinct from the measure adoption and endorsement process of consensus organizations, such as the NQF or AQA. Further, CMS should clarify that measures must be developed through a consensus-based process, such as through the Consortium, in addition to being endorsed by the NQF or adopted by the AQA.**

- In the proposed rule, CMS sets forth certain principles in identifying measures that meet the requirement for having used a consensus-based process for development and the requirement for having been endorsed or adopted by a consensus organization such as the NQF or AQA, and that are appropriate for inclusion as 2008 measures. One of these principles is as follows:

  > "The basic steps for developing the physician level measures may be carried out by a variety of different organizations. We do not interpret the [TRHCA] to place special restrictions on the type or make up of the organizations carrying out this basic development of physicians measures, such as restricting the initial development to physicians-controlled organizations.

> Any such restriction would unduly limit the basic development of physician quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards." (Emphasis added.)

We are concerned about the intent underlying this principle. It is imperative that physician-level measures are defined and developed collaboratively across physician specialties. Measures should be developed and maintained by appropriate professional organizations that periodically review and update the measures with evidence-based information in a process open to the medical profession. Practicing physicians with expertise in the area of care in question should be integrally involved in the design, implementation, and evaluation of PQRI measures. **The AMA strongly urges CMS to clearly articulate that all relevant physicians, across all specialties and subspecialties, be integrally involved in the measure development process and that this process be open and transparent.**

- Table 16 in the proposed rule contains the quality measures that were included in the 2007 Physician Quality Reporting Initiative (PQRI). The AMA notes that a measure developed by the Consortium, endorsed by the NQF, and included in the 2007 PQRI program is missing from Table 16. **We urge CMS to correct this oversight and add to the table the following measure: "dilated macular exam for patients with age-related macular degeneration."**

- CMS proposes to include measures in the final 2008 PQRI selected from those listed in Table 17 of the rule, provided that the measures achieve NQF endorsement or AQA adoption by November 15, 2007. These are measures that are currently under development via the AMA/Consortium. **We have reviewed those measures listed in Table 17 of the proposed rule and corrected them for accuracy, as redlined in Attachment A to these comments. We have also listed a number of measures that should be added to Table 17. The AMA urges CMS to include these measures in the final rule as they are expected to be endorsed by the NQF or adopted by the AQA by November 15, 2007.**

- CMS proposes to include quality measures in the 2008 PQRI that are currently under development by Quality Insights of Pennsylvania, as listed in Table 18, so long as they achieve NQF adoption or AQA endorsement by November 15, 2007.

  It is not clear whether the measures in Table 18 are intended for physicians and non-physicians, or are for non-physicians only, given the way the measures are specified by the Quality Insights of Pennsylvania. We believe it is the intent of CMS to have one set of measures for both physicians and non-physicians, when appropriate.

judgment, and they are derived directly from NCCN Guidelines that are nationally recognized by the oncology community. The NCCN is a not-for-profit association representing the 21 comprehensive cancer centers in the United States, and it makes both its Compendium and NCCN Guidelines freely available to the cancer community. The American Society of Clinical Oncology, the American Cancer Society, and many other cancer-related organizations also have offered support of the *NCCN Drugs and Biologics Compendium* to be a recognized compendium by the Secretary.

As discussed in the CMS' proposed rule, MedCAC extensively evaluated current and potential compendia for coverage of off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen at its meeting of March 30, 2006. While none of the compendia fully satisfied all of the desirable characteristics identified by MedCAC, the *NCCN Drugs and Biologics Compendium* scored highest on all of the criteria used by the Committee to define a robust and evidence-based compendium.

In particular, the Committee scored this compendium the highest (4.5 out of 5) on the question of whether compendia have adequately stated evidence-based criteria (see posted voting results at http://www.cms.hhs.gov/FACA/downloads/id33c.pdf).

Given the need for additional compendia under section 1861(t)(2)(B) of the Act, the widespread support for recognition of the *NCCN Drugs and Biologics Compendium*, and the very positive evaluation of this compendium by the MedCAC, the AMA urges the agency to immediately add the *NCCN Drugs and Biologics Compendium* to the list of recognized compendia to determine the medical acceptability of an off-label use of a drug or biological in an anti-cancer chemotherapeutic regimen.

PHYSICIAN SELF-REFERRAL PROVISIONS

General

The AMA appreciates the opportunity to provide its views on the CMS proposed rules on the self-referral provisions of the Physician Fee Schedule. We are, however, surprised by the timing and extent of this confusing combination of proposed changes and requests for comment on whether certain other changes ought to be proposed, given CMS's delay in issuing the long-awaited Stark II, phase III regulations. In general, the proposed rule creates two levels of uncertainty: significant lack of clarity within the specific proposals themselves; and general instability due to the prospect of annual changes to the self-referral rules being included in the Medicare physician fee schedule rule. We believe the current self-referral laws are already too complex to be understood without legal assistance and too restrictive to be fair. Adding more layers of confusion and regulation serves only to further confound physicians, shift more money to the attorneys that are required to interpret them, and discourage efficient, innovative, quality health care.

Therefore, while arrangements involving the use of contracted technicians, part-time service, and shared facilities would still be permitted, any associated costs, other than the net charge for the test could not be billed. In addition, the professional component would have to be "split billed" rather than reassigned to the practice for global billing, unless the interpreting physician is employed by the practice on a full-time basis—35 hours a week.

We understand that CMS is concerned that the anti-markup and purchased interpretation requirements have led to confusion where a reassignment of payment has occurred under a contractual arrangement. CMS believes that certain arrangements that permit physician groups to bill for services provided by a contractor in a centralized building may lead to program abuse. However, we do not think that the proposed changes represent an understanding of the realities of group practices and how physicians are compensated.

Under the proposed rule, the only technical or professional services a medical group could mark-up would be those performed by the group's full time employees. This would significantly impact the ability of radiology groups, Independent Diagnostic Testing Facilities (IDTF), and group practices with in-office imaging equipment to utilize independent contractors and part-time employees to perform professional interpretation services. This is because suppliers would be limited to billing Medicare no more than the amount actually paid to the independent contractor or part-time employee, even though the supplier must, in addition to paying the physician, also cover the costs and assume the business risk for billing for the physician's services. Thus, suppliers will ultimately incur loses for each service performed by an independent contractor or part-time employee.

With regard to the reassignment proposal, CMS appears unaware with how reassignment of the right to bill and receive payment for the professional component occurs throughout the health care system. Many physicians reassign for their professional interpretations to other medical groups as independent contractors. Often, physicians are paid an aggregate monthly or annual amount for their services and therefore there is no "charge" to report on a claim. The proposed rules do not address how the billing physician or medical group can determine the amount to declare on the claim as the charge for any single specific interpretation, causing confusion as well as potential exposure to false claims liability, as practices would be required to include a "charge" for all diagnostic test services.

2. Burden of Proof

The proposed rule would add a new section to the self-referral regulations to clarify that the burden of proof will be on the billing provider in any appeal of a denial of payment for a designated health service (DHS) where the denial was made on the basis that the service was furnished pursuant to a referral prohibited under Stark. Thus, when CMS denies payment due to a Stark violation, under the proposal, the burden is on the entity submitting the claim to establish that the service was not furnished pursuant to a prohibited referral. Although there are not widespread claims denials for Stark violations, this change offends all notions of due process. In addition, it makes it easier for the government to pursue claims against physicians who have far fewer resources. And, it could provide a greater incentive for

Fiscal Intermediaries and Part B Carriers to increase denials based on alleged Stark violations.

3. In-Office Ancillary Services ("IOAS") Exception

Although there are no specific proposals to amend or limit the IOAS exception, we caution that any changes to this exception will severely limit the ability of physician groups to provide ancillary services for their patients, cancelling out efficiencies and undoubtedly causing access problems.

4. Obstetrical Malpractice Insurance Subsidies

The AMA supports revising the existing Stark exception relating to the provision of medical liability insurance subsidies by hospitals to increase beneficiary access to obstetrical care. Obstetrical care is difficult to obtain in some communities because of high obstetrical medical liability insurance rates, and the existing Stark exception relating to the provision of medical liability insurance subsidies by hospitals is unnecessarily restrictive.

5. Unit-of-Service ("Per-Click") Payments in Space and Equipment Leases

Currently, space and equipment leases that are based upon the number of times a physician uses the space or equipment (i.e., payment on a per-use or per-click basis) are permissible under the Stark exceptions so long as the payment at the beginning of the lease term is at fair market value and does not change during the term in a manner that takes into account the volume or value of DHS referrals by the physician/lessor (or physician/lessee). However, at least in cases where the physician is the lessor, CMS has backtracked and is now proposing that space and equipment leases between a physician/lessor and billing entity/lessee may not include per-click payments to the physician/lessor for services referred by the physician to the billing entity. A reversal of CMS's position, as proposed, could affect many per-click leases that have been put in place based on the existing regulations and would effectively require physicians and hospitals to restructure or terminate any per-click equipment or space lease arrangements that involve the furnishing of services subject to the Stark Law prior to January 1, 2008.

6. Period of Disallowance for Noncompliant Financial Relationships

CMS is not proposing any new regulatory interpretation regarding the period of disallowance for noncompliant financial relationships at this time and thus offers no specific language on the issue. The preamble discussion, however, opens additional questions. For example, with regard to whether CMS should disqualify parties from suing an exception for some additional period where an arrangement has failed to satisfy the applicable requirements, there is no indication as to how broadly such a disqualification would be applied. For example, would failure to satisfy the condition for an exception disqualify the provider from relying on that exception in all other cases or only regarding the particular

arrangement that has previously failed to satisfy the requirements. This provision displays the lack of specificity and detail that appears to be a hallmark of this proposed rule.

7. Ownership or Investment Interest in Retirement Plans

The proposed rule would change the language in the current regulations that a Stark ownership or investment interest does not include an interest in a retirement plan. The proposed regulation would limit this exclusion to state that an interest in a retirement plan does not constitute Stark ownership only if the interest in the retirement plan is offered to a physician through employment. This limitation on the blanket exclusion of retirement plan interests is meant to stop physicians from using retirement plans to purchase entities that bill for DHS but simply represents another example of CMS' broad brush approach to physician practices—punishing and restricting all physicians based on negligible, and likely unsubstantiated, anecdotal evidence of questionable physician investment.

8. Set-in-Advance and Percentage-Based Compensation Arrangements

Currently, many of the compensation exceptions under the Stark law require that compensation be set (or "fixed") in advance, including the space and equipment lease exception, the personal service arrangement exception the fair market value exception, and the academic medical center exception. The existing Stark regulations provide that physician percentage compensation arrangements meet this requirement so long as the specific percentage formula is set forth in sufficient detail before any items or services are provided and the formula is not modified, within the term of the arrangement, in any manner that reflects the volume or value of referrals. Based upon concern that percentage arrangements are being used not only as compensation for physician services, but also in space and equipment leases, CMS is proposing to clarify that percentage compensation arrangements may be used only for paying for personally performed physician services and must be based on the revenues directly resulting from those services and not on some other factor, such as a percentage of the savings by a hospital department unrelated to the physician services provided.

This proposed change to the "set in advance" requirement would essentially prohibit a physician group from receiving payments based on a percentage of collections or similar percentage formula for an office lease, equipment lease, personnel lease, billing service agreement, management services agreement, or any agreement other than a professional services agreement with a physician. Although this would permit the most common form of percentage-based compensation to individual physicians, there are many other payment arrangements, including some with no obvious potential for abuse that would be adversely affected by the proposed change. For example, leases that require lessees to pay a percentage of operating or overhead expenses (taxes, insurance, etc.) as a part of the rent would not qualify under the proposed definition of "set in advance."

9. Stand in the Shoes

CMS proposes to provide that, where a DHS entity owns or controls an entity to which a physician refers patients for DHS, the controlling entity will "stand in the shoes" of the entity to which the referrals are made and will be deemed to have the same compensation arrangements with the physician as the controlled entity. Thus, for example, where a hospital owns or controls a separate entity that contracts with physicians, the hospital will "stand in the shoes" of that entity and have direct compensation relationships with the contracting physicians.

Essentially, this proposal would result in the transformation of some currently indirect compensation relationships between physicians and entities providing DHS into direct relationships. For instance, if a hospital leases equipment from a joint venture in which the hospital owns 80 percent and physicians that refer to the hospital for DHS own 20 percent, current law would find a potential indirect compensation relationship between the physicians and the hospital. However, the "stand in the shoes" proposal would result in disregarding the equipment leasing joint venture, so that the hospital is deemed to be leasing equipment directly from the physicians for Stark purposes. The arrangement would then have to meet the criteria in the equipment leasing exception rather than the indirect compensation exception. Coupled with the proposed restrictions on percentage arrangements, this proposal would require the restructuring of numerous existing hospital-physician joint ventures and lease and management arrangements, including those where the compensation is fair market value and does not vary based upon DHS referrals.

10. Alternative Criteria for Satisfying Certain Exceptions

CMS is considering whether to amend the Stark regulations to provide an alternative method of satisfying the requirements of an exception where there has been an inadvertent violation of a procedural or "form" requirement of the exception (e.g., where there is a missing signature on a lease or personal services agreement that otherwise complies with Stark). To take advantage of this alternative, however, a number of requirements would have to be satisfied, including: (a) the parties self-disclose the violation to CMS, (b) CMS determines that the arrangement otherwise satisfied all the relevant requirements, (c) the violation was inadvertent, (d) the parties did not have knowledge of the violation at the time of the referral or the resulting claim, (e) the arrangement did not pose a risk of program or patient abuse, (f) no more than a set amount of time had passed since the time of the original noncompliance, and (g) the arrangement at issue is not the subject of an ongoing federal investigation, enforcement action or other proceeding. In addition, there would be no appeal or review of a decision to allow the alternative method of compliance, and CMS would have sole discretion as to whether to make such a determination in the first place (i.e., the parties have no right to receive a determination, and there is no time limit on CMS's response).

This proposal introduces a convoluted structure and set of restrictions that serves little purpose and will have a limited effect. Given the discretion afforded CMS and the myriad requirements that must be satisfied, this proposal is a parody of an attempt to assist

physicians. Granting CMS sole discretion (not subject to any type of administrative or judicial review), unlimited time, and the option of simply declining to make a determination, is a perversion of due process.

11. Services Furnished "Under Arrangements"

Under the proposed rule, the definition of "entity" would be revised so that it would cover not only the person or entity that bills Medicare for DHS (as in the current definition), but also the person or entity that provides the DHS. CMS is also considering whether it should adopt a recommendation from MedPAC that would prohibit physician ownership of any entity "that derives a substantial proportion of its revenue from a provider of [DHS]," thereby effectively prohibiting physician ownership of entities that provide equipment or services to hospitals under arrangements. This proposed change would virtually eliminate "under arrangements" service contracts with physicians or physician groups potentially disrupting access and prompting duplication of investment in facilities and equipment.

The challenges associated with this change in the definition of entity are exacerbated by the ambiguity of the proposed language. For example, the proposed language fails to address what is meant by "performed" the DHS. In today's health care environment it is common for equipment to be leased from one party, space leased from another, and personnel employed, leased, or contracted from or by multiple organizations. Thus, the question of who is "performing" the DHS is not answered easily. It is also unclear how CMS would address services that are not DHS when directly furnished (such as most cardiac catheterization procedures, endoscopy, or lithotripsy), but become DHS hospital services when furnished under arrangements. Similar questions arise with regard to the circumstances under which an arrangement service provider would be deemed to be "causing a claim to be presented" by the hospital to Medicare. For example, an imaging service may be provided as a part of an inpatient stay. The hospital will bill Medicare for that patient's stay, and its DRG payment will not likely be affected by the imaging service. In this example it seems unlikely that the "under arrangement" service provider is causing a claim for DHS to be presented, but the language in the proposed regulation is ambiguous. CMS is proposing a change from a clear and objective Stark regulation regarding the definition of "entity," to a rule that is vulnerable to differing interpretations by CMS, providers, and potential *qui tam* relators.

CMS also requests comment on MedPAC's suggestion regarding services furnished "under arrangements." MedPAC recommended that CMS expand the definition of physician ownership in the physician self-referral law to include interests in an entity that derives a substantial portion of its revenue from a provider of DHS. MedPAC's approach, however, would require the undoing of hundreds of contractual arrangements between physician-owned Intermediary Entities and DHS Entities—the majority of which are well-intentioned, commercially reasonable, pro-competitive, and likely to improve the quality and lower the cost of health care.

Conclusion of Self-Referral Provisions

The scope of changes to the Stark regulations in the 2008 proposed physician fee schedule rule is far broader and more fundamental than CMS has proposed previously in an annual payment regulation. Stark is a singularly technical and complex regulation, where a change in definition can have both significant and unintended consequences. Thus, in general, we do not believe that an annual, piecemeal regulatory approach is an appropriate and effective way to make changes to the Stark rules.

Moreover, in important areas the proposed rule lacks the level of detail and specificity needed to give health care providers good guidelines to structure lawful business arrangements, while other areas of the rule are missing proposed regulatory language entirely. The only thing that *is* clear about the proposed rule is that it represent an unfortunate retreat away from earlier phases of the Stark regulations that sought to strike a important balance between eradicating fraud and abuse and protecting those arrangements that promote efficiency and protect patient access to care. There is little doubt that, should these proposed rules become final, they will have a negative effect on innovation, efficiency, and patient access to care. Thus, we urge CMS to withdraw these proposals.

CHIROPRACTIC SERVICES DEMONSTRATION

CMS implemented the two-year demonstration project authorized by section 651 of the MMA that allows chiropractors to provide diagnostic and other services that the chiropractor is legally authorized to perform by the state or jurisdiction in which the treatment is provided. The demonstration ended on March 31, 2007.

The MMA requires that this demonstration be budget neutral (i.e., that the aggregate payment made under the Medicare program does not exceed the amount which would be paid in the absence of the demonstration). CMS will make adjustments in the national chiropractor fee schedule to recover the costs of the demonstration in excess of the amount estimated to yield budget neutrality. To assess budget neutrality, CMS will determine the change in costs based on a pre- and post-comparison of aggregate payments and the rate of change for specific diagnoses that were treated by chiropractors and physicians in the demonstration sites and control sites. CMS states that it will not, however, limit its analysis to reviewing only chiropractor claims, because "the aggregate payments under the expanded chiropractor services may have an impact on other Medicare expenditures." Any needed reduction to chiropractor fees under the physician fee schedule would be made in the calendar years 2010 and 2011 physician fee schedules since CMS anticipates that it will take about two years to complete the claims analysis.

The AMA urges CMS to apply budget neutrality only to the chiropractic codes used in the demonstration project. This demonstration project was intended to explore access to chiropractic services and did not require a physician referral for these services. In the absence of a physician referral, physicians had no involvement in the assessment of what services were required and thus had no opportunity to impact the utilization of services.

Physicians, therefore, should not be penalized for any utilization of chiropractic and "other services" that caused Medicare spending to exceed the amounts that would have been spent on these same services "but for" the demonstration.

If CMS does not limit budget neutrality to the chiropractic codes involved in the demonstration, it should work to incorporate estimates of the impacts on other services into its SGR "law and regulation" factor estimates. Otherwise, the demonstration could lead to additional Medicare physician pay cuts applicable to all physician fee schedule services, not just chiropractic services.

PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

Section 101 of the MMA mandates the use of uniform e-prescribing standards for prescribers who voluntarily elect to electronically transmit prescriptions for drugs covered by the Medicare prescription drug benefit (Part D). In November 2005, the U.S. Department of Health & Human Services (HHS) adopted a final rule establishing three prescribing standards known as the "foundation standards." Use of these standards became effective January 1, 2006. One of these standards is the National Council for Prescription Drug Programs SCRIPT Standard (SCRIPT standard). However, the November 2005 final rule also created an exception to this requirement that allowed electronic prescribers to continue using computer-generated facsimiles in lieu of e-prescribing consistent with the SCRIPT standard. This allowed prescribers to key in information into their existing electronic programs and then utilize a function that enabled them to send an electronically generated facsimile with the prescription and certain prescription-related information to the dispenser. CMS has proposed removing the "facsimile" exemption. HHS has yet to issue final regulations on the remaining six e-prescribing standards that have been proposed.

The AMA supports the use of electronic prescribing. We believe, however, that removing this exemption will inhibit physician adoption of e-prescribing. Specifically, it will cause many prescribers who currently elect to use electronic technology to forgo utilizing it to avoid costly upgrades in existing products/programs. Prescribers will instead use paper. This will slow down the adoption of health information technology in general and e-prescribing in particular. In addition, mandating that all e-prescribers use this standard is premature given that all the e-prescribing standards have not been adopted.

In the proposed rule CMS cites SureScripts data and states that "of the 150,000 prescribers now using software that is capable of generating SCRIPT transactions, only 15 percent are doing so." While the number of physicians utilizing e-prescribing is certainly increasing, there are over one million physician prescribers in the United States. Therefore, the vast majority of prescribers are not using e-prescribing at all; or, alternatively, are using e-prescribing via fax functionality without software that supports the SCRIPT standards. This underscores that there are large numbers of prescribers who would be adversely affected by the elimination of the facsimile exemption, and who would be required to undertake costly upgrades or revert to paper transactions to avoid this requirement.

In a recent article published in the April 2007 edition of *Health Affairs,* researchers at the Center for Studying Health System Change reported the results of a study that analyzed physicians' experiences with commercial electronic prescribing systems. Numerous barriers to adoption of electronic prescribing were reported. The authors found that while physicians are "generally positive" about the many benefits of e-prescribing, they concluded that "[t]he results of this study suggest that sizable gaps may exist between policymakers' vision of e-prescribing and physicians' actual use of commercial e-prescribing products." Furthermore, the smallest practices surveyed were 5 practitioners or more and were "likely among the earliest adopters of e-prescribing in their local markets...." In stark contrast, approximately 50 percent of physician practices have fewer than 5 physicians yet account for 80 percent of outpatient visits. (The foregoing numbers do not include solo practitioners.) The study found that additional staff time was needed after e-prescribing programs had been adopted to interact with vendors, pharmacies, and state officials. The impact of this drain on administrative resources will be hardest felt among the smallest group practices and solo practitioners. These are the same physicians who continue to struggle to incorporate health information technology in general into their practice as they have fewer resources.

The AMA continues to believe that CMS's original conclusion that prescribers and dispensers who already make use of electronic prescribing, if required through a federal mandate to comply with the e-prescribing foundation standards, would in all likelihood revert back to paper prescriptions. CMS acknowledges in the proposed rule that the majority of costs will be shouldered by the physicians who currently do not possess the ability to send prescriptions electronically using the SCRIPT standards and therefore would require system upgrades. As is the case with health information technology in general, the financial benefits often do not accrue to the physicians. Physicians in small practices are small business owners and will have to balance this mandate against other federal requirements. For the smallest practices that are struggling to incorporate health IT, a mandate for adoption is an invitation to abandon electronic technology altogether.

In addition, patients should be able to choose where to receive their prescriptions. If the ability to fax is removed for e-prescribers this will put physicians in the untenable and administratively onerous position of trying determine whether the patient's desired pharmacy is able to conduct electronic data interchange (EDI).

The AMA is also concerned that the lessons learned from the implementation of HIPAA have been forgotten. The industry's history with mandatory adoption of HIPAA standards for transactions and code sets is evidence that transitioning to standards is more of an evolutionary process than it is one of simply "flipping a switch." The proposed rule calls for a one-year implementation timeframe following publication of the final rule. This timeframe is wholly inadequate given the significant remaining barriers and the fact that it has taken years to implement other standards.

While CMS views the rate of e-prescriber adoption to be moving at a slower rate than it anticipated, the creation of incentives by the commercial payers and others in the private sector have aided physician adoption of e-prescribing. The foregoing has created a positive momentum that could be jeopardized should CMS remove the fax exemption. Should CMS move ahead with removing the fax exemption to the use of the SCRIPT standard for e-prescribing, it could very well have the unintended consequence of significantly hampering the nascent adoption of health IT.

MEDICARE TELEHEALTH SERVICES

We are pleased that CMS is proposing to add the neurobehavioral status exam to the list of Medicare-covered telehealth services. We also urge CMS to appropriately reflect additional costs due to this added coverage in calculations of the SGR.

CMS has declined to add neuropsychological testing services to the list of Medicare telehealth services. CMS questions whether a patient with suspected or confirmed brain damage or mental illness such as schizophrenia can be taught how to use a computer by a practitioner who is in a remote location. **We urge CMS to seek additional information concerning these services and then reconsider its decision not to include these services on the telehealth list.**

RECALL AND REPLACEMENT DEVICES

Recently there has been a recall of 73,000 implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) because of a faulty capacitor that can cause the batteries to deplete sooner than expected. This is on top of recalls in ICDs and pacemakers in CY 2004 and CY 2005. We agree with CMS, as stated in the proposed rule, that these recalls raise issues both with regard to the additional costs of replacement devices and the additional physicians' services and diagnostic tests that Medicare beneficiaries who have these devices often need. In fact, the manufacturer of the recently recalled devices recommends that patients with the recalled device consult with their physician, and if necessary, begin a routine of monthly evaluations. This will result in additional physician visits, as well as additional diagnostic tests.

We appreciate that CMS recognizes the additional physician visits and diagnostic tests that will result from these device recalls. **We urge CMS to ensure that these additional costs are calculated in the SGR target. In addition, CMS should work with the physician community to establish a method by which physicians can identify those visits and services that result from the device recall. CMS should then be reimbursed for any additional expenditures on these physicians' services from the device manufacturer.**

We appreciate the opportunity to provide our views on the critical foregoing matters and stand ready to work with CMS to achieve a successful solution to each of these issues.

Sincerely,

Michael D. Maves, MD, MBA

ATTACHMENT A

We suggest the following corrections to Table 17: AMA/PCPI Measures:

- AOE/OME (The first 3 measures are only for patients with AOE and the final 5 measures are only for patients with OME. Please see redlined edits below.)
    - ~~Patients with~~ Acute Otitis Externa (AOE)~~: or Otitis Media with Effusion (OME) who receive~~ Topical Therapy.
    - ~~Patients with~~ AOE~~: /OME who have a~~ Ppain assessment.
    - ~~Patients with~~ AOE: Systemic antimicrobial therapy – avoidance of inappropriate use~~/OME who are inappropriately prescribed antimicrobials.~~
    - ~~Patients with AOE/~~Otitis Media with Effusion: Diagnostic evaluation - ~~who have an~~ Aassessment of tympanic membrane mobility.
    - ~~Patients with AOE/~~OME: ~~who undergo h~~Hearing testing.
    - ~~Patients with AOE/~~OME: ~~who inappropriately receive~~ Aantihistamines or ~~/~~decongestants – Avoidance of inappropriate use~~.~~
    - ~~Patients with AOE/~~OME: ~~who inappropriately receive~~ Ssystemic antimicrobials – Avoidance of inappropriate use~~.~~
    - ~~Patients with AOE/~~OME: ~~who inappropriately receive s~~Systemic corticosteroids – Avoidance of inappropriate use~~.~~

- *Anesthesiology and Critical Care* (Remove "in ventilated patients" in one of the measures as redlined below.)
    - Anesthesiology and Critical Care: Prevention of Ventilator-Associated Pneumonia—Head elevation. **Formatted:** Font: Not Italic
    - Anesthesiology and Critical Care: Stress Ulcer Disease (SUD) Prophylaxis in Ventilated patients. **Formatted:** Font: Not Italic
    - Anesthesiology and Critical Care: Prevention of Catheter-Related Bloodstream Infections ~~in Ventilated patients~~—Catheter Insertion Protocol. **Formatted:** Font: Not Italic
    - Anesthesiology and Critical Care: Perioperative Temperature Management for Surgical Procedures Under General Anesthesia. **Formatted:** Font: Not Italic

- *Atrial Fibrillation* (Insert the word "therapy" in one of the measures as redlined below. Please see additional edits as redlined below.)
    - Atrial Fibrillation: Assessment of Thromboembolic Risk Factors ~~in patients with Atrial Fibrillation.~~ **Formatted:** Font: Not Italic
    - Atrial Fibrillation: Chronic Anticoagulation Therapy ~~in patients with Atrial Fibrillation.~~ **Formatted:** Font: Not Italic
    - Atrial Fibrillation: Monthly INR Measurements ~~in patients with Atrial Fibrillation.~~ **Formatted:** Font: Not Italic

- *Chronic Kidney Disease* (Since submitting these measures to CMS, they have been refined and strengthened. One measure has been deleted because of no known gap in care; two measures have been combined into one (laboratory testing); another two

measures have been combined into one (elevated hemoglobin); and two measures have been added to better reflect comprehensive care for patients with CKD. Please see additional edits as redlined below.)

~~GFR Calculation in patients with Chronic Kidney Disease (CKD).~~

- Chronic Kidney Disease: Blood Pressure Measurement ~~in patients with CKD.~~
- Chronic Kidney Disease: Plan of Care for ~~patients with CKD and~~ Elevated Blood Pressure.
- Chronic Kidney Disease: ACE Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy ~~in patients with CKD.~~
- Chronic Kidney Disease: Laboratory Testing (Calcium, Phosphorus, PTH and Lipid Profile)

  ~~Calcium, Phosphorus and Intact Parathyroid Hormone Measurement in patients with CKD.~~

  ~~Lipid Profile in patients with CKD.~~
- Chronic Kidney Disease: Plan of Care - Anemia

  ~~Hemoglobin Monitoring in patients with CKD.~~

  ~~Erythropoietin Overuse in patients with CKD and normal Hemoglobin.~~
- Chronic Kidney Disease: Influenza Vaccination
- Chronic Kidney Disease: Referral for AV Fistula

- *ESRD* (Adjust the wording as redlined below.)
  - ESRD: Influenza Vaccination ~~in patients with End Stage Renal Disease (ESRD).~~
  - ESRD: Vascular Access ~~for~~ Ppatients Receiving~~Undergoing~~ Hemodialysis.
  - ~~Permanent Catheter~~ ESRD: Vascular Access - ~~for~~ Ppatients Receiving ~~Hemo~~Ddialysis with a Permanent Catheter~~.~~
  - ESRD: Plan of Care for ~~ESRD patients with~~ Anemia.
  - ESRD: Plan of Care for Inadequate Hemodialysis ~~in ESRD patients.~~
  - ESRD: Plan of Care for Inadequate Peritoneal Dialysis.

- *GERD* (Adjust the wording as redlined below.)
  - ~~Assessment of GERD Symptoms in Patients Receiving~~ GERD: Continuous Medication Therapy – Assessment of GERD Symptoms~~for GERD.~~

- *Hepatitis C* (Since submitting these measures to CMS, the measure requiring Hepatitis A and B Vaccinations in patients with HCV has been split into two separate measures as redlined below. In addition, one measure (combination antiviral therapy) was missing from the list. Please see additional edits as redlined below.)
  - Hepatitis C: Testing for ~~of patients with~~ Chronic Hepatitis C (HCV): confirmation of ~~for~~ Hepatitis C Viremia
  - Hepatitis C: ~~Initial~~ Hepatitis C RNA t~~T~~esting before initiating therapy
  - Hepatitis C: HCV Genotype Testing Prior to Therapy.
  - Hepatitis C: Consideration for Antiviral Therapy ~~in HCV Patients.~~
  - Hepatitis C: Combination Antiviral Therapy

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- Hepatitis C: HCV RNA Testing at Week 12 of Therapy.
- Hepatitis C: Hepatitis A ~~and B~~ Vaccination
- Hepatitis C: Hepatitis B Vaccination
- Hepatitis C: ~~Counseling~~ Education ~~patients with HCV~~ Regarding RiskUse of Alcohol Consumption.
- Counseling ~~of patients~~ Regarding Use of Contraception Prior to ~~Starting~~ Antiviral Therapy.

- *MDD Care* (Adjust the wording as redlined below.)
  - ~~Patients who have~~ Major Depressive~~on~~ Disorder: Diagnostic evaluation~~who meet DSM IV Criteria~~
  - ~~Patients who have~~ Major Depressive~~on~~ Disorder: ~~who are assessed for~~ Ssuicide assessment~~risks.~~

- *Osteoarthritis* (Adjust the wording as redlined below.)
  - ~~Patients with~~ Osteoarthritis: ~~who receive~~ Assessment for use of Anti-Inflammatory or Analgesic~~a~~ OTC Medications~~.~~
  - ~~o~~Patients with Osteoarthritis: Function and pain ~~who have an~~ assessment ~~of their pain and function.~~

- *Pathology* (Adjust the wording as redlined below.)
  - Pathology: Breast cancer resection pathology reporting - ~~patients who have a~~ pT category and pN category with~~and~~ histologic grade ~~for their cancer.~~
  - Pathology: Colorectal cancer resection pathology reporting - ~~patients who have a~~ pT category and pN category with~~and~~ histologic grade ~~for their cancer.~~

- *PAG Care* (Adjust the wording as redlined below.)
  - Pediatric Acute Gastroenteritis (PAG): Documentation of hydration status ~~in Pediatric Patients with Acute Gastroenteritis (PAG).~~
  - Pediatric Acute Gastroenteritis (PAG): Weight measurement ~~in patients with PAG.~~
  - Pediatric Acute Gastroenteritis (PAG): Recommendation of appropriate oral rehydration solution ~~in PAG patients.~~
  - Pediatric Acute Gastroenteritis (PAG): Education ~~parents of PAG patients.~~

- *Perioperative Care* (Since submitting these measures to CMS, one measure has been revised and the title has subsequently changed as redlined below. Please see additional edits as redlined below.)
  - Perioperative Cardiac risk assessment (history).
  - Perioperative Cardiac risk assessment (current symptoms).
  - Perioperative Cardiac risk assessment (physical examination).
  - ~~o~~Perioperative Cardiac risk assessment (electrocardiogram) Avoidance of Perioperative Electrocardiogram - Overuse
  - Perioperative ~~Cardiac risk assessment (~~Ceontinuation of Beta Blockers~~)~~.

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- *Prostate Cancer* (Adjust the wording as redlined below.)
  - Prostate Cancer: ~~Appropriate~~ Initial evaluation ~~of patients with Prostate Cancer.~~ **Formatted:** Font: Not Italic
  - Prostate Cancer: Overuse Measures - ~~Inappropriate use of~~ Bone Scan for staging Low-Risk ~~Prostate Cancer~~ patients. **Formatted:** Font: Not Italic
  - Prostate Cancer: T~~Review of t~~reatment options for~~in~~ patients with clinically localized ~~Prostate Cancer.~~disease **Formatted:** Font: Not Italic
  - Prostate Cancer: Adjuvant Hormonal therapy for High-risk ~~Prostate Cancer~~ patients. **Formatted:** Font: Not Italic
  - Prostate Cancer: Three-dimensional radiotherapy ~~for patients with Prostate Cancer~~ **Formatted:** Font: Not Italic

- *Dermatology* (Three dermatology measures are included in the PQRI 2007 program. Based on feedback received on those measures through the NQF review process, the PCPI has revised and updated its available measures for melanoma. Because these updated measures are a natural extension of the previous measures, because there currently are no other measures available for dermatologists for PQRI 2008, and because of the impact of melanoma on the Medicare population, we encourage CMS to place these measures in Table 17 for inclusion in PQRI 2008.)
  - Melanoma: Process of care measures for melanoma - bundled
  - Melanoma: Continuity of care - recall system
  - Melanoma: Coordination of care – communication with primary care physician
  - Melanoma: Overutilization of imaging studies in Stage 0-1A Melanoma

- *Eye Care* (Eight eye care measures are included in the PQRI 2007 program. Four NQF-endorsed eye care measures (1 covering glaucoma, 1 AMD, and 2 diabetic retinopathy) are included in Table 16 for inclusion in PQRI 2008. Based on feedback received on the four measures not endorsed by NQF, and the need for additional measures in the areas of glaucoma, AMD, and cataracts, the PCPI has revised and updated its available measures for eye care. Because these updated measures are a natural extension of the previous measures, because they provide for 3 measures for glaucoma and 3 measures for cataracts, and because of the impact of glaucoma, AMD, and cataracts on the Medicare population, we encourage CMS to place these measures in Table 17 for inclusion in PQRI 2008.)
  - Primary Open-Angle Glaucoma: Reduction of Intraocular Pressure by 15% or Documentation of a Plan of Care
  - Primary Open-Angle Glaucoma: Counseling on Glaucoma
  - Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery
  - Cataracts: Comprehensive Pre-operative Package for Cataract Surgery with IOL Placement
  - Cataracts: Counseling on Cataract Prevention

- Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplements (Revised measure)

- *Geriatrics* (Six geriatric measures are included in the PQRI 2007 program. Five NQF-endorsed measures are included in Table 16 for inclusion in PQRI 2008. Based on initial feedback on the Advance Care Plan measure, the PCPI has revised this measure and it is currently out for NQF member comment. In addition, two additional measures on falls have been developed that build on the NQF-endorsed measure – Screening for Future Fall Risk. Because these measures are a natural extension of the current fall screening measure and because all three measures address areas that are applicable to multiple specialties, we encourage CMS to place these measures on Table 17 for inclusion in PQRI 2008.)
  - Advance Care Plan (Revised measure)
  - Falls: Risk Assessment
  - Falls: Plan of Care

- *Oncology* (Four oncology measures are included in the PQRI 2007 program. These measures were developed in advance of a PCPI expert work group to develop oncology measures in collaboration with ASCO and ASTRO. Based on the work group review of the measures in the 2007 program and a thorough review of the relevant guidelines for breast, colon and rectal cancer, the PCPI has revised and updated its available measures for oncology. Because these updated measures are a natural extension of the previous measures, because there currently are few other measures available for medical oncologists or radiation oncologists for PQRI 2008, and because of the impact of cancer on the Medicare population, we encourage CMS to place these measures in Table 17 for inclusion in PQRI 2008.)
  - Oncology: Cancer Stage Documented
  - Oncology: Hormonal therapy for stage IC-III, ER/PR positive breast cancer
  - Oncology: Chemotherapy for Stage III colon cancer patients
  - Oncology: Plan for chemotherapy documented before chemotherapy administered
  - Oncology: Treatment summary communicated-radiation oncology
  - Oncology: Normal tissue dose constraints specified
  - Oncology: Pain Intensity Quantified
  - Oncology: Plan of Care for pain
  - Oncology: Pathology report - Medical Oncology
  - Oncology: Pathology report - Radiation Oncology

- *Pediatric ESRD* (The PCPI is working with the American Society of Pediatric Nephrology to expand 2 of the existing adult ESRD measures to be appropriate for patients under age 18 who are receiving dialysis. Because there currently are no measures in PQRI 2008 that are appropriate for pediatric nephrologists, and because Medicare covers all patients receiving dialysis, regardless of age, we encourage CMS to place these 2 measures in Table 17 for inclusion in PQRI 2008.)

  - Pediatric ESRD: Adequacy of hemodialysis
  - Pediatric ESRD: Anemia management

- *Prenatal Care* (The PCPI has recently completed a formal update of its Prenatal Care measures. Two of the Prenatal Care measures [Anti D Immune Globulin and Screening for HIV] have been endorsed by NQF. Because there are currently few measures in PQRI that are appropriate for obstetricians, and because of the clinical importance of Anti D Immune Globulin and HIV prevention, we encourage CMS to place these 2 measures in Table 17 for inclusion in PQRI 2008.)
  - Prenatal Care: Anti-D Immune Globulin
  - Prenatal Care: Screening for Human Immunodeficiency Virus (HIV)

- *Spinal Stenosis* (The PCPI with AAOS, AAPMR, AANS, NASS and NCQA recently convened an expert work group to develop measures that would be applicable to multiple specialties by addressing an area of high significance to the Medicare population – degenerative lumbar spinal stenosis. These measures are applicable to neurosurgery, orthopaedics, physical medicine and rehabilitation, chiropractry and physical therapy. In summary, because the addition of these measures broaden the number of measures that these specialties can report and because of the impact of the topic on the Medicare population, we encourage CMS to place these measures in Table 17 for inclusion in PQRI 2008.)
  - Spinal Stenosis: History and Physical on or Before the Date of Diagnosis
  - Spinal Stenosis: Documentation of Neurogenic Symptoms Prior to Surgical Intervention
  - Spinal Stenosis: Documentation of Neurogenic Symptoms Prior to Epidural Steroid Injections (ESI)
  - Spinal Stenosis: Assessment of Patient Response to Medical and Interventional Treatment
  - Spinal Stenosis: Assessment of Patient Function and Pain Status Prior to Surgical Treatment
  - Spinal Stenosis: Assessment of Patient Response to Surgical Treatment
  - Spinal Stenosis: Shared Decision-making

- *Radiology* (Two radiology measures that focus on imaging in stroke patients are included in the PQRI 2007 program. Given that these measures are only applicable to a small percentage of radiologists whose work focuses on neuroradiology, the Consortium, together with the American College of Radiology and the National Committee for Quality Assurance, recently convened an expert work group to develop measures that would be applicable to more radiologists by addressing two topic areas of high significance – mammography screening and radiation dose reduction. One additional measure that was developed is an expansion of one of the measures developed in the stroke work group to all carotid imaging studies, regardless of patient diagnosis. In summary, because there currently are few other measures available for radiologists for PQRI 2008, both of which may not be applicable to a large percentage of radiologists, and because of the impact of the topic areas on the Medicare population, and because of

their focus on patient safety, we encourage CMS to place these measures in Table 17 for inclusion in PQRI 2008.)

- Radiology: Stenosis Measurement in carotid imaging reports
- Radiology: BI-RADS data collection
- Radiology: Inappropriate use of BI-RADS category 3 in mammography screening
- Radiology: Communication of suspicious findings from the diagnostic mammogram to the practice managing ongoing care
- Radiology: Communication of suspicious findings from the diagnostic mammogram to the patient
- Radiology: Reminder system for screening mammograms
- Radiology: CT radiation dose reduction
- Radiology: Exposure time reported for procedures which use fluoroscopy

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

Organization : **Joe Cunningham**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Joe Cunningham

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

Organization : **Jordan Underwood**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Les V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Thank you for your consideration of this serious matter.
Jordan Underwood

Submitter : **Ms. Kelly Guenser** **Date: 08/31/2007**

Organization : **Puget Sound Family Physicians**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please see attached word document.

CMS-1385-P-14778-Attach-1.DOC

14778

August 31, 2007

Via Electronic Submission
Centers for Medicare & Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Re: File Code CMS-1385-P
Physician Self-Referral Provisions

Dear Sirs:

I am writing you on behalf of Puget Sound Family Physicians, LLC ("PSFP") a physician group practice. We specialize in family practice. We have multiple office locations and offer a full array of medical services, including adult medicine, pediatrics, obstetrics and gynecology, dermatology, mammography and ultrasound, minor surgery, and in–office laboratory services.

PSFP includes a diverse group of physicians, including women and men, seasoned practitioners and more recent medical school graduates, part-time and full time physicians, physicians who primarily see walk-in patients, and doctors who primarily care for an established patient roster.

We have concerns about certain of the proposed Stark regulatory amendments. Our concerns are discussed below.

1. Diagnostic tests

You have proposed limiting the amount that can be billed for the professional component of a purchased diagnostic test to the lower of (1) the net charge to the billing physician or medical group, or (2) the billing physician's or medical group's actual charges. *72 Fed. Reg. 38180 (July 12, 2007).*

You have proposed that this anti-markup rule would apply to situations where the treating physician reassigns his/her right to bill to the billing physician or the group, except in cases where the physician providing the diagnostic service described by Social Security Act Section 1861(s)[1] (other than clinical laboratory tests described by Act Section 1833(a)(2)(D)), is a full-time employee of the group. Thus, you are proposing that work done by part-time practitioners be treated as a purchased service.

Our group includes several part-time physicians, many of whom are young women with small children who specialize in obstetrics and gynecology or pediatric medicine. In addition, our group has a

[1] Act Section 1861(s) applies to the following services: "diagnostic X-ray tests . . . including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act), diagnostic laboratory tests, and other diagnostic tests.

walk-in clinic and some physicians working in the walk-in clinic are not full-time employees. Professional practices struggle to accommodate part-time practitioners and our group believes that our patients are well served by the mix of full-time and part-time physicians.

It would be virtually impossible for us to comply with the proposed regulatory changes, and remain financially viable, without terminating all of our part-time physician employees (some of whom are owners of the practice) or prohibiting them from providing the affected diagnostic tests.

Further, the regulations do not define how we would calculate the interpreting physician's "net charge to the . . . medical group." It appears that we would not be allowed to count our practice overhead as a component of the net charge to the group, even though the group (and the practitioner indirectly through our overhead allocation process) bears this expense. A medical practice cannot long survive if it cannot include overhead and the cost of capital in its fee structure.

Under existing rules, a medical group cannot mark up the technical component of a purchased diagnostic test (other than certain clinical lab tests). We understand that you have proposed extending this anti-mark up provision to the professional component because of continuing concerns that physicians will order unnecessary diagnostic tests if they can profit from the same.

However, we find it difficult to conclude that the Medicare system would be benefited by restricting the amounts that practices are allowed to bill for the professional component of diagnostic tests performed by its own part-time physicians. Undoubtedly the result will be that practices will either eliminate part-time positions or prohibit part-time practitioners from providing the full range of services which they can capably provide.

2. In-office Ancillary Services

You have expressed concern that the in-office ancillary services exception encourages physicians to expand the care they deliver by developing in–office facilities. You commented favorably on ancillary services provided in response to the patient condition that brought the patient to the office; particularly in situations where the ancillary services are provided while the patient waits for results and a post-result physician visit.

The recent Federal Register Notice states that specialists have vocalized their objections to group practice physicians who perform in-house services which the specialists would like to have referred to them. Clearly, there are ongoing changes in the way the medicine is practiced. Individual specialists and individual generalists may not agree about what services are best referred out, however, local medical communities have significant experience in identifying when good medicine requires a referral.

There are a number of other factors which influence and regulate referral patterns, including: physician competencies and interests, state licensure of medical technologies, requirements of health insurance payers, local laws relating to "any willing provider", malpractice concerns, credentialing,

professional accreditation, medical ethics, the corporate practice of medicine doctrine, local prevailing charges for services, state certificate of need laws, and hospital endeavors to shape the care delivery systems in their markets. In the midst of this complex, highly regulated, competitive and changing environment, we have serious concerns about the long-term (and possibly unintended) consequences that may result from CMS' redefining (through Medicare payment policies), what ancillary services a physician can appropriately provide in his/her office. We believe that the concerns you have expressed may be best left to local health care policy makers and to market forces.

3. Percentage Based Compensation

Finally, you have proposed re-defining when compensation is deemed to have been "set in advance." As redefined, percentage based compensation arrangements could only include revenues directly resulting from personally performed physician services, thus eliminating the possibility that physician compensation may be based (in part) on care provided by ancillary personnel, incident to the physician's services.

Within a medical practice, the allocation of resources, overhead, and revenue can be an extremely sensitive issue. Even within a family practice, there are differences in the practices of subspecialists which impact the resources allocated to them. In the context of these realities, practices have developed somewhat complex physician compensation and overhead formulas.

The proposal to eliminate incident to-DHS services from physician compensation formulas is very restrictive and appears to be based on a number of assumptions that may or may not be accurate. One such assumption is that the allocation formula at a clinic will encourage the physician to order unnecessary tests in order to realize a profit because they will be allocated an inappropriate portion of the resulting net revenues, if any.

However, in actuality compensation formulas also allocate costs and one of the goals of a compensation program is to encourage the proper use of resources, to share financial risk among the physicians and to develop financial resources for the long-term viability of the practice. These are complex and difficult issues which medical practices address with a view to the long term.

Care delivered by a physician thorough his/her assigned staff, who are directly supervised by that physician, seems vastly different from percentage compensation arrangements pertaining to equipment and office space rentals between the physician and a practice. We understand that the latter was your concern. (See, *Id. at 38184.)* We encourage you allow medical groups to continue to implement physician compensation arrangements which are flexible in the treatment of revenues and expenses associated with incident to services.

Conclusion

Thank you in advance for your attention to the concerns described above.

Puget Sound Family Physicians

By: Kelly Guenser

SEA_DOCS:860276.3 [13797-00100]

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

Organization : Dr. David Garfunkel

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am an anesthesiologist in private practice in New Jersey. I wish to support the proposed increase in payment to anesthesiologists. This long overdue increase will allow us to practice with less fear regarding poor compensation. Thank you very much.
David Garfunkel, M.D.

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

Organization :

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:
My name is Ashley Hull and I am currently an athletic training student at an institution in Ohio. I am writing to state my argument against the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
I feel that these changes to the hospital Conditions of Participation have not been carefully inspected, and fear that these proposed rules will create a lack of need for athletic trainers in the clinical setting.
As an athletic training student, I am taught and trained to work with and rehabilitate the physically active population, in which some are insured under Medicaid and Medicare services. My education, clinical experience, and national certification exam ensure that my future patients will receive quality health care. If these rules and regulations are to be passed, state law and hospital medical professionals will deem me qualified to perform services.
By making these changes to the CMS, not only will you be taking away American s ability to receive health care services, but also my right to a job as an athletic trainer in the clinical setting after graduating with a four year, Bachelor s degree in Athletic Training. I feel that it is irresponsible for CMS to restrict American s ability to receive services by athletic trainers.
I strongly encourage the CMS to consider the recommendations of myself, my fellow student athletic trainers, and certified athletic trainers before making a final decision. 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,
Ashley Hull, ATS

Submitter : **Dr. Chandur Piryani** **Date: 08/31/2007**

Organization : **Pain Diagnostics Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1385-P-14781-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 (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 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

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 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,

Chandur Piryani, MD
305 Division Street
Iron Mountain, MI 49801

Submitter : Dr. Stuart Glassman **Date:** 08/31/2007

Organization : Granite Physiatry/Concord Hospital

Category : Physician

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

I strongly support CMS's plan to extend the 30 day re-certification requirement to 90 days. The 30 day requirement has been burdensome to physician practices, and has not been an effective means of controlling utilization of therapy services. Following proprer referral patterns, reviewing the initial therapy plan of care, and having timely patient follow-up office visits is felt to be the more accurate way of overseeing and following utilization, not whether the form for ongoing therapy is signed after I versus 3 months. The aspect of Local Coverage Determination guidelines, therapy caps and medical necessity requirements will be adequate to ensure proper utilization of therapy serviees.

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

Organization : **Kent Whaley**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Kent Whaley

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

Organization : **Tufts University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am currently employed as an athletic at the college setting and have been working as a certified athletic trainer for 18 years. My education consists of a BS from an accredited athletic training college and a MS in Sports Health Care from AT Still University.

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

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

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

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

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

Sincerely,

Patricia M Cordeiro, MS, ATC, CSCS

repackage CAP drugs in certain situations. Specifically, CMS requests comments on whether a CAP vendor should be allowed to supply bevacizumab (Avastin®) for the treatment of wet age-related macular degeneration ("AMD"), or other CAP drugs, if they are repackaged in a patient-specific dose. Additionally, CMS indicates that it plans to issue instructions that will allow CAP-participating physicians to use the "furnish as written" option to obtain Avastin for the treatment of wet AMD outside of CAP in pre-filled syringes depending on the physician's local Carrier's coverage policy and any applicable state laws and regulations, in order to minimize apparent wastage.

Genentech appreciates CMS efforts to improve operational aspects of the Part B CAP, including ensuring that the program does not impose excessive burden on participating physicians and Medicare beneficiaries. It appears, however, that CMS' proposal to allow a CAP vendor to repackage products included on the CAP drug list goes beyond its statutory authority and unnecessarily compromises the safety of Medicare beneficiaries.

As CMS indicates in the Proposed Rule, per Section 414.906(a)(4) of the Code of Federal Regulations, the approved CAP vendor must "deliver CAP drugs directly to the participating CAP physician in unopened vials or other original container as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer." This regulatory provision was established in accordance with Congressional intent when creating CAP as a voluntary alternative to the buy-and-bill reimbursement methodology used by physicians for Part B drugs; CAP was never intended as a means to provide pharmacy services, or to be a source of compounded, reconstituted or "ready-to-use" drugs.

Not only would the CMS proposal expand CAP far beyond its statutory intent, it also could jeopardize the safety of Medicare beneficiaries. Genentech is concerned that CMS does not appear to fully understand that many CAP drugs require special handling because they are "cold-chain" products or must be stored under special conditions, especially after they are opened, mixed, and/or reconstituted. CMS proposals could have significant implications and unintended consequences regarding the safety, sterility, and shipping conditions for CAP products. Under its proposals, CMS would permit CAP vendors to repackage or reconstitute single-use products before shipping them to physicians, an activity the Food and Drug Administration ("FDA") does not even allow manufacturers to do, and one which could jeopardize the purity, potency, and sterility of CAP drugs, especially those packaged in single-use containers. For example, if a liquid packaged in a single use container is opened and aliquotted into multiple doses, the evidence-based safety and sterility standards, including the expiration date for the product, will be compromised.

Genentech strongly believes that in the absence of legislative changes, CMS is precluded from implementing the proposals described above. We also note that oversight of repackaging FDA-approved drugs and biologics is the responsibility of the FDA, not CMS, and as such, CMS should refrain from interfering with FDA authority in this area.

Moreover, we are not aware of any data illustrating that patients who are under the care of physicians participating in CAP do not have access to products included (or not included) on the CMS approved CAP drug list. In fact, CMS already has established a mechanism for physicians to obtain CAP products using the buy-and-bill methodology when it is necessary for patient care (i.e., in emergency situations). CAP-participating physicians also have the ability to obtain products or formulations not included on the approved CAP drug list through the buy-and-bill methodology (i.e. the "furnish as written" option). In addition to the lack of a sound policy reason to allow CAP vendors to deliver "ready-to-use" drugs, we do not believe there is any

reason to issue a program transmittal informing physicians that they may obtain pre-filled syringes of Avastin for the treatment of wet AMD outside of CAP when the product is included on the CAP drug list and is currently available to physicians (and their patients) participating in the program.

Due to the reasons outlined above, Genentech urges CMS to withdraw its proposals regarding whether a CAP vendor should be allowed to repackage CAP drugs into patient-specific doses in certain situations and use the "furnish as written" option to obtain Avastin for the treatment of wet AMD because these proposals violate the FDA's guidance on compounding and risk the safety of Medicare beneficiaries.

Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen

Congress recognized the importance of ensuring Medicare beneficiary access to medically-accepted off-label uses of drugs and biologicals in anti-cancer treatment regimens by requiring Medicare coverage of such uses if they are listed in an approved compendium. Genentech is pleased by CMS' attempts to improve the process by which the list of approved compendia is updated, as we believe it is incumbent on CMS, and in line with Congressional intent, to continue recognizing a reasonable number of compendia for coverage purposes. Despite CMS' efforts, however, we are concerned that the compendia provisions in the Proposed Rule are too vague and must be clarified before finalized in order to avoid unintended consequences on Medicare beneficiaries' access to care.

Insuring Availability of Multiple Compendia

As CMS correctly notes in the Proposed Rule, Section 1861(t)(2) of the Social Security Act ("SSA") specifies three compendia—American Hospital Formulary Service-Drug Information (AHFS-DI), American Medical Association Drug Evaluations (AMA-DE), and United States Pharmacopoeia-Drug Information (USP-DI), or its successor publication—for use in determining medically acceptable indications for Medicare coverage of anti-cancer drugs. Since AMA-DE is no longer in publication and USP-DI has changed ownership and is no longer being published under the name USP-DI, the "approved" list of compendia recognized for Medicare coverage purposes, and subsequent patient access to off-label anti-cancer therapies, faces serious risk of decreasing.

Specifically, if only one compendium remains on the "approved" list, therapeutic choices available to Medicare beneficiaries could potentially be restricted, and decisions as to which indications are covered would, in practice, be left largely to a single, non-governmental organization. Current compendia differ in a number of ways that affect how they gather and review evidence, as well as which uses are supported by that evidence; having more than one compendium prevents the potential that a single compendium could determine Medicare coverage for all off-label uses of anti-cancer drugs.

Inclusion of DrugPoints® as a Successor to USP-DI

CMS indicates in the Proposed Rule that a determination must be made whether DrugPoints, Thomson Micromedex's replacement publication for USP-DI, is in fact a successor publication and therefore should be retained for use under the Section 1861(t)(2) of the SSA. Genentech believes that CMS should acknowledge DrugPoints as a successor publication to USP-DI since the two products are comparable—they both provide concise summary drug information for use

by clinicians. DrugPoints also includes enhancements not available in USP-DI such as additional sections for each listing and a display of the ratings for each product with the evidence-base underlying the recommendation. Genentech requests that CMS explicitly indicate in the Final Rule that DrugPoints is a successor publication to USP-DI and qualifies as one of the approved compendia for Medicare coverage purposes of off-label anti-cancer therapies.

If, however, CMS does not determine that DrugPoints is a successor publication, we think it is important that the number of approved compendia is not limited to only one, which, as described above, would be undesirable for ensuring Medicare beneficiary's access to important cancer therapies. If CMS concludes that DrugPoints does not qualify as a successor publication, we request that it: (1) make available the reasoning for this decision for public comment (in accordance with our comments below about removing a compendium); (2) add one or more compendia under the authority of 1862(t)(2) so the options are not limited to one; and (3) retain DrugPoints as an approved compendia at least until one or more additional compendia has been added to the approved list.

Proposed Definition of a Compendium

Genentech is concerned that CMS' proposed definition of a compendium fails to require information necessary for a physician to adopt it as an effective and practical resource. Specifically, if a compendium does not include information on which indications for a product are "medically accepted," we fail to understand how the compendium would be useful to providers from both a clinical and Medicare coverage perspective.

CMS also proposes to require a compendium be indexed by drug or biological, rather than by disease. A number of factors, including the disease in question, and the availability of drugs or biologicals to treat that disease, may make it more useful and efficient for clinicians if it is organized by disease, regardless of whether such organization also constitutes a disease treatment guideline.

To consider the method of organization a defining element for whether a compendium is an approved for Medicare coverage purposes seems irrelevant, particularly in an era of electronic publications and databases. Instead, we believe the operative question should be whether a compendium contains reliable information about "medically accepted indications" in a fashion that is readily accessible to various users, including prescribing clinicians, beneficiaries, and Medicare contractors. We are concerned that insistence on organization by drug or biological may lead CMS to arbitrarily exclude from consideration under 1861(t)(2) authoritative compendia that are otherwise reasonable. In short, CMS should not exclude from consideration a compendium as "authoritative" and/or find its exclusion appropriate because it is not indexed by drug or biologic, or because it is indexed by drug and biologic as well as by disease.

Adding versus Revising the List of Approved Compendia

Section 1861(t)(2) of the SSA contemplates revision of the list of compendia in two ways: 1) by allowing the Secretary of the Department of Health and Human Services ("DHHS"), through CMS, to add "other authoritative compendia" to the three listed in the statute, and 2) by allowing the Secretary/CMS to revise the list "as appropriate." Exercising either of these provisions requires interpreting the meaning of the terms: "authoritative" and "as appropriate."

We believe that by separating the provision for *adding* other authoritative compendia from the

provision for *revising* the list of compendia in statute, Congress intended for CMS to establish separate and different processes for accomplishing these actions. Specifically, the use of the words "other authoritative compendia" makes it explicit that the specified compendia are "authoritative" and appears to allow the creation of criteria and a process for adding other "authoritative" compendia. Significantly, because the authority to add compendia already exists, there would appear to be no need to "revise" the list unless the purpose of the revision was to remove one or more compendia from the list. Furthermore, because all compendia on the list must be authoritative, it would appear that the list can only be "revised" when one or more listed compendia become "non-authoritative." Thus, the law appears to allow CMS to establish a process for revising (i.e., deleting) compendia from the list that is different from the process for adding compendia. We discuss this concept, and our recommendation to CMS in implementing this distinction, below.

Criteria by Which the Addition of Compendia Are To Be Judged

Based on language in the Proposed Rule, CMS appears to believe that a clearly articulated process for addressing which compendia should be listed for Medicare coverage purposes is desirable. We agree with CMS' intent that a transparent process is necessary, but we believe that the proposed process is not clear, would take longer than necessary, and could lead to poorly justified and arbitrary decisions.

In particular, we are very concerned by the vagueness in CMS' proposal to apply criteria for determining whether a compendium should be added to the approved list. The Proposed Rule describes the desirable characteristics recommended by the Medicare Evidence Development & Coverage Advisory Committee (MedCAC); we agree that these criteria appear desirable and the majority of which would be appropriate for determining which compendia should qualify as authoritative or otherwise be appropriate under 1862(t)(2).[5] CMS notes, however, that it will "consider a compendium's attainment" of these characteristics, without giving any indication of *how* it will do so.

The Proposed Rule notes that none of the currently designated compendia, and in fact none of the six compendia reviewed by the MedCAC, meet all of its recommended criteria. Thus, it appears that CMS will be compelled to exercise significant judgment regarding which criteria will be considered most important or how they will be weighed. Because CMS has not explicitly indicated in the Proposed Rule whether some characteristics are more important than others, it is unclear if one or more of the characteristics would be considered critical to determining a compendium's candidacy and failure to achieve such critical criteria would automatically disqualify of a compendium for inclusion. While we presume a compendium could fail to exhibit one or more characteristics recommended by MedCAC, yet still be considered acceptable for coverage purposes, we request CMS to clarify this in any relevant final regulations.

The Proposed Rule also states that CMS may consider "additional reasonable factors" in making its determinations without providing specifics of what it might ultimately consider "reasonable." Further, CMS has provided no assurance that it will evaluate all candidate compendia similarly using the same criteria and weighting those criteria identically. For example, CMS proposes to consider a compendium's grading of evidence and the process it uses to determine such grading, yet no detail is provided on how this consideration is to be made or whether it will be applied identically in each case.

[5] We note that one of the characteristics is "quick throughput," the desirability of which and connection to the authoritative character of a compendium, depends, in part, on the definition of "quick."

We recognize that CMS faces a difficult challenge—the number of requests to review additional compendia is likely to be small, the number of possible considerations large, and the ability to clearly articulate *ex ante* a fully developed scheme for review is not a simple task. CMS' current proposal, however, is extraordinarily broad, causing the likely outcomes to be unclear and unpredictable, which could jeopardize beneficiaries' access to medically necessary cancer therapies. Given these circumstances and the severity of unintended outcomes, we think that at a minimum, CMS should articulate for public review and comment its reasoning when determining whether to include a compendium to the approved list. CMS' currently proposed process allows for comment on the requests, but not on CMS' decisions. We urge CMS to revise its proposed procedure to permit public comment on CMS' reasoning relating to any request, generated internally or externally. Specifically, we recommend that, similar to national coverage determinations (NCDs), CMS publish a "proposed decision" for each compendia reviewed and allow the public to submit comments on its proposal for 30 days and then publish a "final decision" 60 days after it has considered those comments.

Lastly, we believe the proposed timeline for CMS to review compendia-related requests is too long. We believe that the entire process can be accomplished in 6 months, similar to the timeline for NCDs and ask CMS to explain why it believes this process should take longer. The proposed timeline for review could be detrimental to Medicare beneficiaries with cancer whose access to life-saving therapies may be in large part dependent on the addition of approved compendia for Medicare coverage purposes.

Process for Possible Removal of Compendia

We believe that the issue of public notice and comment is particularly critical should CMS need to address any request for removal of a compendium. Once compendia are included on the list for use in determining medically accepted indications, they become inextricably linked to not only Medicare coverage, but to how clinicians treat patients and to the standard of care. The two currently listed compendia have been used by Medicare for over a decade and are of central importance in determining treatment regimens and subsequent coverage of off-label uses of anti-cancer therapies. Any compendium subsequently added will similarly become woven into the fabric of clinical and coverage decisions.

We believe that this matter may be particularly concerning because requests for removal of compendia may originate with other compendia for competitive reasons. In our view, the potential for such an occurrence reinforces the need for a thorough, deliberative process that includes identification of the requestor (as CMS has proposed) and the opportunity for public comment prior to removal.

A compendium should be removed from the approved list only after a comprehensive and systematic review and evaluation demonstrates material failures in its reliability as authoritative; after the sponsor has had an opportunity to address any ostensible deficiencies; and after notice to the public and full opportunity to comment on the agency's reasoning has occurred with respect to its proposed removal. We believe that the public's interest would be best served if this notice were accomplished by publication in the *Federal Register.* Removal of any compendium will necessitate revisions of local, and possibly national, coverage policies that is a time-consuming process involving its own notice-and-comment requirements, which CMS should make appropriate accommodation for in its timelines.

Specifically, we advocate the following steps for addressing any request for removal:

- Publication of a notice of request for removal that identifies the requestor, includes the complete text of the request including the reasons why the compendium should be removed, and includes solicitation of public comment on the request;

- Publication of a complete review of the compendium against the criteria used to determine whether a compendium is authoritative and a proposal for its retention or removal from the list. The review should include consideration of any public comments, identify any specific shortcomings and deficiencies of the compendium proposed for removal, and articulate the specific justification for the proposal;

- Allow an opportunity for public comments on the proposed decision and a reasonable period of time (e.g., until publication of the next edition of the compendium) to allow the compendium to cure any cited deficiencies;

- Publication of a final decision, that includes specific reasons for retention or removal, after a review of comments on the proposed decision and a determination as to whether the compendium cured the cited deficiencies; and

- Provision for continued use of the indications in the removed compendium until such time as CMS and its local contractors can develop new coverage determinations that take into account the removal of the compendium.

Because the process for removal of a compendium from the list should be deliberative and thoroughly vetted, a longer timeframe than the 6-month timeline we have proposed for adding compendia is appropriate. The need to allow a compendium to cure any cited deficiencies and to allow CMS and its contractors to develop new coverage determinations, as appropriate, require that the timeframe for removing a compendium from the list should be well over one year and possibly longer depending largely on the compendium's review and publication cycles.

Clarifying When a Use is "Not Indicated" and Therefore Not Covered

Genentech is concerned that CMS, its contractors, and physicians may be interpreting language in the SSA inconsistently with regard to how many compendia, and which compendia, should be included on the list of approved compendia for Medicare coverage purposes. Genentech believes CMS should specify in the Final Rule exactly what requirements must be met for a compendia-listed indication to be covered by Medicare.

Section 1862(t)(2)(B)(ii)(I) of the SSA specifies that if an indication is supported by one citation in one compendium, that indication must be covered by Medicare unless (a) the Secretary makes a determination that the use is not medically appropriate, or (b) the use is specifically identified as "not indicated" in one or more compendia.

Our interpretation of this section of the statute is that a compendium must state specifically that a use is "not indicated" in order for that citation to contradict a listing in any other compendium supporting use. In other words, unless the compendium explicitly uses the terms "not indicated" with respect to a particular use of a drug or biological, the listing in question should be considered a medically appropriate indication and one that is therefore covered. Conversely, if terminology other than "not indicated" is used (such as "not recommended," "recommended in some cases," or "equivocal"), Section 1862(t)(2)(B)(ii)(I) should not apply. "Not indicated" is an

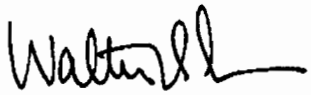
absolute term that conveys to physicians that a use is dangerous and that no benefit is provided by a drug or biological, whereas "not recommended," "recommended in some cases," "equivocal," or other, similar term(s) may mean that the benefits are unknown or may not outweigh the risks. Hence, we believe any citation using words like "recommended in some cases" or "equivocal" satisfies the requirement for a "use that is supported by one or more citations" in a compendium. We request that CMS clarify in the Final Rule that unless a product listing in a compendium explicitly includes the phrase "not indicated," it should be considered medically appropriate and therefore covered under Medicare.

Conclusion

In summary, Genentech appreciates the opportunity to comment on the Physician Fee Schedule 2008 Proposed Rule, and urges the Agency to make the policy recommendations described above. We look forward to working with CMS to ensure coverage and payment for drugs and biologicals, and their related administration procedures, under Part B of the Medicare program is appropriate and does not compromise beneficiary access to care.

Please contact Heidi Wagner or me at (202) 296-7272 if you have any questions about our comments or need additional information.

Sincerely,



Walter Moore
Vice President, Government Affairs

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

Organization : **Andria Whaley**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Andria Whaley

Submitter : Mrs. Jenny Stenehjem **Date:** 08/31/2007

Organization : AANA

Category : Other Practitioner

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
Jenny Stenehjem CRNA
560 Queen's Ct
Moorhead, MN 56560

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

Organization : BayWest Health & Rehab

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

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

Organization : **jose melendez**

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
Baltimorc, MD 21244-8018

Re: CMS-1385-P
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : Dr. Katherine Liao **Date:** 08/31/2007

Organization : Pain Diagnostics Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

**see attachment

CMS-1385-P-14794-Attach-1.DOC

14794

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

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

Organization : **Don VanCurnen**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. 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.
Don VanCurnen

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

Organization : **Kellie Cunningham**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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Thank you for your consideration of this serious matter.
Kellie Cunningham

Submitter : Dr. Alison King **Date:** 08/31/2007

Organization : Procter

Category : Health Care Industry

Issue Areas/Comments

Background

Background

RE: PHYSICIAN FEE SCHEDULE

1. P&G respectfully requests that CMS reevaluate payment rates for two tests used in the diagnosis of osteoporosis: dual energy x-ray absorptiometry (DXA, CPT code 77080) and vertebral fracture Assessment (VFA, CPT code 77082). We recommend that CMS collaborate with outside experts to develop accurate estimates of the work and costs associated with axial DXA and VFA and to revise payment policies. Fair reimbursement to physicians will help ensure appropriate patient access to these preventive services.

We are concerned that current and planned cuts in Medicare payment for DXA and VFA will reduce patients access to secondary and tertiary prevention, causing an increase in bone fractures and associated costs to the Medicare program. The Medicare population accounts for 87% of osteoporosis-related fracture costs in the U.S. (Burge et al. JBMR 2007). Both observational research and modeling studies suggest that increased osteoporosis testing and treatment will produce savings to the Medicare program (Newman et al. JCOM 2003; King et al. Ost Int 2005; The Lewin Group 2007). However, the January 2007 cuts in Medicare payment have already caused physician offices to curtail DXA use and professional development activities related to osteoporosis (survey of ISCD, AACE, ACR, and TES members, April-May 2007).

Restricting the availability of DXA and VFA to imaging centers and hospital outpatient departments may create significant access barriers, particularly among ethnic minorities and rural populations. These barriers include reduced service availability, lack of transportation, increased travel time, referral requirements, appointment scheduling, lengthy intake procedures and waiting (Scheppers et al. Fam Practice 2006; Okoro et al. Prev Med 2005). For mammography, delayed referral was found to be independently associated with patient age over 65 and the presence of more than one chronic illness, both of which are common in patients at risk for osteoporosis (Gimotti et al., HSR 2002). The perception that preventive services are not needed was also a powerful demotivator among lower-income, rural, blacks (Strickland et al. J Rural Health 1996). These challenges are compounded for asymptomatic conditions like osteoporosis.
Reduced access to osteoporosis testing may exacerbate disparities in care. Late diagnosis of health conditions in minority populations often leads to more serious disease outcomes and poorer prognosis. For example, black hip fracture patients have a greater number of comorbid illnesses and longer hospital stays than white patients, and they are more likely than whites to be nonambulatory at discharge (Furstenberg & Mezey J Chron Dis 1987). Black women are also more likely than white women to die following a hip fracture (Jacobsen et al. AJPH 1992).

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

RE: TRHCA SECTION 101(b): PQRI

2. We support the proposal to retain four of the 2007 osteoporosis measures (listed below and in Table 16 of the proposed rule, CMS-1385-P), as well as screening for falls, in the final set of 2008 PQRI measures.
? Osteoporosis Management Following Fracture.
? Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture
? Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older
? Osteoporosis: Pharmacologic Therapy
Incentives for reporting osteoporosis quality measures may help change care patterns, leading to improved screening, diagnosis, and management of osteoporosis.

A considerable body of evidence documents the underdiagnosis and undertreatment of osteoporosis in older women and men (US Surgeon General, Bone Health and Osteoporosis, 2004). Although the relationship between bone density and fracture is stronger than the relationship between cholesterol and heart attack (Marshall et al. BMJ 1996), screening for fracture risk lags. Modest growth in Medicare bone mass measurement followed the expansion of coverage in 1998 (King et al. Ost Int 2005), but growth has attenuated in recent years. In 2002, the US Preventive Services Task Force recommended routine osteoporosis screening in women aged 65 years and older (Ann Int Med, 2002). However, less than 10% of female Medicare beneficiaries received a Medicare-reimbursed DXA test in 2006 (BESS data, CMS ORDI, August 2007).

Separate quality measures for screening and therapy are needed because an osteoporosis diagnosis frequently does not result in treatment (King et al Osteoporosis Int 2005; Pressman et al. Ost Int 2001). Even for high-risk patients who have already fractured (Klotzbuecher et al. JBMR 2000, Johnell et al. Ost Int 2004), treatment is uncommon.

HEDIS data demonstrate the substantial need for improvement in care following fracture. In 2005, only 20% of women in Medicare Advantage plans were either tested or treated for osteoporosis in the six months following a fracture (NCQA, The state of health care quality, 2006, Washington, DC).

3. To promote primary, secondary, and tertiary prevention of fragility fractures, we recommend that CMS specifications for 2008 PQRI measures distinguish DXA testing from pharmacologic therapy. In the 2007 specifications for two of the osteoporosis measures (#40 osteoporosis management following fracture, and #39 screening or therapy in woman aged 65 years and older), the numerator includes both patients with a DXA test ordered and those for whom treatment was prescribed. Separate CPT II codes are used to report these subgroups. Thus, CMS is already collecting data that distinguish which patients are tested and which are treated. We recommend that CMS reporting of 2008 measures include the DXA and treatment subgroups, as well as the total. This will enable better feedback on quality of care in confidential reports to individual providers, as well as evaluation of whether CMS policies or medical interventions differentially affect

testing and treatment rates at the aggregate level.

Thank you for considering these suggestions for strengthening Medicare payment policies and quality initiatives to improve preventive care for patients at risk for fragility fractures.

Sincerely,

Alison B. King, Ph.D.
Public Policy & Government Relations
Procter & Gamble Health Care
607-836-6675

CMS-1385-P-14798-Attach-1.PDF

1-1798

P&G

August 31, 2007

VIA HAND DELIVERY AND E-MAIL
http://www.cms.hhs.gov/eRulemaking

Acting Deputy Administrator Herbert Kuhn
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1385-P; Comments Regarding the Proposed Physician Fee Schedule Rule for Calendar Year 2008

Dear Acting Deputy Administrator Kuhn:

Procter & Gamble appreciates the opportunity to comment on physician payment and quality reporting provisions of the proposed physician fee schedule rule for 2008 (CMS-1385-P).[1] Our comments address provisions affecting the prevention and management of osteoporosis.

RE: PHYSICIAN FEE SCHEDULE

1. P&G respectfully requests that CMS reevaluate payment rates for two tests used in the diagnosis of osteoporosis: dual energy x-ray absorptiometry (DXA, CPT code 77080) and vertebral fracture Assessment (VFA, CPT code 77082). We recommend that CMS collaborate with outside experts to develop accurate estimates of the work and costs associated with axial DXA and VFA and to revise payment policies. Fair reimbursement to physicians will help ensure appropriate patient access to these preventive services.

We are concerned that current and planned cuts in Medicare payment for DXA and VFA will reduce patients' access to secondary and tertiary prevention, causing an increase in bone fractures and associated costs to the Medicare program. The Medicare population accounts for 87% of osteoporosis-related fracture costs in the U.S. (Burge et al. JBMR 2007). Both observational research and modeling studies suggest that increased osteoporosis testing and treatment will produce savings to the Medicare program (Newman et al. JCOM 2003; King et al. Ost Int 2005; The Lewin Group 2007). However, the January 2007 cuts in Medicare payment have already caused physician offices to curtail DXA use and professional development activities related to osteoporosis (survey of ISCD, AACE, ACR, and TES members, April-May 2007).

Restricting the availability of DXA and VFA to imaging centers and hospital outpatient departments may create significant access barriers, particularly among ethnic minorities and rural populations. These barriers include reduced service availability, lack of transportation, increased travel time, referral requirements, appointment scheduling, lengthy intake procedures and waiting (Scheppers et al. Fam Practice 2006; Okoro et al. Prev Med 2005). For mammography, delayed referral was found to be independently associated with patient age over 65 and the presence of more than one chronic illness, both of which are common in patients at risk for osteoporosis (Gimotti et al., HSR 2002). The perception that preventive services are "not needed" was also a powerful demotivator among lower-income, rural, blacks (Strickland et al. J Rural Health 1996). These challenges are compounded for asymptomatic conditions like osteoporosis.

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[1] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed Rule, 72 Fed. Reg. 38122 (July 12, 2007).

Reduced access to osteoporosis testing may exacerbate disparities in care. Late diagnosis of health conditions in minority populations often leads to more serious disease outcomes and poorer prognosis. For example, black hip fracture patients have a greater number of comorbid illnesses and longer hospital stays than white patients, and they are more likely than whites to be nonambulatory at discharge (Furstenberg & Mezey J Chron Dis 1987). Black women are also more likely than white women to die following a hip fracture (Jacobsen et al. AJPH 1992).

RE: TRHCA—SECTION 101(b): PQRI

2. We support the proposal to retain four of the 2007 osteoporosis measures (listed below and in Table 16 of the proposed rule, CMS-1385-P), **as well as screening for falls, in the final set of 2008 PQRI measures.**

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Sincerely,

Alison B. King, Ph.D.
Public Policy & Government Relations
Procter & Gamble Health Care
607-836-6675

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

Organization : **Heather VanCurnen**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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Thank you for your consideration of this serious matter.
Heather VanCurnen

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

Organization : Agawam public school Athletic Trainer

Category : Health Care Professional or Association

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

BRIEF INTRO ABOUT SELF ie. Where you work, what you do, education, certification, etc.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilitics 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,

Timothy Jacques, ATC

Submitter : **Miss. Kristen Dvorzsak** **Date: 08/31/2007**

Organization : **Student at TCU**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Kristen Dvorzsak and I am a sophomore athletic training student at Texas Christian University. I am planning to graduate with a double major in athletic training and education so that I may go on to one day work in a clinic or a high school setting.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
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Sincerely,
Kristen Dvorzsak
Student Athletic Trainer

Submitter : **Dr. David M. Ward** **Date: 08/31/2007**

Organization : **UCSD Medical Center**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Please see attached comment letter.

CMS-1385-P-14802-Attach-1.DOC

August 30, 2007

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

Re: RESOURCE-BASED PE RVUs – PLASMA EXCHANGE

Dear Centers for Medicare and Medicaid Services:

I direct the therapeutic apheresis program at the UCSD Medical Center, where we perform hundreds of plasma exchange (PE) procedures each year in our hospital-based apheresis unit. This treatment modality is used very successfully to manage a range of difficult neurological, hematological, renal and other disorders associated with humoral autoimmunity.

Not uncommonly, patients are referred to our center from as far as 75 to 100 miles away. It would be highly preferable for patients who now must make long trips on a repeated basis for PE procedures to be able to have those treatments provided in a freestanding physician office or clinic. Several of my colleagues, including former fellows now working in communities across the U.S., would like to offer PE in their private clinics. It would certainly be a great benefit to those of our patients who now are forced to travel to UCSD from as far as southern Orange County to have access to a more convenient local apheresis provider.

It is my understanding that CMS has proposed to re-value this procedure with about 10.4 practice expense RVUs. At the current rate of about $36 per RVU, this would translate to a Medicare payment rate of about $375.

I'm not in a position of knowledge to debate how this rate was established, but I can assure you that it is entirely unrealistic for an office-based specialist to provide the technical PE service for $375. Consider our routine costs for a single PE procedure:

Disposable apheresis tubing set (UCSD high volume rate)	$170
Trained nurse operator ($35-40/hr x 4 hr)	$140-160
Miscellaneous supplies (needles, anticoagulant, etc.)	$40
	$350 - 390

That $350 to $390 cost does not include the cost of the blood cell separator equipment spread across its useful life of about 5 to 7 years, or the equipment maintenance contract, or the general office practice overhead expenses that must be included in this resource-intensive medical procedure.

Clearly, a payment amount of around $375 will not allow this resource-intensive, space-consuming procedure to be performed. Therefore, if these 10.4 RVUs are not amended to appropriately reflect all procedure-related costs and overhead costs, you will have effectively assured that physicians cannot establish office-based apheresis to meet the needs of patients in their local communities.

I hope that you can resolve the administrative issue or correct the misinformation that led to this serious understatement of the costs of plasma exchange.

Sincerely,

David M. Ward, M.D.
Medical Director, Apheresis Program
Professor of Clinical Medicine
Associate Medical Director, Kidney Transplantation
University of California, San Diego Medical Center

Submitter : Ms. Kevin O'Sullivan **Date:** 08/31/2007

Organization : Barrington Orthopedic Specialists

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:
My name is Kevin O'Sullivan and I am a clinical based athletic trainer in an outpatient physical medicine rehabilitation facility. As a certified and licensed health care professional, I have enjoyed great success in treating and progressing many individuals with physical deficits.
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,
Kevin O'Sullivan, ATC, CSCS

Submitter : **Dr. Pilar Kirkland** **Date: 08/31/2007**

Organization : **Dr. Pilar Kirkland**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Sample Comment Letter:

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Pilar L. Kirkland, M.D.

Submitter : Mr. Justin Aquines **Date:** 08/31/2007

Organization : National Spasmodic Torticollis Association

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

On behalf of The National Spasmodic Torticollis Association, we are pleased to submit these comments on the Proposed Physician Fee Schedule update for 2008 in general, and particularly on the agency s proposals concerning DRUG COMPENDIA.

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

Organization : **Ashley Cunningham**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

Re: CMS-1385-P
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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.
Ashley Cunningham

Submitter : **Dr. Michelle Plagenhoef** **Date: 08/31/2007**

Organization : **Dr. Michelle Plagenhoef**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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

Thank you for your consideration of this serious matter.

Submitter : Ms. Megan Supp **Date:** 08/31/2007

Organization : Cooper Medical Supply

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Megan Supp and I am a National Certified and NJ State licensed Athletic Trainer. I currently work for Cooper Medical Supply, as their DME Coordinator fitting orthopedic braces. I graduated from Temple University in 2003 with my BS and worked in the traditional athletic training setting for 3 years.

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

Submitter : **Mrs. Stephanie Brening** **Date: 08/31/2007**

Organization : **Mrs. Stephanie Brening**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a board certified and state licensed athletic trainer as well as an instructor at Lee University in Clefeland, Tennessee. In this setting, I work with collegiate athletes on a daily basis. I have a BS degree in althetic training as well as a Masters of Arts in Teaching.

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

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

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

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Sincerely,

Stephanie Brening, MAT, ATC/LAT
Cleveland, TN

Submitter : Mr. Ronnie Whorton **Date:** 08/31/2007

Organization : American Association of Nurse Anesthesthetist

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,

Ronald C. Whorton, CRNA
10065 Hwy 41
Leeds, Alabama 35094

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

Organization : **East Stroudsburg University**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14811-Attach-1.DOC

14811

August 30, 2007

Centers for Medicare and Medicaid Services (CMS)
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Sir or Madam:

My name is Emily Hildebrand and I am currently a professor in the CAATE-accredited Athletic Training Education Department at East Stroudsburg University of Pennsylvania. I am certified by the national Board of Certification® in athletic training and credentialed to practice as an athletic trainer in Pennsylvania through the State Board of Medicine. Currently I am the Head Athletic Trainer for Notre Dame Middle and High School in East Stroudsburg, Pennsylvania. I also work as a per diem athletic trainer for the Athletic Training Program at Coordinated Health located in the Lehigh Valley of Pennsylvania. I am one of the newcomers in this Athletic Training profession and have experienced so much but continue to learn more on a daily basis.

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. With a Masters of Science in Heal Education, I am well aware of this nation's increase in a continued rise in health care costs. 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,

Emily Hildebrand, MS, ATC

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

Organization : Alexandria Orthopaedic Associates

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 14 years working in a clinical setting. I am responsible for the clinical flow and care of our patients in our clinic in rural MN. I have also received my MBA in health care.

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

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

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

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

Sincerely,

Mike Doyle MBA, ATC
Clinical Services Coordinator
Alexandria Orthopaedic Associates

Submitter : **Mrs. Amanda Hanic** **Date: 08/31/2007**

Organization : **Benchmart Physical Therapy**

Category : **Other Practitioner**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please see attached letter in regards to Athletic Training Services in the state of Georgia

CMS-1385-P-14813-Attach-1.TXT

14813

Dear Sir or Madam:

My name is Amanda and I am a certified athletic trainer. I received a Bachelor of Science as well as a Master of Education from one of the top universities in Georgia. Currently, I am employed with Benchmark Physical Therapy, one of the leading therapy clinics in the Southeast as a clinician and a business development manager. I hold a current Georgia license to practice.

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

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

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

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Sincerely,

Amanda R. Hanic, ME.D, ATC/L

Submitter : Mr. Kyle Sturtz **Date:** 08/31/2007

Organization : Gundersen Lutheran

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer at Gundersen Lutheran Medical Center in La Crosse, WI. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

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

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

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Sincerely,

Kyle Sturtz, ATC, CSCS

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

Organization : **Lisa Snyder**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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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.
Lisa Snyder

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

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

The potential for fraud and over-utilization of physical therapy services exists when a referring physician has a financial interest in the ownership of a physical therapy clinic. Many paticnts report that physicians that own their own PT clinic have told them that they have to go to their own facility and cannot receive treatment elsewhere. Please eliminate physical therapy as a designated health service furnished under the in-office ancillary services exeption. In doing this CMS would reducc a significant amount of abusc, overutilization, and fraud. Thank you for your consideration in this extremely important issue.

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

Organization : Luther Midelfort

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dcar Sir or Madam:
Please allow mc to introducc myself. My name is David Webster and I am a certified/licensed athletic trainer. I work for Luther Midelfort in Eau Claire, Wisconsin. Luther Midclfort is a multi-specialty clinic and I work in the Physical Therapy/Orthopedic department. I also work with four area high schools providing out-rcach scrvices to thcir student athletes. I received my Bachelors degree from thc University of Wisconsin-Madison and my Master degree from Michigan Statc Univcrsity.
I am writing today to voice my opposition to the therapy standards and requirements in regards to thc 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 rceeived the proper and usual vetting, I am more concerned that thcse proposcd rules will create additional lack of access to quality health care for my patients.
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Sincerely,
David Webster, ATC/LAT

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

Organization : Florida Medical Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14818-Attach-1.PDF

14818

Karl M. Altenburger, M.D., *President*
Steven R. West, M.D., *President-Elect*
James B. Dolan, M.D., *Vice President*
Vincent A. DeGennaro, M.D., *Secretary*
W. Alan Harmon, M.D., *Treasurer*
Madelyn E. Butler, M.D., *Speaker*
Alan B. Pillersdorf, M.D., *Vice Speaker*
Patrick M.J. Hutton, M.D., M.B.A.,
Immediate Past President

FLORIDA MEDICAL ASSOCIATION, INC.

P.O. Box 10269 • Tallahassee, Florida • 32302 • 123 S. Adams St. • 32301
(850) 224-6496 • (850) 222-8827-FAX • Internet Address: www.fmaonline.org

August 31, 2007

Herb B. Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Room 455-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington D.C. 20201

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

Dear Mr. Kuhn:

The Florida Medical Association ("FMA") is pleased to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Proposed Rule (CMS-1385-P).[1]

The FMA is a professional association representing more than 16,000 physicians on issues of legislation and regulatory affairs, medical economics, public health, education, and ethical and legal issues assistance. The FMA also advocates on behalf of physicians and their patients to promote the public health, to ensure high standards in medical education and ethics, and to enhance the quality and availability of health care. FMA would like to extend its appreciation for the opportunity to comment on the proposed regulations. This letter will comment on the following sections:

- The Sustainable Growth Rate (SGR)
- Geographic Practice Cost Indices (GPCIs)
- Physician Quality Reporting Initiative
- E-Prescribing

[1] Medicare Program, Proposed Rule, (CMS-1385-P). *Federal Register*, Volume 72, No. 133, July 12, 2007, p. 38121.

A. IMPACT: SUSTAINABLE GROWTH FACTOR, BUDGET NEUTRALITY & RESULTING CUTS IN REIMBURSEMENT

The sustainable growth calculation (SGR) methodology continues to be a flawed system for compensating physicians. In order to preserve beneficiary access to care, physicians must receive annual updates that reflect practice expense increases. Inflation affects us each year as we must pay more for office space rent, professional liability insurance, staff salaries, information technology and other medical equipment etc. In this proposed rule, CMS announced its most recent estimate of a 9.9 percent reduction in the conversion factor from $37.8975 in 2007 to $ 34.1456 in 2008. If these cuts begin on January 1, 2008, average physician payment rates will be less in 2008 than they were in 1995, despite substantial practice cost inflation. These reductions are not cuts in the rate of increase, but are actual cuts in the amount paid for each service. **Physicians simply cannot absorb these severe payment cuts and, unless CMS or Congress acts, physicians will be forced to reevaluate their relationship with Medicare and will be forced to avoid, discontinue or limit the provision of services to Medicare patients.** The FMA believes that patient access to health care is negatively impacted by the budget neutrality restrictions of the current Medicare physician payment structure. FMA strongly recommends that the SGR be repealed and replaced with an updated system that reflects changing costs of providing the services such as the Medicare Economic Index (MEI).

While we understand that a complete overhaul of the SGR formula is not possible without congressional action, we urge CMS to exercise its authority to make administrative improvements to the Medicare physician payment system. In particular, we strongly recommend that CMS take steps to re-evaluate the assumed geographic differences in the cost of providing services to assure that payments approach the costs of services provided efficiently by physicians. Consistent with the position of the American Medical Association (AMA), we ask CMS to remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula.

We agree with CMS that physicians' decisions are central to the health care their patients receive, and believe that the task of identifying ways to provide better support for utilization decisions is critical to development of a unified approach for improving quality, avoiding unnecessary costs and reducing overall Medicare program expenditures. We commend CMS for the leadership it has shown in working with physicians and other organizations to build a consensus around quality and efficiency measures.

However, the FMA believes that the Medicare health care delivery and payment systems are seriously flawed. The current systems are dangerously fragmented and promote perverse incentives that encourage both the under and over provision of care. It is critical that the Medicare program become more patient-centered and that it recognize the sanctity of the patient-physician relationship. We urge CMS to consider these issues and the resources required to provide quality care by thoughtfully formulating and clearly delineating policies with meaningful quality measures, appropriate incentives and timely reimbursement for demonstrable success.

B. GEOGRAPHIC PRACTICE COST INDICES (GPCIs)

CMS proposes to update the GPCIs to reflect more recent data. We strongly support this endeavor. We are concerned that the data sets used to calculate geographic adjustment of the components of the fee schedule are inaccurate and outdated. Medicare's physician fee schedule, which specifies the amount that Medicare will pay for each physician service, includes adjustments to help ensure that the fees paid in a geographic area appropriately reflect the cost of living in that area and the costs associated with the operation of a practice. This geographic adjustment is a critical component of the physician payment system. An adjustment that is too low can impair beneficiary access to physician services, while one that is too high imposes unnecessary expenditures on the federal government. We believe that there is good reason to be concerned about the appropriateness and accuracy of the geographic adjustments. Despite several attempts, the FMA has not been able to examine the data used to construct the 2008 GPCIs for Florida. Therefore we are unable to verify that the calculations are accurate. Based on our initial research, we have very real reason to believe that they may not be. We strongly urge CMS, through its contractor, to make the underlying source data available to state medical societies.

We will address each of the three components that make up the GPCIs: (1) physician work; (2) practice expense; and (3) malpractice:

➢ PHYSICIAN WORK GPCI

The physician work GPCI was updated in 2001, 2003, and 2005 using data from the 2000 Census. CMS defines physician work as the amount of time, skill, and intensity a physician puts into a patient visit. We contend that there should be no difference in the work of physicians in different locations regardless of where the work occurs. We also believe that the premise underlying the selection of proxies to establish the relative physician resource cost differences among areas compared to the national average in a market basket of goods is fundamentally flawed. One of the basic premises behind the resource based relative value scale as it was originally conceived is that the relative value of physician work should not vary across geographic regions.

The proposed physician work GPCI does not reflect the 1.000 floor mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) for 2006 and extended in the Tax Relief and Health Care Act of 2006 (TRHCA) through 2007. We understand that the agency does not have the authority to extend the work GPCI floor for 2009 and beyond, but we want to express our strong support of the provision in the Children's Health Assistance and Medicare Protection Act of 2007 (CHAMP), passed by the U.S House of Representatives on August 31, which extends the work GPCI floor through 2009. CMS states in the rule on page 47502 of the proposed rule, (GPCI) "Indices were developed that measured the relative physician resource cost differences among areas compared to the national average in a 'market basket' of goods." We believe that payment errors are related to and a function of the miscalculation of relative physician resource cost differences among areas compared to the national average and inadequate data sources.

On page 47503, Table 6 lists the specific occupation categories used in development of physician work GPCI. The work GPCI is based on a national sample of median hourly earnings of workers in six professional categories: engineers, mathematicians, teachers, social workers, registered nurses, and writers. Even though the proxies have been utilized for more than 10 years they have never been validated. The proxies result in the redistribution of Medicare payments across the country, using locality-based measurements that bear no proven relationship to the salaries of physicians. Physician earnings were not used in the calculation of the work adjuster, for the stated reason that physicians derive much of their income from Medicare payments, and an index based on physician earnings would be affected by Medicare's geographic adjustments. The problem with this theoretical construct is that the earnings of non-physicians have nothing to do with the earnings of physicians.

We understand CMS is obligated to implement the provisions of the Omnibus Budget Reconciliation Act (OBRA) of 1989 that called for 25 percent of the cost of living variation across regions to be incorporated within the fee schedule. The FMA believes the current method for implementing the congressionally mandated adjustment is flawed, and believes the work GPCI floor should be maintained. We recognize that any alternative proposals will have both strengths and weaknesses. If the work GPCI floor is eliminated, we urge CMS to explore more accurate methods of making the adjustment for cost of living variation and select the method that produces the least amount of variation across payment localities.

- PRACTICE EXPENSE GPCI

The practice expense (PE) GPCI is developed from three data sources: non-physician employee wages, office rents and equipment and supplies. Below we address the non-physician wages and office rent components respectively.

Non-physician Medicare allowable employee compensation

Employee wage data employed by CMS continue to be based on the 2000 Census. To calculate an employee price adjuster, CMS uses the median hourly earnings of four occupational classes found in physician offices: Clerical Workers, Registered Nurses, Licensed Practical Nurses, and Medical Technicians.

While salary data on these four occupational codes CMS utilizes are conveniently available nationwide, much has changed in medicine since the four occupational codes were selected. Non-physician staff salaries have migrated towards more highly compensated professional staff. As a proxy measure the data do not include or account for the variations in costs related to the most highly compensated employed staff: advanced practice providers, physician assistants, administrators, managers, IT programmers, attorneys, accountants, coding and other specialists – many of whom must be recruited from the national, higher priced, market.

FMA asserts that small differences between proxy measurements and the real cost of providing services leads to large differences in payment to Medicare providers throughout the country. We believe that the failure of proxy measurements to reflect the actual cost of providing services has undermined the accuracy of payments for services in different localities

nationwide. We recommend that CMS revise its employee wage proxy categories to establish more accurate measures of the employee wage costs.

Rent Component

Office rents will be calculated in 2008 using HUD rents in the 50th percentile for the physician office rent proxy. We appreciate CMS's acknowledgement that there is a persistent trend toward higher rents across the country. We feel this is especially true in areas at risk for natural disasters, like the vast majority of counties in the state of Florida. These extra costs must be considered in order to assure there is a sufficient supply of Medicare providers, especially in vulnerable areas.

We feel it absolutely essential for CMS to use a dataset that more accurately captures the cost of commercial rents. In general, the HUD residential proxy for commercial rent adequately captures geographic variation in the price of land. It does not, however, reflect the property tax crisis that Florida physicians face and the property insurance crisis that coastal physicians face. In addition, the GPCI formula fails to consider a critical cost in Florida and throughout the Gulf Coast. Specifically, physicians who are not employed by a health care system must prepare for a hurricane-based interruption. Our estimates indicate business interruption insurance functions as an additional 4-5.5 percent increase in office rent.

The HUD fair market rents increased from 9.1 percent (rest of Florida) to 27.4 percent (Fort Lauderdale) from 2004 to 2007. Our projections show increases for triple-net commercial leases and owner-occupied practices that range from 21 percent to 42 percent. Thus, the 2008 GPCI will fail to compensate the vast majority of Florida physicians for rising office rent.

The failure of the practice expense GPCI to fully capture higher building insurance payments, increasing property tax levies and the current business interruption insurance has a sizeable impact. In fact, our projections show the true Rest of Florida practice expense GPCI could be as high as 104.2 rather than the proposed 93.7.

Without a supplemental appropriation for physicians facing the property tax and insurance crisis, we believe access to physician services will suffer. The proposed PE GPCIs will further induce Florida physicians to stop participating in the Medicare program and potentially result in a shortage of quality providers and reduced patient access.

➢ MALPRACTICE (MP) GPCI

Malpractice premium increases are a major driver in the GPCI increases in the Miami-Dade locality. As mentioned above, the FMA has not been able to examine the data used to construct the 2008 GPCIs for Florida to see how the Miami-Dade malpractice data compare to that of other Florida counties.

➢ PAYMENT LOCALITY STRUCTURE

The Medicare statute requires that physician payments be adjusted for certain differences in the relative costs among areas. CMS has expressed concern about the potential impact of increased variations in practice costs within payment locality boundaries, and has studied potential alternatives for several years. CMS is also concerned about the potential redistributive effects of locality changes, given that by statute; changes must be applied in a

budget neutral manner. The FMA shares CMS' concerns about the redistributive effects of locality changes, and does not support taking from one locality to give to another.

However, as demonstrated by the U.S. House of Representative's passage of the Children's Health Assistance and Medicare Protection Act of 2007, member of Congress are willing to dedicate new monies to resolve the GPCI problem in California. The FMA believes that this philosophy, i.e. forgoing budget neutrality, should be extended to any and all necessary country-wide, GPCI improvements.

The agency has identified possible locality reconfigurations to be adopted for California in this proposed rule. CMS would like to study the impact of such a change in California before considering applying the policy more broadly. We feel that although this may be a worthy endeavor, it is premature to consider expanding any of the three options under consideration for California nation-wide given the serious inadequacies of the data used to calculate geographic differences in physician work and office practice expense.

Clearly, proposed options 1 and 2 will not provide any assistance to counties in Florida. These options are based on the premise that "if a county geographic adjustment factor (GAF) is more than five percent greater than the GAF of the locality in which the county resides, it would be removed from the current locality." Florida has no counties that meet this criterion, and only one county (of 67) -- Miami-Dade in locality 04) whose county GAF is greater than five percent above the other county's GAFs. Therefore neither of these options is applicable to Florida. Option 3 involves an interesting concept: grouping counties within a state into localities based on similarity of GAFs even if the counties are not geographically contiguous. We believe many of the current Florida locality groupings were created for administrative convenience, and may in fact, be to the detriment of Florida physicians. Assuming CMS can identify valid data and measurements for physician work, practice and malpractice expenses, we believe localities should be established based on practice costs and not dictated by which option is the least administratively burdensome for CMS.

C. PHYSICIAN QUALITY REPORTING INITIATIVE TRHCA SECTION101(b): PQRI

FMA urges the Administration to access the $1.35 billion Physician Assistance and Quality Initiative Fund to help offset the negative 2008 payment update. Financing for quality reporting should come from a distinct, separate financing mechanism that is outside of the budget neutrality provision and focused solely on the improvement of health care quality.

We believe that its decision to apply the $1.35 billion available in the Physician Assistance and Quality Improvement Fund to buy down the deleterious effects of the 9.9 percent payment cuts scheduled to take effect Jan. 1, 2008 is counter to the intent of Congress and the recommendation of the Medicare Payment Advisory Commission. CMS should overcome the "legal and operational" problems associated with applying the funds to the negative update, as the dire situation posed by the harmful cuts surely prevails over the administrative hurdles. For example, CMS could explore applying the $1.35 billion to past year's SGR debt.

FMA's members are committed to achieving excellence in care for all of their patients. We commend the dedicated and competent CMS staff that has worked diligently to implement a system for reporting data on quality measures area, as required by the statute. FMA is

concerned however, that the process for developing the 2008 Physicians Quality Reporting Initiative (PQRI) is advancing despite the very short time the 2007 PQRI has been operational. Furthermore, we are concerned that the program is going forward without any attempt to evaluate the most basic elements of the 2007 PQRI program, such as impact on patient care, physician participation rates, and implementation costs. While we understand that CMS is required by the Tax Relief and Health Care Act of 2006 (TRHCA) to implement the 2008 program, we urge the agency to use its discretion to closely review the 2007 program before moving ahead.

FMA also is concerned that the requirement that measures for the 2008 program be developed "through the use of a consensus-based process" is too broad. For any reporting system to improve quality, the measures must be meaningful to clinical care and relevant to the specific specialty physicians. Therefore, direct physician involvement in the development, testing and implementation of quality measures is the only way to ensure measures are appropriate and clinically-relevant. While we appreciate that the proposed rule recognizes the American Medical Association's Physician Consortium for Performance Improvement (AMA-PCPI) as a source for the development of quality measures eligible for inclusion in PQRI 2008, we urge CMS to go further and consider the AMA-PCPI as the only entity appropriate for the development of physician-level quality measures. The AMA-PCPI process is consensus-based and is physician-led. This characteristic will ensure physician buy-in on measures which is essential for an effective quality reporting program. Further, tasking the AMA-PCPI as the only group for developing physician measures significantly reduces the risk of duplicative or contradictory measures and ensures measure harmonization.

D. PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

The E-Prescribing and the Prescription Drug Program final rule published in the November 7, 2005 Federal Register (70 FR 67568) established standards for the electronic transfer of information in the context of the Medicare Part D Prescription Drug Program. CMS correctly recognized that many physicians using electronic medical records (EMRs) did not yet have direct/interfaced e-prescribing functionality, so they exempted computer-generated facsimiles (faxes) from the specific data transfer standards or "scripts".

This allowed the 15-20 percent of physicians using electronic health record (EHR) to continue generating fax prescriptions. The evolution of the process saw written paper, then fax/ printer, computer to fax, and now interactive computers. Pharmacies finally have the capability for those systems. These improvements in technological capability and new standards and programs rendered older systems incompatible with newer ones, and required significant investments to upgrade. Now a very limited number of prescription programs (e.g. SureScripts) have integrated software connecting newer vendor programs to pharmacies. This has created an interfacing challenge for the large number of diverse electronic medical record programs implemented over the last 15 years. CMS now proposes to eliminate the computer-generated fax/prescriptions exemption for ALL provider/dispenser transactions, effective one year from the issuance of the CY 2008 physician fee schedule final rule. This will have a dramatic effect on the industry, but not as CMS intends. In the approximately 18 months since the standardized prescription system was set up, physicians have not kept up with government

expectations in the acquisition of electronic capability, and we estimate that only a small portion of the 15-20 percent already online have interfaced, computer to computer eRx. The disparate timing of pharmacy standards and implementation with the upgrading required by the 150,000 physicians involved makes the current deadline unrealistic. The main barriers for these EHR-legacy practices are cost and change management, including physician/provider relationships with the vendor. Many vendors are no longer in business or were acquired by others, resulting in changes to their programs and accordingly, to maintenance contracts.

In the proposed rule, CMS implies that practices will "revert to paper" (prescriptions) once the exemption is withdrawn. Many practices may very well do so, especially those that handle a significant number of patients requiring Schedule II drugs, as there is still no legal option for electronically transmitting Schedule II drug prescriptions. These offices may in fact choose to use paper for all Medicare beneficiary (and other patient) prescriptions due to administrative and financial considerations. CMS concedes that this can result in data entry errors and may negatively impact patient safety. Also, patients will be burdened with making extra trips to their physicians' offices to pick up their paper prescriptions, which could be detrimental to patient compliance. In CMS' own words, this result would be "counterproductive to achieving standardized use of non-fax electronic data interchange for prescribing." We predict that Medicare providers may follow the example of so many Florida physicians who have decided not to participate in the Medicaid program due to administrative hassles such as this and low reimbursement. We are concerned that opting out of Medicare will become a viable option for providers if CMS attempts to "accelerate" eRx adoption by penalizing those providers who have already made an investment in expensive IT systems.

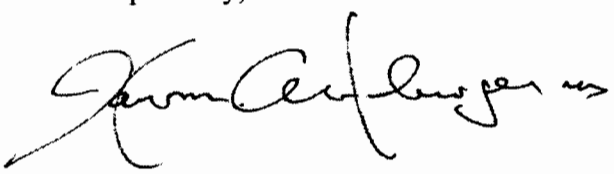
CMS rightfully understands that electronic file scripting will be more efficient, will eliminate mistakes due to illegibility, and will save money with formulary changes. However, the only advantage to the physician is that the file is automatically tied to the chart. Vendors believe that, at best, only 50 percent of practices can be ready by 2009. The Institute of Medicine (IOM) recommended a timeline of 2010. As of yet, no state has addressed the legality of Schedule II drugs in this format either. We suggest that CMS proceed with the late 2008 deadline for computer-generated e-file for newly-installed EMRs. For those Medicare providers with legacy systems, an additional year should be granted to comply with the IOM recommendations. FMA believes this will compel EMR vendors to develop affordable eRx upgrades etc., allow more physicians to make this transition and realize the ultimate financial and safety benefit for their patients.

CONCLUSION

FMA appreciates the opportunity to comment on this proposed rule. As a concerned group of agency constituents, our comments seek to provide CMS with actionable input to help ensure ongoing access to high quality, efficient provision of Medicare services in the state of Florida. We hope that our comments highlight our sincere interest in working with the Agency to ensure care is cost effective, properly reimbursed and readily accessible to Medicare

beneficiaries. Should you have any questions on the items addressed in this comment letter, please contact red Whitson, FMA Director of Medical Economics, 800-762-0233, fwhitson@medone.org.

Respectfully,



Karl M. Altenburger, M.D., President

cc:
Rick Ensor
Edith Hambrick
Stephanie Monroe
Drew Morgan

Submitter : **Miss. Kristin Bruce** **Date: 08/31/2007**

Organization : **Miss. Kristin Bruce**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer that works in the secondary school setting. I have a bachelor s degree in Kinesiology from California State University of Fullerton. I provide our students with emergency care,rehabilitation, and am responsible for the prevention of injuries. Most of our students wouldn t receive any rehabilitation for their injuries because their insurance doesn t cover it or their parents cannot afford it.

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,

Kristin Bruce, ATC

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

Organization : **Travis Snyder**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Travis Snyder

Submitter : **Ms. Brittany Richards** **Date: 08/31/2007**

Organization : **Physical Therapy Plus**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1385-P-14821-Attach-1.DOC

14821

Mr Kerry N. Weems-Administrator/Designate
Centers for Medicare and Medicaid Services
U.S. Dept of Health and Human Services
Attention: CMS-1385-P

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule and other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems:

My name is Brittany Richards and I am a physical therapist working as a clinic director in an outpatient/orthopedic private practice setting. I have my Doctorate in Physical Therapy and have been practicing for nearly 3 years. The clinic is located in a very populated area with 3 local hospitals and several other physical therapy clinics in close vicinity. I am writing in regards to the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self referral and the "in-office ancillary services" exception.

The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician owned physical therapy services (POPTS). My clinic has seen the effects of POPTS and the negative impact it has on private practice clinics. At the end of 2006 I was informed that one of our strongest orthopedic referral sources was starting their own physical therapy clinic. The owners of my clinic were initially approached to assist in this however they declined due to our current stance and the stance of the APTA against POPTS clinics. Since this time we have lost approximately 30% of our business which has placed significant financial burdens on our clinic. In other circumstances I have seen patients in the past who have felt that they were strongly urged to go to the office that was recommended by their physician (the physician owned physical therapy services). They were unaware of their freedom to choose their physical therapist as a healthcare provider. Due to the repetitive nature of physical therapy services it is no more convenient for the patient to receive services in the physician's office than an independent physical therapy clinic. Physician direct supervision is not needed to administer physical therapy services. In fact, an increasing number of physician owned physical therapy clinics are using the reassignment of benefits laws to collect payment in order to circumvent "incident-to" requirements. I believe this is a way for physicians to exercise power through coercion. I do not feel that the best interest of their patients is

always in mind. This type of arrangement hurts not only the profession of physical therapy but ultimately the patients and the public.

In closing, I hope the above information has been helpful and presented in a fashion that clearly describes my viewpoints and opposition to the current practice of physician owned physical therapy practices. I would like to thank you for your consideration of my comments.

Sincerely,

Brittany Richards PT, DPT
Clinic Director-Physical Therapy Plus (St Matthews)
4121 Dutchmans Lane Ste 608
Louisville, KY 40207
(502) 896-6686

Submitter : Mrs. CAROL PANZA **Date:** 08/31/2007

Organization : Mrs. CAROL PANZA

Category : Nurse

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

I SUPPORT A RAISE IN THE ANESTHESIA CONVERSION FACTOR TO IMPROVE ACCESS TO CARE FOR MEDICARE BENEFICIARIES.

CMS-1385-P-14822-Attach-1.DOC

11822

William S. Panza, MD
New Bern Anesthesia Associates
2719B Neuse Blvd
New Bern, NC 28562

August 31, 2007

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

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

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am a retired nurse and medicare beneficiary from Emerson, NJ. 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. I am concerned that I will have limited access to anesthesia services as a Medicare beneficiary. I support the increase in the Medicare payment for anesthesia services. The current amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists, including my son, 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 we have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Carol Panza

Submitter : **Mr. Stephen Comess** **Date: 08/31/2007**

Organization : **United Anesthesia Services, PC**

Category : **Individual**

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Stephen E. Comess

Submitter : **Dr. David M. Ward** **Date: 08/31/2007**

Organization : **UCSD MEDICAL CENTER**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

See attached comment letter.

CMS-1385-P-14824-Attach-1.DOC

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

Organization : **University of Colorado**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing as Chairman of Anesthesiology the only academic center in the region and as such we see a disproportionately large percentage of Medicare patients. Therefore, I wish 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.

Because we currently take another financial penalty with the anesthesiology teaching rule, the proposed increase is doubly important to the seniors of our Rocky Mountain region seeking advanced medical care at the University.

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.

Thomas K. Henthorn, M.D.

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

Organization : **Paul Elms**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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Thank you for your consideration of this serious matter.
Paul Elms

Submitter : Mr. Martin Hendricks **Date:** 08/31/2007

Organization : National Athletic Trainers Association

Category : Other Technician

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam:

I have been a healthcare worker for almost 20 years. I have progressed from Basic EMT to Right hand of Orthopedie Surgeons. My background and experience doesn't fit neatly into one catagory, but I do fit most certainly in my position in the hospital and clinic setting I work. Nobody else can do my job, and the patients I care for can not get the care they need without me. It has taken years to develop the capabilities I possess to meet the needs patient's require, even if those capabilities don't fit into the compensible fee schedules catagories you are proposing.

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.

Please reconsider this proposal and consider the impact it would have on the availability of services in our healthcare system, knowing there are shortages in the areas only those like me can fill. I am not a luxury item. I am the interchangable part that enables the machine to continue working.

Sincerely,

Martin J. Hendricks, ATC, OTC, RMA

Submitter : **Ms. Margaret Boiano** **Date: 08/31/2007**

Organization : **VNUS Medical Technologies Inc**

Category : **Device Industry**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Please see below attachment!
Thank-You!
Margaret Boiano
Director of Reimbursement

CMS-1385-P-14829-Attach-1.DOC

14829

VNUS®
MEDICAL TECHNOLOGIES, INC.

August 29, 2008

Via Electronic

Herb Kuhn, Acting Deputy Administrator
Attention: **CMS-1385-P; PE RVUs Methodology Section**
Centers for Medicare and Medicaid Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850
http://www.cms.hhs.gov/eRulemaking

CMS-1385-P: Proposed Revisions to the Physician Fee Schedule for Calendar Year 2008

Dear Mr. Kuhn,

On behalf of VNUS Medical Technologies, Inc. (VNUS), we are pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed changes to the Practice Expense methodology and how it will impact the physicians using our technology specifically to:

Practice Expense RVUs for CPT codes 36475 and 36476

VNUS is a manufacturer of the technology used in endovenous ablation therapy of incompetent veins (e.g., varicose ulcers and venous insufficiency). For elderly Medicare patients; this is a crucial therapy to reduce painful swelling in the legs, restore mobility and function, and enable patients to regain and enjoy a high quality of life.

We agree with the beliefs of CMS to maintain the integrity of the physician fee schedule. In addition, to the continual need for improvements in the system for calculating the payment of the services rendered. However, we are still concerned about the accuracy on the proposed PE RVUs for CPT Codes 36475 and 36476 for the Endovenous Radiofrequency Ablation Procedures.

- **36475-** *endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency, first vein treated*
- **36476-** *endovenous ablation therapy ..., inclusive of all imaging guidance ..., second and subsequent veins treated in a single extremity through separate access sites.*

Since both of these codes were just established in 2005 and reflected accurate PE expenses; we encourage CMS to use the more appropriate 2006 PE RVU values for 2008 and the transition period.

As stated, in our previous comment letters, on both the proposed and final revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and the Five-Year Review of Relative Value Units, we believe these cuts are misvalued and do not truly reflect the cost associated in doing these procedures.

Further reductions in the PE RVUs could jeopardize patient access to this beneficial medical procedure. The proposed non-facility practice expense reduction could also translate into more costs for CMS by dis-incenting MDs from performing these procedures in the less costly non-facility setting as compared to the hospital outpatient setting. Vascular Surgeons, General Surgeons and Interventional Radiologists in particular will be impacted negatively given the combined impact with the proposed rule to reduce the PE RVUs and the effect of reducing the conversion factor by 9.9% in 2008.

We are concerned about the accuracy and decrease in PE RVU calculations for the RF ablation procedures (CPT 36475 and 36476) for the following reasons:

⇒ Compared to older existing CPT codes PE values, modified under the new payment methodology, based on the five year review, the 2006 PE RVU for 36475 & 36476 are more refined and indicate the most accurate PE data available to date for these procedures.

- In 2005, CMS reviewed and accepted, the RUC recommendations on the practice expense for these newly established codes listed in the table titled "*AMA RUC and HCPAC RVU Recommendations and CMS Decisions for New and Revised 2005 CPT Codes.*" 2005-CMS-1429-FC-Refinement of Relative Value Units for Calendar Year 2005 and Interim Relative Value Units for 2004.

- Addendum B and C in the forgoing rule listed the 2005 Relative Value Units for CPT codes 36475 and 36476 which became effective January 1,2005.

- The Practice Expense Subcommittee of the RUC survey process considered and recommended the payment adequacy from the appropriate submitted data when CPT codes 36475 & 36476 were established for 2005. In CY 2006 the PE RVUs were maintained at 2005 PE values level.

- CPT codes 36475 and 36476 was not on the list of CPT codes, to be reviewed by the different specialties societies for the 5-year PE RVUs review, nor was it considered for analysis, since they were recently assessed by RUC and accepted by CMS.

⇒ The proposed changes for 36475 & 36476 has resulted in significant reductions in the PE values and is well below the average PE RVUs reduction range for CPT codes.

Code	2006 Non-Facility PE RVUs	CMS Proposed 2008 Non-Facility PE RVUs	CMS Proposed 2010 Non-Facility PE RVUs	2006 vs. 2010 total % variance	2006 Facility PE RVUs	CMS Proposed 2008 Facility PE RVUs	CMS Proposed 2010 Facility PE RVUs	2006 vs. 2010 total % variance
36475	51.54	43.52	35.43	(31%)	2.54	2.22	1.88	(26%)
36476	7.9	6.96	6.09	(23%)	1.14	1.00	.83	(27%)

⇒ It is unclear what data CMS used to revalue the PE expenses for CPT 36475 and 37646 for CY 2007 through 2010, since the PE RVU for 36475 & 36476 were appropriately valued so recently by RUC in the 2005 PE RVUs.

⇒ For CPT codes 36475 and 36476, a significant portion of the non-facility practice expense is related to office clinical staff and disposable supplies used for each procedure.

⇒ These cuts in reimbursement will make it financially less practical for physicians to perform these safe and effective procedures in the office setting. Ultimately resulting in more patients treated in the hospital setting, which will be more costly to Medicare due to the sum of cost to pay APC- facility related reimbursement fees plus professional fees to physicians.

Recommendation:

Revise the PE RVUs for 36475 and 36476 to reflect the accuracy of the costs of doing these procedures. VNUS strongly recommends that CMS correct the proposed undervalued reductions in PE RVUs for endovenous procedures described by CPT codes 36475 and 36476 by using the more appropriately 2006 PE values for 2008 and the transition period.

CPT	Description	2006 Non- Facility PE RVUs	2006 Facility PE RVUs
36475	Endovenous RFA, 1st vein treated	51.54	2.54
36476	Endovenous RFA, vein add-on	7.9	1.14

The 2006 values closely reflect accurate PE expenses then the proposed PE calculations cost data related to this technology.

Using the 2006 values falls more in line with how CMS is calculating new codes PE RVUs during this period, as stated on page 46 of CMS-1385-P ..."*PE RVUs for codes that are new during this period will be calculated using only the current PE methodology and will be paid at the fully transitional rate.*"

Since the goal is to advance the accuracy of Medicare's payments and achieve better value for Medicare spending. We urge CMS again, to avoid changes that could drive more patients to the hospital setting because of financial/reimbursement considerations, especially when the procedures can be safely furnished in a more cost-effective manner in the office setting.

As stated in the MedPac June 2007 report to Congress; Promoting Greater Efficiency in Medicare, "*.... when services are misvalued, Medicare is paying too much for some services and not enough for others and therefore is not spending taxpayers' and beneficiaries' money wisely.*"

Should you have any questions, please contact me at 408-360-7560 or Gail Daubert at 202-414-9241.

As always, thank you for your consideration.

Sincerely,

Margaret Boiano
Director of Reimbursement
VNUS Medical Technologies, Inc.

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

Organization : **Gladys Deason**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Gladys Deason

Submitter : Mr. Scott Rouse **Date:** 08/31/2007

Organization : Hardin Memorial Hospital

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer that works for Hardin County Board of Education and Hardin Memorial Hospital. I have worked in the collegiate setting for athletic training and clinical/high school. I have two Master's degree's; one in Sports Administration and the other in Teaching. During my time in the secondary school setting I have been able to help many high school students receive proper treatment of their injuries while working with Hardin Memorial Hospital. I have been a certified athletic trainer for 13 years and enjoy working in the clinical setting.

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

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

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

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

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

Sincerely,

Scott Rouse, ATC, MASE, MAT

Submitter : **Mrs. Sandra Alevras** **Date: 08/31/2007**

Organization : **Lake County Physical Therapy**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please read attachment. Thank you.

CMS-1385-P-14832-Attach-1.DOC

14832

August 31, 2007

Mr. Kerry Weems
Administrator Designate
Centers for Medicare & Medicaid Services
US Dept. of Health & Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: Physician Self Referral Issues, Medicare Program

Dear Mr. Weems:

I appreciate you taking the time to read my opinions regarding this issue. I am the office manager for Lake County Physical Therapy and have had the opportunity to speak with a high number of patients on a daily basis. I am quite concerned with some of the comments that our patients have made regarding this very issue.

It is not uncommon for a patient to ask me when scheduling an appointment, is it okay to come to you? My doctor said I have to go where he sends me. I always explain to a patient that they have the right to go where they want for therapy. Our returning patients know they can come to us and we have a high percentage of returning patients who would never think of going elsewhere because of the care they receive from us.

I take the phone calls for six locations and have had patients tell me after returning to their physician that their physician wants them to only go to a specific place for therapy so they need to cancel their appointment.

I also do a follow up calls with all our patients to see how therapy is going. So often I will be told by patients that they really like coming to therapy. Where they went before the people were cold and didn't have them doing all the exercises we do. They have said they didn't feel they were getting better the last time they went to therapy elsewhere.

Physicians who do have relationships with us who have their own therapy only sent us the lowest paying cases. They like to keep the best for themselves – of course!

This really has to be about the patient, not the physicians. A new patient will go where a physician tells them to go. They need to trust their doctor and they feel that person would not do anything to harm them. Patients who have had therapy before question more. Some may have been to a facility they like and will challenge the doctor on this point. Patients should NOT BE BULLIED into making decisions that are not always in their best interest because they are seen as dollar signs.

I implore you and all those in the legislative bodies to do what is right for the patient, to stop this abuse and see the patient as a human being with feelings, emotions and needs that have a right to get the best care possible.

Thank you for your time.

Sincerely,

Sandra Alevras

Submitter : **Mr. Ron Hutchins** **Date: 08/31/2007**

Organization : **Wooster School**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a licensed athletic trainer working at an independent school in Danbury, Connecticut. I have a BS degree in Sports Medicine: Athletic Training as well a MS degree in Health Promotions: Performance Enhancement and Injury Prevention. I presently hold the certification of Certified Athletic Trainer from the National Athletic Trainer's Board of Certification as well as the advanced certification of Performance Enhancement Specialist from the National Academy of Sports Medicine. However much of my practice concerns athletic health care and the reason I write you is my concern over the suggested CMS changes.

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

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

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

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

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

Sincerely,

Ron Hutchins MS, LATC, PES

Submitter : Dr. Daniel Duvall **Date:** 08/31/2007

Organization : Riverbend GBA (FI)

Category : Physician

Issue Areas/Comments

CORF Issues

CORF Issues

Some CORFs historically have focused on Wound Care or Pulmonary Rehabilitation, with the majority of their services and revenue coming from RN services or the three Pulmonary Rehab services, respectively. The CFR specifies that CORFs must provide the full range of core services. It remains unclear whether "specialization" of the CORF, in which 90+% of the services are deliviered to a rehab subgroup (Pulmonary Rehab) or a non-rehab subgroup (wound care), is prohibited by the CFR. Could you clarify your modifications of the discussion of respiratory services and RN services to unambiguously address your intent with respect to this situation? Thank you.

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

Organization : **Othel Deason**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Othel Deason

Submitter : **Dr. Omeed Khodaparast** **Date: 08/31/2007**

Organization : **American Society of Anesthesiologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Thank you for your consideration of this serious matter.

Submitter : Mrs. carol Lee **Date:** 08/31/2007

Organization : AANA

Category : Other Practitioner

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
Carol Lee crna
Name & Credential
3415 Rivershore Drive
Address
Moorhead, MN 56560
City, State ZIP

Submitter : Miss. Melissa Fuller **Date:** 08/31/2007

Organization : American Kinesiotherapy Association

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14838-Attach-1.PDF

14838

American Kinesiotherapy Association
118 College Drive #5142
Hattiesburg, MS 39406

August 30, 2007

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

COMMENTS ON THERAPY STANDARDS AND REQUIREMENTS

Dear Sir or Madam:

The American Kinesiotherapy Association (AKTA) is pleased to submit comments on CMS-1385-P - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008; which was published in the Federal Register Vol. 72, No. 133 (July 12, 2007). These comments will address our concerns with: the justification given for the proposed changes; the process by which the proposed changes were developed and presented; and the potential impact of enacting the proposed changes.

Justification for the proposed changes?
The Centers for Medicare and Medicaid Services (CMS) have not provided any justification for these sweeping changes that are proposed. These changes are not demanded to achieve quality or lack of quality. They are not demanded in order to improve access to services and, in fact, will have a detrimental effect on access. CMS has not given any economic justification for these changes nor has it addressed the economic impact on either the hospitals or other rehabilitation facilities nor, we believe, the potential increase in cost to Medicare. In the case of rural health clinics, CMS appears to be creating a whole new set of services.

There is no compelling law mandating these changes. These changes are not necessary to interpret the law and CMS has failed to identify any "compelling public need" for this change. In fact, the proposed changes in the physical therapy standards can best be described as a "solution in search of a problem." Even if there were a compelling reason, CMS has created a set of rules so complicated and convoluted that they are practically unenforceable. These rules will place significant burden on the hospitals, rural health clinics and other rehabilitation facilities with no return on investment.

While CMS cites a need to update standards for physical therapists and physical therapy assistants, there is no need for this. The current standards contained in the Hospital Conditions of Participation (COP), as well as outpatient therapy standards, are consistent with state law and staff models of rehabilitation facilities, both those that operate under Medicare parts A and B reimbursement schemes. Employers—including hospitals—are concerned that the degree creep in the physical therapy profession (which moves physical therapists to a three-year clinical doctorate degree) only succeeds in increasing salaries and driving up costs. This degree creep also limits the current and future physical therapy workforce and supports the American Physical Therapy Association's (APTA) primary agenda and stated goal of direct access, which is opposed by MedPAC.

CMS states that it wants to develop a consistent definition of for physical therapists (PT) and physical therapy assistants (PTA). This should not be confused with the existing definition of "physical medicine and rehabilitation practice" which is much broader than simply these two

provider types. What CMS proposes with these rules is well beyond a consistent definition of PT or PTA, but serves to define an entire field of medicine on the basis of one or two allied health provider classifications. The end result is that CMS is seriously limiting the ability of hospitals and other providers to hire appropriate staff for the delivery of physical medicine and rehabilitation services. If CMS wants to have a consistent definition of PTs and PTAs, it only needs to defer to state law, which fully defines these professions.

Process through which the proposed changes were developed and presented
The AKTA checked with some of the members of Coalition to Preserve Patient Access to Physical medicine and Rehabilitation Services and none had been consulted on these proposed changes. To the best of our knowledge, no groups outside of the APTA and AOTA were consulted. This is a serious oversight, bordering on negligence on CMS's part. Similarly, the hospital rehabilitation administrators we spoke with were unaware of these proposed changes. If the providers and facilities were not consulted, who was? Is CMS even aware that Kinesiotherapists are widely employed outside of Veterans Hospitals? Is CMS aware of the many groups of well qualified and credentialed specialty therapy providers, which includes athletic trainers, lymphedema therapists, balance medicine specialists and others? The AKTA anticipate serious, negative unintended consequences that will affect both patient access to PM&R services and the quality of services they receive.

Not all CMS-statutorily recognized health professionals are state licensed or certified. When this occurs, CMS has typically established coverage standards in consultation with the appropriate professional associations representing those health professionals for both licensure and non-licensure states. This combination of deferring to state licensure requirements and consultation with all affected provider groups generally works well, especially in a time of workforce shortages. This also allows for the flexibility needed in local staffing models, and the growing demand for highly-trained specialty providers. CMS clearly did not consult with physical medicine and rehabilitation (PM&R) physicians and other rehabilitation providers outside of the physical therapist lobby.

This is particularly egregious because it has buried Medicare Part A changes in what is typically viewed as Medicare Part B sections of proposed rules. Is it CMS's goal to prevent any health professional other than a physical therapist from providing physical medicine and rehabilitation services? If this is the case, under what statutory authority have you pursued this objective? Is there no role in rehabilitation for highly trained and educated specialty therapy providers—only generic physical therapists? Is there no role for a kinesiotherapist to continue working with wounded veterans to build the strength and endurance necessary to learn how to walk because his legs have been lost because an Improvised Explosive Device exploding underneath his truck?

What AKTA finds most disturbing about this apparent oversight is that the changes that CMS is now promulgating develop policies for reimbursement (and de facto, practice) that align directly with the Vision Statement of the American Physical Therapy Association, which reads in part that physical therapy

> ..."will be provided by physical therapists who are doctors of physical therapy and who may be board-certified specialists. Consumers will have direct access to physical therapists in all environments for patient/client management, prevention, and wellness services. Physical therapists will be practitioners of choice in patients'/clients' health networks and will hold all privileges of autonomous practice..."

Since the AKTA was not consulted by CMS in the development of the proposed rules, we must question whether this proposal has gone through any of the normal vetting process, either

associated with the Hospital Conditions of Participation or other requirements related to quality. The AKTA questions whether these proposed regulations seem more focused on delivering reimbursement to a selected group of providers than focused on delivering quality services to Medicare beneficiaries. It is also curious to note that these major revisions to the Hospital Conditions of Participation (COP) were incorporated in a Physician Fee Schedule proposed rule, which is a Medicare Part B section. Although CMS states otherwise, there was no broad-based public discussion on these revisions. Additionally, there is no statutory deadline that CMS is required to meet. CMS has presented no research or data indicating that patients are at risk for harm nor has there any justification presented for this major change other than a desire to update the standards for PTs and PTAs and develop a "consistent" policy across provider types.

In proposing the current change, CMS perpetuates its incorrect—and we believe illegal—application of outpatient therapy provider standards to the 2005 therapy-incident to rule. The policy adopted by CMS in the 2005 physician Fee Schedule final rule and its citation of Section 1862(a)(20) of the Social Security Act as the justification for that change. At the time that policy was under consideration by CMS, the AKTA and members of the Coalition to Preserve Patient Access to Physical Medicine and Rehabilitation repeatedly asked for data supporting CMS position and were repeatedly told that it was not necessary for the agency to engage in such justification because CMS was merely following what Congress mandated in Section 1862(a)(20).

While we disagreed then and continue to disagree with CMS's 2005 interpretation (as opposed to the agency's interpretation of the intent of Section 1862 (a)(20) published in both 2001 and 2003), we can't help but note that when Congress enacted Section 1862(a)(20), it DID NOT apply that policy to 1861(p) of the Social Security Act nor did it apply the language of 1862(a)(20) to other providers of services. Therefore we believe that adoption of this proposal absent specific Congressional directive and absent any compelling health or safety concerns is unwarranted and unauthorized.

It is important to note that, just as with the current proposal, CMS also failed to consider input from the medical community at large. When enacting the 2005 therapy - "incident to" rules for PM&R services (and only PM&R services), CMS overlooked recommendations by the AMA and ignored dissent by the American Academy of Physical Medicine and Rehabilitation and the American Academy of Neurology, two organizations whose membership were directly impacted by the changes. This gives some credence to the notion that CMS is acting at the behest of a small group of professional associations.

Potential impact of the proposed changes

CMS provides no clinical or financial justification for this proposed change, nor has the agency provided any cost information on what the expected impact of this change will be on hospitals and other providers. While it is accepted by the AKTA that proposed rule changes by CMS should be about patient quality and access to care, we estimate that thousands Kinesiotherapists will no longer be able to work in hospitals and other rehabilitation facilities. Likewise, thousands of Athletic Trainers, Lymphedema Therapists, low-vision therapists and others will no longer be able to provide services in these provider settings. This exacerbated workforce shortage will amplify problems with access to quality rehabilitation services. The load of rehabilitation cannot and should not be borne by only physical therapists, occupational therapists, PT assistants and OT assistants.

It is clear that CMS did not consider the economic impact of this proposed change. It did not consider the disruptive impact of this change and provides no indication that in pursuing this change, public health will in any way be positively affected. To the contrary, AKTA believe that

quality, access and the delicate economic balance of hospitals and rehabilitation facilities will be harmed.

AKTA believes that it is irresponsible for CMS to propose what equates to a mandatory staffing requirement – a monopoly if you will – under Medicare Part A at a time of workforce shortages. Unlike Part B, where specific staffing requirements exist as a condition of payment (generally mandated by federal statute), Part A providers have traditionally been given wider latitude in staffing decisions. Staff who are not recognized under Part B as independent providers of care are able to see and provide services to patients being treated by a Part A provider. The Part A providers is given this staffing latitude because none of these professionals is seeking independent reimbursement. The professionals, however, are doing exactly the same tasks as a physician, physician assistant or nurse practitioner would be doing in this capacity. In this case, Medicare trusts the judgment of the hospital and physician—and state legislatures and health departments—to only use qualified personnel.

For those hospitals and other providers unable to recruit or retain the physical therapists and physical therapy assistants necessary to meet patient demand you will likely see facilities close or dramatically scale back service availability. Patients in need of physical medicine or rehabilitation services will simply have to go without services, suffering needless pain or the continuation of a treatable chronic condition. One need only look at the current shortages in nursing staff to illustrate the potential effects of these changes.

These proposed standards clearly override State government's authority to determine scopes of practice for health care professionals and license those professionals. Current Hospital COP for most providers provides staffing flexibility to the provider. For example, the COP stipulates that if Rehabilitation services are provided, "The organization of the service must be appropriate to the scope of the services offered.

> (1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.
> (2) Physical therapy, occupational therapy, or speech therapy, or audiology services, ***if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law*** (emphasis added)."

The current standard defers to the collective judgment of the medical staff and recognizes the authority of the state to determine the appropriate scope of practice for various health professionals. The AKTA does not understand how an individual working at CMS could believe his or her judgment could realistically apply to every type of rehabilitation services in every type of hospital or facility in every urban, suburban, rural or medically underserved geographic area. Likewise, it is unreasonable to believe that the judgment of a CMS employee—or even a small team of employees—is superior to the collective judgments of the state legislatures, health departments and regulatory agencies throughout the United States who make these determinations for individual states. CMS employees generally are not clinicians practicing daily in physical medicine and rehabilitation.

Recommendations

The AKTA hopes that CMS will understand and acknowledge that in each unique rehabilitation setting, personnel standards defer to the judgment of the hospital's medical staff and state law, similar to all other areas of medical practice. The Hospital Conditions of Participation and other staffing models are consistent with state law and the medical judgment of the facilities' staffs. Additionally, these are quality standards monitored by the Joint Commission, CARF and other similarly authorized organizations and agencies.

American Kinesiotherapy Association
118 College Drive #5142
Hattiesburg, MS 39406

We are seeking an explanation from CMS as to why the delivery of rehabilitation services is so extraordinary as to demand a major deviation from the norm of deferring to the authority and judgment of the medical staff and the state legislature. We would like an explanation as to why CMS is imposing is bureaucratic judgment on decisions best left in the hands of state and local officials? Again, CMS has offered no compelling economic or quality justification for these arbitrary changes, couched under the guise of consistency.

For all of the reasons detailed above, the American Kinesiotherapy Association strongly urges CMS to:

1. Withdraw the proposed changes to the Therapy Standards and Requirements.

2. Convene a working group with representation of the range of providers furnishing rehabilitation services, as well as the health professionals working in rehabilitation departments, to discuss with CMS: workload, staffing, personnel qualifications and scope of services delivered, and attempt to achieve a policy via consensus.

Thank you for the opportunity to provide comments on the Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008; Therapy Standards and Requirements.

Sincerely,

Melissa Fuller, MA, RKT
Executive Director, American Kinesiotherapy Association

Article 130 General Provisions
Subarticle 1, Introductory Summary

6503 Practice of a profession.
Admission to the practice of a profession (1) entitles the licensee to practice the profession as defined in the article for the particular profession, (2) entitles the individual licensee to use the professional title as provided in the article for the particular profession, and (3) subjects the licensee to the procedures and penalties for professional misconduct as prescribed in this article (sections sixty-five hundred nine, sixty-five hundred ten, and sixty-five hundred eleven).

?6504 Regulation of the professions.
Admission to the practice of the professions (licensing) and regulation of such practice shall be supervised by the board of regents (section sixty-five hundred six) and administered by the education department (section sixty-five hundred seven), assisted by a state board for each profession (section sixty-five hundred eight).

?6529. Power of board of regents regarding certain physicians.
Notwithstanding any provision of law to the contrary, the board of regents is authorized, in its discretion, to confer the degree of doctor of medicine (M.D.) upon physicians who are licensed pursuant to section sixty-five hundred twenty-four or sixty-five hundred twenty-eight of this chapter. Each applicant shall pay a fee of three hundred dollars to the education department for the issuance of such degree.

Education Law
Article 131-A, Definitions of Professional Misconduct Applicable to Physicians, Physician's Assistants and Specialist's Assistants

?6530. Definitions of professional misconduct. | ?6531. Additional definition of professional misconduct, limited application. | ?6532. Enforcement, administration and interpretation of this article.

?6530. Definitions of professional misconduct.
Each of the following is professional misconduct, and any licensee found guilty of such misconduct under the procedures prescribed in section two hundred thirty of the public health law shall be subject to penalties as prescribed in section two hundred thirty-a of the public health law except that the charges may be dismissed in the interest of justice:
1. Obtaining the license fraudulently;
2. Practicing the profession fraudulently or beyond its authorized scope;

Submitter : **Mrs. Lori Marker** **Date: 08/31/2007**

Organization : **Mrs. Lori Marker**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Aug. 31, 2007

Re: Docket ID CMS-1385-P

Dear Sir or Madam:

The therapy standards proposed by CMS in the Physician Fee Schedule will harm the patients of athletic trainers and create access problems. There is a strong possibility that with these Byzantine and onerous rules will, in fact, decrease the quality of services provided to Medicare beneficiaries. These CMS proposed rules are not supported by any objective reports or other rationale that has been made public.

As a 37 year old adult female and mother of two young kids, I am alarmed about the impact this will have on my ability to secure quality and affordable healthcare from professionals, such as athletic trainers. I have personally used the services of an athletic trainer several times and I would not hesitate to seek out an athletic trainer again should the need arise. Why is it then that during this time when HSA's are becoming more popular and the consumer is in greater control of selecting healthcare providers that you are trying to remove athletic trainers from the equation?

Even with my limited exposure to the healthcare system I am aware that Medicare's rules are adopted in the private sector. Do you realize the trickle-down effect your decisions will have? Do you realize the impact your decisions will have on access and the cost of medical services? Do you realize that your decisions could adversely impact my children's access to quality care during their school years? Heaven forbid as I grow older that I incur a serious injury because as a senior what will I do when there is little or no access to quality and affortable healthcare?

These provisions are unnecessary and unreasonable. I want to have access to quality healtcare providers - including athletic trainers - and the ability to chose the best provider for me especially now that I have a Health Spending Account and that flexibility.

I respectfully request that all rules past and present that restrict the ability of athletic trainers to lawfully practice their profession be reversed by CMS. Further, I recommend that the broadest possible panel including sports medicine consumers of physical medicine and rehabilitation services providers be established to review future therapy rules prior to such efforts to insert them into the Federal Register.

Sincerely,

Lori Marker

Submitter : Mr. Jerry Rohrig **Date:** 08/31/2007

Organization : AANA

Category : Other Practitioner

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
_Jerry L.Rohrig CRNA_____
Name & Credential
__3038 24th Av. S.W._____
Address
__Fargo, ND 58103_____
City, State ZIP

14842

August 29, 2007

To whom it may concern,

My name is R.Robert Franks. I am an Assistant Director of Sports Medicine at Cooper Bone and Joint Institute, a center of excellence at Cooper University Hospital.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the physician self-referral provisions proposed in 1385-P. Initially, I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting. CMS seems to have come to these proposed changes without clinical or financial justification, and without the input of various healthcare professionals, especially the physicians who will be tasked with hiring enough staff to adequately treat our patients with rehabilitation needs.

The workforce shortage to fill rehabilitation positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans to further restrict their ability to receive those services.

However, I am more concerned that these proposed rules will create additional lack of access to quality health care for patients in my facility. The current standards of staffing in hospitals and other rehabilitation facility's flexibility are pertinent in ensuring patients receive the best, most cost-effective treatment available. As a physician and administrator, it is my duty to see that these jobs are filled by the most qualified individuals, regardless.

Current hospital Conditions of Practice, state law and hospital medical professionals have given me and my fellow physicians and administrators the authority to determine who is qualified to provide rehabilitation services. These proposed regulations attempt to circumvent those standards and force new ones on my clinical practice.

I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B rehabilitation facility.

Thank you for your time and consideration in this matter.

Sincerely,

R. Robert Franks, D.O.
Assistant Director, Sports Medicine
Cooper Bone and Joint Institute
Cooper University Hospital

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

Organization : **children's national medical center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionatcly 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 : **Holie Grissom** **Date: 08/31/2007**

Organization : **Holie Grissom**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. 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.
Hollie Grissom

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

Organization : **Sam Grissom**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. 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.
Sam Grissom

Submitter : Dr. Mike Diede **Date:** 08/31/2007

Organization : BYU

Category : Other Health Care Professional

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

CMS,

As a certified athletic trainer I find it troubling that CMS continues to discount the ATC as an allied health care professional who is qualified to perform therapy and rehabilitation which is clearly not PT interventions. Athletic trainers are qualified and currently performing the duties outlined for change. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Mike Diede

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

Organization : American Society of Hand Therapists

Category : Occupational Therapist

Issue Areas/Comments

Background

Background

The American Society of Hand Therapists (ASHT) is a professional organization comprised of licensed occupational and physical therapists, some of whom have earned the advanced designation, Certified Hand Therapist (CHT). Hand therapists specialize in the treatment & rehabilitation of the upper extremity, many of whom are reimbursed under the Medicare Physician Fee Schedule (MPFS) and are affected by Medicare Part B payment policies. We appreciate the opportunity to comment on the rule containing revisions to payment policies under the MPFS and other Part B payment policies for calendar year 2008, as published in the Federal Register on July 12, 2007 at 72 Fed. Reg.38122. ASHT presents the following comments on the MPFS proposed rule:

GENERAL

GENERAL

Additionally, ASHT echoes the comments submitted by the American Occupational Therapy Association (AOTA) and the American Physical Therapy Association (APTA) on the Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed Rule and Submission of Data on Quality Measures via a Medical Registry or Electronic Health Record.

ASHT requests that due consideration be given to these comments. Thank you for the opportunity to comment on the MPFS proposed rule. ASHT looks forward to a continuing dialogue with CMS on coverage and payment policies that affect the ability of occupational therapists to provide quality care to Medicare beneficiaries.

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Referral Relationships between Hand Therapists and Physicians

In the proposed rule, CMS announced that it is seeking comments on the referral relationships between physicians and providers of designated health services (DHS), which would include hand therapy services. CMS noted its concerns that the in-office ancillary services exception to the physician anti-referral law (Stark): (1) encourages physicians to create physical and therapy practices and (2) enables physicians to order and then subsequently perform ancillary services instead of making a referral to a specialist such as a hand therapist.

Under the laws of most states, therapists are not obligated to obtain a referral from a physician before evaluating and treating a client. However, regulations other than state law impact the referral relationship between therapists and physicians. For example, Medicare Part B requires therapists to obtain a physician signature on the therapy plan of care as a prerequisite for payment. These requirements force the therapist to rely on the physician for a referral. Referral requirements are but one of the reasons why a number of therapists forge strong working relationships with physicians. Therapists also are compelled to collaborate with physicians and other members of the care team in order to assure the delivery of quality services. The Institute on Medicine has highlighted in their report, Health Professions Education: A Bridge to Quality, that collaborations among clinicians is essential to ensure patient safety and quality of care. ASHT believes individuals rights to direct their own health care can be enhanced by the collaborative approach to rehabilitation that therapists embody. Collaboration, including consultation with physicians, is critical to meet the needs of the Medicare population.

There is a broad spectrum of ways in which therapists collaborate with physicians. Some therapists choose to be employed by a physician practice and extol the benefits of the teamwork that such close collaboration brings. At the same time, many other therapists have chosen to establish therapist owned practices and cherish their independence while maintaining strong working relationships with referring physicians. ASHT strongly supports billing for therapy services under an occupational therapy private practice (OTPP) number and a physical therapy private practice (PTPP) number. The OTPP and PTPP numbers allow the Medicare program to monitor when such services are billed and ensure that therapy services are provided by qualified individuals, the same oversight regarding qualified individuals providing hand therapy services do not exist when such services are billed as incident to the physician.

Changes to the in-office ancillary services exception to the Stark law would greatly impact hand therapists. Given the diversity among hand therapists practice arrangements with physicians (e.g., employed by a physician and billing under their OTPP or PTPP number, employed by a physician and billing incident to a physicians services, and employed by a therapist owned OTPP, PTPP and independently billing Medicare Part B), there are a number of professionals whose livelihood would be impacted regardless of the change.

ASHT supports CMS policy objective in the Stark law to ensure appropriate utilization and billing of Medicare outpatient services consistent with the Medicare coverage guidelines and free of improper physician self-referral.

TRHCA-- Section 201: Therapy CapS

TRHCA-- Section 201: Therapy CapS

ASHT continues to oppose the underlying policy to apply a financial cap on therapy services. ASHT asserts the therapy cap is an arbitrary and inappropriate solution to control the utilization of therapy services. As CMS stated in the preamble of the proposed rule with respect to changes in therapy certification timing, CMS has instituted many other means of ensuring appropriate utilization of therapy services.

ASHT is concerned that current law allowing for the exceptions process will expire on December 31, 2007. ASHT continues to advocate that Congress take action to either repeal the arbitrary cap or extend the exceptions process. The feedback that ASHT has heard from therapists regarding the cap exceptions process has been positive with regard to the diagnoses (ICD-9 codes) that are acceptable for automatic exceptions. However, if a repeal of the cap is not enacted by Congress, ASHT would be pleased to assist in improving the cap exceptions process. ASHT continues to be aware that CMS can not ultimately provide a permanent solution to the financial cap on therapy services; rather, maintains that there must be a long term Congressional solution with the guidance of CMS.

ASHT affirms that the therapy cap is an arbitrary policy and we continue to advocate that Congress repeal the cap or at a minimum, extend the exceptions process. If the exceptions process stands, ASHT would offer CMS input to modify the process to assure appropriate utilization.

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

ASHT supports CMS in requiring that a consensus based process must be used for developing quality measures. ASHT also supports the process of requiring National Quality Forum (NQF) or AQA Alliance (AQA) endorsement of the measures. ASHT would also support CMS considering other valid national endorsement bodies for purposes of reviewing and adopting PQRI quality measures. Furthermore, CMS should assure that initial development of measures is done in an open, all encompassing process emphasizing participation by all appropriate professional associations and encouraging use of registries for data submission.

Therapy Standards and Requirements

Therapy Standards and Requirements

ASHT strongly supports the MPFS rule proposal, in proposed regulation 42 C.F.R. ? 424.24, to permit a plan of care to cover therapy services for up to 90 days and that recertification would be required for therapy services provided beyond 90 days. This positive change to the certification and recertification timing allows for variation among patients needs and puts decision-making back in the hands of treating practitioners.

ASHT agrees that there may be public policy reasons to ensure that physicians, or other appropriate practitioners, review the therapy plan of care and attest to a continuing medical need for therapy services. However, the length of time for recertification at 30 days was arbitrary and not based upon any data about the need for recertification. ASHT also supports CMS rationale for changing the certification requirement because many other means of ensuring appropriate utilization currently exist.

Physicians rely on close communication with the therapist to track the progress and effectiveness of therapy and will choose to see the beneficiary again based on their consultation with the therapist. The proposed 90 day recertification requirement puts making medical decision squarely where it belongs, back into the hands of the treating physician, in coordination with the therapy practitioner.

ASHT strongly supports CMS action in the MPFS proposed rule that allows physician s discretion to determine when and how therapy services are reassessed, with a 90 day benchmark, rather than the current 30 day policy.

CMS-1385-P-14848-Attach-1.DOC

14848

ASHT
AMERICAN SOCIETY OF HAND THERAPISTS

401 NORTH MICHIGAN AVENUE
CHICAGO, IL 60611-4267
312.321.6866 phone
312.673.6670 fax
www.asht.org

August 30, 2007

The Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: **Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed Rule**

Dear Sir or Madam:

The American Society of Hand Therapists (ASHT) is a professional organization comprised of licensed occupational and physical therapists, some of whom have earned the advanced designation, Certified Hand Therapist (CHT). Hand therapists specialize in the treatment & rehabilitation of the upper extremity, many of whom are reimbursed under the Medicare Physician Fee Schedule (MPFS) and are affected by Medicare Part B payment policies. We appreciate the opportunity to comment on the rule containing revisions to payment policies under the MPFS and other Part B payment policies for calendar year 2008, as published in the Federal Register on July 12, 2007 at 72 Fed. Reg.38122. ASHT presents the following comments on the MPFS proposed rule:

PHYSICIAN SELF-REFERRAL PROVISIONS

In-Office Ancillary Services Exception (72 Fed. Reg. 38181)

Referral Relationships between Hand Therapists and Physicians

In the proposed rule, CMS announced that it is seeking comments on the referral relationships between physicians and providers of designated health services (DHS), which would include hand therapy services. CMS noted its concerns that the in-office ancillary services exception to the physician anti-referral law (Stark): (1) encourages physicians to create physical and therapy practices and (2) enables physicians to order and then subsequently perform ancillary services instead of making a referral to a specialist such as a hand therapist.

Under the laws of most states, therapists are not obligated to obtain a referral from a physician before evaluating and treating a client. However, regulations other than state law impact the referral relationship between therapists and physicians. For example, Medicare Part B requires therapists to obtain a physician signature on the therapy plan of care as a prerequisite for payment. These requirements force the therapist to rely on the physician for a referral. Referral requirements are but one of the reasons why a number of therapists forge strong working relationships with physicians. Therapists also are compelled to collaborate with physicians and other members of the care team in order to assure the delivery of quality

services. The Institute on Medicine has highlighted in their report, "Health Professions Education: A Bridge to Quality," that collaborations among clinicians is essential to ensure patient safety and quality of care. ASHT believes individuals' rights to direct their own health care can be enhanced by the collaborative approach to rehabilitation that therapists embody. Collaboration, including consultation with physicians, is critical to meet the needs of the Medicare population.

There is a broad spectrum of ways in which therapists collaborate with physicians. Some therapists choose to be employed by a physician practice and extol the benefits of the teamwork that such close collaboration brings. At the same time, many other therapists have chosen to establish therapist owned practices and cherish their independence while maintaining strong working relationships with referring physicians. ASHT strongly supports billing for therapy services under an occupational therapy private practice (OTPP) number and a physical therapy private practice (PTPP) number. The OTPP and PTPP numbers allow the Medicare program to monitor when such services are billed and ensure that therapy services are provided by qualified individuals, the same oversight regarding qualified individuals providing hand therapy services do not exist when such services are billed as incident to the physician.

Changes to the in-office ancillary services exception to the Stark law would greatly impact hand therapists. Given the diversity among hand therapists' practice arrangements with physicians (e.g., employed by a physician and billing under their OTPP or PTPP number, employed by a physician and billing incident to a physicians services, and employed by a therapist owned OTPP, PTPP and independently billing Medicare Part B), there are a number of professionals whose livelihood would be impacted regardless of the change.

ASHT supports CMS' policy objective in the Stark law to ensure appropriate utilization and billing of Medicare outpatient services consistent with the Medicare coverage guidelines and free of improper physician self-referral.

TRHCA—SECTION 201: THERAPY CAPS (72 Fed. Reg. 38205)

ASHT continues to oppose the underlying policy to apply a financial cap on therapy services. ASHT asserts the therapy cap is an arbitrary and inappropriate solution to control the utilization of therapy services. As CMS stated in the preamble of the proposed rule with respect to changes in therapy certification timing, **CMS has instituted many other means of ensuring appropriate utilization of therapy services**.

ASHT is concerned that current law allowing for the exceptions process will expire on December 31, 2007. ASHT continues to advocate that Congress take action to either repeal the arbitrary cap or extend the exceptions process. The feedback that ASHT has heard from therapists regarding the cap exceptions process has been positive with regard to the diagnoses (ICD-9 codes) that are acceptable for automatic exceptions. However, if a repeal of the cap is not enacted by Congress, ASHT would be pleased to assist in improving the cap exceptions process. ASHT continues to be aware that CMS can not ultimately provide a permanent solution to the financial cap on therapy services; rather, maintains that there must be a long term Congressional solution with the guidance of CMS.

ASHT affirms that the therapy cap is an arbitrary policy and we continue to advocate that Congress repeal the cap or at a minimum, extend the exceptions process. If the exceptions process stands, ASHT would offer CMS input to modify the process to assure appropriate utilization.

THERAPY STANDARDS AND REQUIREMENTS

***Outpatient Therapy Certification Requirements* (72 Fed. Reg. 38193)**

ASHT strongly supports the MPFS rule proposal, in proposed regulation 42 C.F.R. § 424.24, to permit a plan of care to cover therapy services for up to 90 days and that recertification would be required for therapy services provided beyond 90 days. This positive change to the certification and recertification

timing allows for variation among patients' needs and puts decision-making back in the hands of treating practitioners.

ASHT agrees that there may be public policy reasons to ensure that physicians, or other appropriate practitioners, review the therapy plan of care and attest to a continuing medical need for therapy services. However, the length of time for recertification at 30 days was arbitrary and not based upon any data about the need for recertification. ASHT also supports CMS' rationale for changing the certification requirement because many other means of ensuring appropriate utilization currently exist.

Physicians rely on close communication with the therapist to track the progress and effectiveness of therapy and will choose to see the beneficiary again based on their consultation with the therapist. The proposed 90 day recertification requirement puts making medical decision squarely where it belongs, back into the hands of the treating physician, in coordination with the therapy practitioner.

ASHT strongly supports CMS' action in the MPFS proposed rule that allows physician's discretion to determine when and how therapy services are reassessed, with a 90 day benchmark, rather than the current 30 day policy.

TRHCA – SECTION 101(B): PHYSICIAN QUALITY REPORTING INITIATIVE (PQRI)

***Requirements for Measures Included in the 2008 PQRI* (72 Fed. Reg. 38196)**

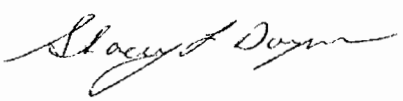
ASHT supports CMS in requiring that a consensus based process must be used for developing quality measures. ASHT also supports the process of requiring National Quality Forum (NQF) or AQA Alliance (AQA) endorsement of the measures. ASHT would also support CMS considering other valid national endorsement bodies for purposes of reviewing and adopting PQRI quality measures. Furthermore, CMS should assure that initial development of measures is done in an open, all encompassing process emphasizing participation by all appropriate professional associations and encouraging use of registries for data submission.

* * * * * * * *

Additionally, ASHT echoes the comments submitted by the American Occupational Therapy Association (AOTA) and the American Physical Therapy Association (APTA) on the Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed Rule and Submission of Data on Quality Measures via a Medical Registry or Electronic Health Record.

ASHT requests that due consideration be given to these comments. Thank you for the opportunity to comment on the MPFS proposed rule. ASHT looks forward to a continuing dialogue with CMS on coverage and payment policies that affect the ability of occupational therapists to provide quality care to Medicare beneficiaries.

Sincerely,



Stacey L. Doyon, OTR/L, CHT
President
American Society of Hand Therapists (ASHT)

Submitter : **Miss. Lindsey Anderson** **Date: 08/31/2007**

Organization : **NATA**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

The therapy standards proposed by CMS in the Physician Fee Schedule will have severe repercussions. The most pertinent reasons for overturning the proposed therapy standards includc:

1) many paticnts (Medicarc and others) will lose access to services
2) quality of services will decrease because of this loss of access
3) therc are major workforce shortages in this field
4) athletic trainers arc legally authorized to do the work and they are qualified and highly capable
5) thc CMS rules are anti-choice at a time when provider choice and improved outcomes are driving the rest of the healthcare system.

Thank you,
Lindsey Anderson

Submitter : **Mr. todd underdahl** **Date: 08/31/2007**

Organization : **aana**

Category : **Other Practitioner**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
__Todd Underdahl CRNA_____ .
Name & Credential
__6419 15th street north_____
Address
__Fargo, ND 58102_____
City, State ZIP

The two articlcs cited by the QlO as support for this measure [Bloch (2004) and Schunk (2000)] emphasize the importance of pain as an element of function and outcomcs measurement. These findings and conclusions support our comments above. Starke (2005) is an article that appeared in a magazine which is not a peer-reviewed publication. Likewise, the Barr article (which was retrieved from a website) does not meet criteria for a scientific article that has been published in a refereed journal.

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

By virtue of communication with NQF, FOTO notes and appreciates the interest of the NQF in conducting a call for functional status measures that would be applicable to patients receiving rehabilitation thcrapy or other interventions including chiropractic. Functional status measures have the considerable advantage of focusing the clinician as well as the payer on the results of care; on outcomes as opposed to process. NQF recognizes the gap that exists in measure development. While FOTO has ovcr 15 years of experience in developing and using functional status measures and has amassed a database that contains over 1.9 million episodcs of care and has over 30 papers using the FOTO data published in peer-reviewed journals, these measures, according to CMS still need to navigate the consensus-based process such as that used by NQF. Despite NQF s interest in performing a call for functional status measures, the cost of such an undertaking, estimatcd at $450,000, is prohibitive. FOTO would urgc CMS to give serious consideration to underwriting a call for functional status measures that can expedite the agency s movement from process measures into the outcomes paradigm.

The AQA is also referenced in the proposed rule as well as in section 1848(k)(2) of the Act as a consensus organization for the purpose of identifying measures that havc successfully completcd rcview by a consensus organization, utilizes certain essential practices of a voluntary consensus standards body under NTTAA and the OMB A 119 relating to openness, balance of interest, and consensus. While the breadth of formal participation among stakeholders that have an interest in healthcarc quality mcasures dealing with physician care is notable, accessing the AQA process for the development or endorsement of functional status measures ean be difficult.

Specifically, communications with AQA with respect to the development of functional status measures also generated interest at that organization. However, the AQA ultimately indicated they would only consider for endorsement measures developed and adopted by the AMA s Physician Consortium for Performance Improvement (PCPI). Since PCPI has made a firm operational decision to only deal with professional societies, private enterprises such as FOTO despite their extensive business and scientific history and experience and robust database, are excluded from consideration by both PCPI and AQA. Thus, the only avenue left availablc for FOTO and other experienced private entities would be the NQF which may be able to conduct a call for measures at a cost approaching a half million dollars.

FOTO notes with interest the agency s preference to use quality measures meeting the NTTAA and OMB A 119 criteria for voluntary consensus standards, but that neither this CMS preference nor the NTTA or OMB A 119 preclude CMS from selecting measures for PQRI based upon a lesser degree of consensus when necessary to meet CMS program needs as determined by the Secretary. In the absence of a CMS decision to underwrite a NQF call for functional status measures, FOTO would cncourage CMS to seriously consider exercising its prerogative to seleet measures for PQRI that possess a lesser degree of consensus such as those functional status measures developed by FOTO.
[THE WEBSITE IS MALFUNCTIONING AND WILL NOT ALLOW ADDITIONAL COMMENTS]

Therapy Standards and Requirements

Therapy Standards and Requirements

Outpatient Therapy Certification Requirements
The signature of a physician or NPP in the mcdical record indicating approval of the plan of care for outpatient therapy services certifies the initial need for therapy services furnished under Part B. For other covered medical and health services furnishcd by providers and suppliers of outpatient services, certification is required only once, either at the beginning or at the end of a series of visits. Recertification is not required for most health services. In 1988, in an attempt to control the expanding utilization of therapy services, we added a 30-day recertification requirement for outpatient therapy services to our regulation at ? 424.24. This requires that a physician certifies a plan of care for
30 days, regardless of the appropriate length of trcatment. To continue treatment past 30 days, the physician is required to recertify the plan.

CMS proposcs to change the plan of treatment recertification schedule in ? 424.24 24 to require recertification every 90 days after beginning treatment. Currently, thc physician must initially certify a plan of trcatment at the time the plan is established or as soon thereafter as possible. If the need for treatment continues beyond 30 days, the plan of treatment must be reccrtified every 30 days until discharge. The proposed rule would require that the physician (or NPP, as appropriatc) would continuc to review and certify the initial plan of care as soon as possible, but that the certification would apply for an episode length based on the patient s needs, not to exceed 90 days and would be recertified every 90 days thereafter. Payment would continue to be denied if services were provided without a ccrtified plan of care. Over-utilization of serviccs would continue to be monitored, as it is now, by Medicare contractors based on data analysis assisted by systcm cdits.

Thc agency proposcs to continue to rcview thc utilization of therapy services to assess any changes in practice that might be related to the proposed changes in regulations regarding certification of a plan of care for an appropriate length of treatment. After 2 years, if CMS determines that there are changes in practice that suggcst inappropriate utilization of therapy services based on the certification timing, you will consider whether to reinstate the 30-day recertification requirement.

FOTO would like to offcr a specific comment related to identification of over- or under-utilization of therapy services. In general, since a physician does not have data commonly from which to make a decision regarding the appropriateness of initiation or continuation of therapy, requiring or not requiring recertification of thcrapy by physicians scems mcaningless.

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

Organization : **Harvey Elms**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.
Harvey Elms

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

Organization : **Anesthesia Partners of Montana, P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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

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

Thank you for your consideration of this serious matter.

Sincerely,

David Rietz, MD
Anesthesiologist
Billings, Montana

Submitter : Mr. WILLIAM F PANZA **Date:** 08/31/2007

Organization : Mr. WILLIAM F PANZA

Category : Individual

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

SUPPORT FOR INCREASED ANESTHESIA CONVERSION FACTOR

CMS-1385-P-14859-Attach-1.DOC

14859

August 31, 2007

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

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

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am a medicare beneficiary from Emerson, NJ. 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. I am concerned that I will have limited access to anesthesia services as a Medicare beneficiary. I support the increase in the Medicare payment for anesthesia services. The current amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists, including my son, are being forced away from areas with disproportionately high Medicare populations.

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

Thank you for your consideration of this serious matter.

Sincerely,

William F. Panza

Submitter : **Ms. Sharon Donato** **Date: 08/31/2007**

Organization : **Roland Park Country School**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Sharon Donato and I have been working as a Certified Athletic Trainer for fourteen years. While I have worked at the professional, scholastic and recreational levels of sport, I currently work at Roland Park Country School in Baltimore, Maryland, providing athletic health care coverage to a population of approximately 700 girls and young women.
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,
Sharon M Donato MAEd, ATC, CSCS

Submitter : Dr. Carli Hoaglan **Date:** 08/31/2007

Organization : Baylor Deparment 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

Rc: 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.

Whcn the RBRVS was institutcd, 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 : **Shelly DiCesaro** **Date: 08/31/2007**

Organization : **Shelly DiCesaro**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer about to defend my doctoral dissertation at the University of Pittsburgh. I have been a certified Athletic Trainer for over 10 years and have worked in both the clincal, collegiate and academic setting.

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

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

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

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

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

Sincerely,

Shelly DiCesaro, MS, ATC, CSCS

Submitter : Dr. Priscilla Garcia **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:

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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. Brant Phelps **Date:** 08/31/2007

Organization : Alabam Othopaedic Clinic

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

No changes need to be made. Patient care is at it's best in these situations. Our PT's and LPTA's work hand in hand with some of the best physicians in our area for the benefit and well-being of our patients. I believe it would be a mistake to remove PT from the exception list. I suggest that further investigation be made in the specific clinics on which these opinions of abuse and fraud are based. Thank You.

Submitter : Dr. Bonnie McKenzie **Date:** 08/31/2007

Organization : Anesthesia Associates, LLP

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am practicing anesthesia in an area of high medicare and medicaid. It comprises about 2/3 of our cases, but only 1/3 of our income. My income is about 100,000 to 125,000 below national average for anesthesiologists in similar situations/practices. Our hospital does not subsidize our department in any way and we have no group benefits. This is not a sustainable arrangement and will likely force me, and the other anesthesiologists in our group, to look for more stable practices elsewhere.

Submitter : **Mr. Milt Wood** **Date: 08/31/2007**

Organization : **Southern Bone**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See Attached

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Kristen Kucera **Date:** 08/31/2007

Organization : Duke University Medical Center

Category : Hospital

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer, epidemiologist, and assistant professor at Duke University Medical Center.

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,
Kristen L Kucera, PhD, LAT, ATC

Submitter : Tkeresa E. Kennedy **Date:** 08/31/2007

Organization : Harvard University

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer currently employed at Harvard University with the Sports Medicine Department. I am nationally Board Certified, licensed by the Commonwealth of Massachusetts, and possess post graduate education. I provide athletic training services to high level athletes within a network of other certified athletic trainers, dual credentialed physical therapist/certified athletic trainers, physicians, and other affiliated practitioners. My role is to provide athletic injury and illness assessment, practitioner referral, physical medicine and manual therapy treatment, and rehabilitation services. My services are invaluable in the delivery of health care to the active and athletic population.

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

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

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

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Sincerely,

Theresa E. Kennedy, MS, ATC

Submitter : **Dr. Kisteria Martin** **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 : **Mr. David Parks** **Date: 08/31/2007**

Organization : **UHZ Sports Medicine Institute**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is David Parks and I am the clinical director for the UHZ Sports Medicine Institute in Coral Gables, Florida. I received my BS at the University of Massachusetts and my MS in Sports Medicine at Illinois State University. I have been a certified athletic trainer for 16 years and have worked side by side orthopedic surgeons here at UHZ Sports Medicine for the past 15 years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P. While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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

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

Sincerely,

P. David Parks, MS, ATC, LAT, CSCS, PES

Submitter : **Dr. Daniel Tolpin** **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 : Mrs. JANICE JOYNER PANZA **Date:** 08/31/2007

Organization : Mrs. JANICE JOYNER PANZA

Category : Attorney/Law Firm

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

I SUPPORT THE INCREASED ANESTHESIA CONVERSION FACTOR

CMS-1385-P-14872-Attach-1.DOC

14872

August 31, 2007

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

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

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am an attorney from New Bern, NC. I am glad to see that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue. I am concerned that I will have limited access to anesthesia services as a Medicare beneficiary. I support the increase in the Medicare payment for anesthesia services. The current 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, like New Bern, with disproportionately high Medicare populations.

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

Thank you for your consideration of this serious matter.

Sincerely,

Janice Joyner Panza

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

Organization : **Dr. Robert Haselow**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

(Please see attached letter written on my behalf by attorney Janet Newberg)

CMS-1385-P-14873-Attach-1.DOC

14873

Newberg Law Office

4707 Highway 61, #223
White Bear Lake, MN 55110
Phone: 651-653-4587
Fax: 612-395-9134
janet@newberglawoffice.com

September 14, 2007

Center for Medicare and
Medicaid Services
Department of Health
and Human Services
ATTN: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Re: Comments on Proposed Regulations
File Code CMS-1385-P
Physician Self-Referral Provisions
In Office Ancillary Services
Per Click Payments – Space and Equipment Leases
Services Furnished "Under Arrangements"

Dear CMS:

Dr. Robert Haselow, a radiation oncologist in practice in Minneapolis, Minnesota appreciates the opportunity to provide additional written comments on the "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" published in the Federal Register as a proposed notice on July 12, 2007. Dr. Haselow's comments focus on the following issues:

Physician Self-Referral Provisions
In Office Ancillary Services
Per Click Payments – Space and Equipment Leases
Services Furnished "Under Arrangements"

Introduction

Dr. Haselow has witnessed a disturbing proliferation of financial relationships between and among physician groups treating cancer patients, oncology groups, and certain for-profit corporations. These suspect financial relationships result in virtual monopolies in the provision of radiation therapy services, adversely affect patients' ability to freely choose their medical providers, provide incentives to referring physicians to only order the types of radiation therapy services for which they will profit, and drive competing not-for-profit hospitals and other entities out of the radiation therapy business.

Within the last year or two, Dr. Haselow believes these suspect financial relationships have proliferated among urology groups treating men for prostate cancer, oncology groups, and large for-profit corporations. Dr. Haselow is aware of a business model that has been employed nationally, and is in the process of being employed in the Twin Cities that involves the following:

- A for-profit company will target a premier urology group in a community and offer to provide a "turnkey radiation oncology service". The proposal will focus on bringing into the group radiation therapy services for patients with prostate cancer, including the very lucrative Intensity Modulated Radiation Therapy ("IMRT") services
- The for-profit "pitch" will emphasize the increase in revenues the urology group will attain by capturing these referrals within the group's business structure. The pitch may also include an opportunity for the physicians to joint venture in an equipment leasing company which will lease the radiation therapy equipment "to" the group.
- The company will recruit a radiation oncologist – usually from an existing radiation oncology center – to provide the radiation therapy services for the urology group. The oncologist will not be offered ownership in the business, but will be paid via a services contract only.
- The radiation therapy services will typically be set up in a location separate from the urology practice itself. The radiation oncologist and his/her technical staff will function separate and apart from the group on a day-to-day basis. There is little or no integration of the physicians, staff, locations or services.
- The urology group benefits from the revenue flowing from its referrals and, if available, the equipment lease. The for-profit company may share in those revenues directly and/or through its share of the equipment leasing fees, as well as through a management fee.
- In Minnesota, legislation enacted in 2003 prohibits the development of new radiation therapy centers unless hospitals are involved in the development plan. Dr. Haselow believes that a urology group, a large oncology group and a national for-profit corporation have partnered with a hospital system to implement the business model set forth above in a Twin Cities suburb.

Dr. Haselow believes the implementation of this business model results in abuse and waste in the health care system. Under this model, the group referring patients for radiation therapy services (the urologists) monetarily benefits from their referrals. The large for-profit corporation benefits from these referrals either through its participation in management services contracts and/or through its share of equipment leasing fees. The oncologists also financially benefit through their orders for radiation therapy services.

Each of the billing entities in this business model rely on the "In Office Ancillary Services Exception" ("IOASE") to the Stark regulations to protect themselves from federal fraud and abuse enforcement efforts. Dr. Haselow believes the entities' reliance on the

IOASE is wholly misplaced, and does not reflect the intent of Congress, CMS and Representative Pete Stark when the IOASE was enacted.

Physician Self-Referral Prohibition – In Office Ancillary Services Exception

Dr. Haselow understands that CMS is not currently issuing a proposal to amend the In Office Ancillary Services Exception to Stark. However, CMS does solicit comments as to whether certain services should not qualify for this exception, and whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned (or leased) by the nonspecialists. Dr. Haselow firmly believes that radiation therapy services should *not* qualify for the exception, and referring physicians should not be able to cloak their referral of patients for radiation therapy services using equipment the referring physicians own or lease under this exception.

a. Radiation Therapy Services Should Not Qualify for the IOASE

It is clear from a review of the legislative history leading up to the establishment of the statutory IOASE that Congress only intended to protect those types of services physicians provided within their own practices that were necessary to diagnose or immediately treat their patients. Representative Stark himself testified that the exception would "most commonly apply to in-office lab tests or x-rays", and that the IOASE "reflects a judgment that there is often a clear need for quick turn-around time on crucial tests". 135 Cong. Rec. H240-01 at 6 (Feb. 9, 1989). Thus, the focus has always been on the types of services that were truly ancillary to the medical services being provided by the physician or group. See 66 Fed.Reg. 856, 881 (Jan. 4, 2001). In-office laboratory tests designed to aid in the diagnosis of a patient (a rapid strep test, for example) and in-office imaging tests (x-rays, for example) would clearly fall within both the definition and the intent of Congress and CMS in defining an in office ancillary service.

Radiation therapy services do not bear any of the hallmarks of true in office ancillary services. Radiation therapy is not performed to diagnose a patient. It also is not performed by the referring physician group to aid in the immediate treatment of a patient. Finally, these services are not performed by the non-specialist physicians (here, the urologists) or their staffs. Instead, the services are performed by and under the supervision of highly specialized physicians – the radiation oncologists. Radiation therapy services are in no way "ancillary" to the services of the referring physicians, and should be eliminated from the list of services that qualify for the IOASE.

b. Non-specialist Physicians Should Not Be Able to Use the IOASE to Refer Patients for Supplies and Services Involving the Use of Equipment Owned or Leased by the Non-specialist Physicians

Dr. Haselow believes that in some of the troublesome financial arrangements between referring physician groups, oncologists and large for-profit corporations, the referring physicians have additional opportunities to profit from their referrals through their participation in joint ventures with some or all of the other entities in equipment leasing

companies that lease the radiation therapy equipment "to" their own group. Dr. Haselow believes this practice is abusive, and incentivizes the referring physicians to narrow their choice of treatment options for their patients to the treatment for which they will profit through these leasing agreements. Accordingly, Dr. Haselow concurs with CMS' proposal that the definition of "entity" set forth at §411.351 be revised so that a DHS entity includes both the person or entity that performs the DHS, as well as the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS. Of course, this revision would not be necessary to address the evils of the radiation therapy business models identified in these comments if CMS simply removed radiation therapy services from the list of services that qualify for the in office ancillary services exception.

Conclusion

Dr. Haselow thanks you for the opportunity to comment on this proposed rule. If you have any questions about the items addressed in this comment letter, please do not hesitate to contact Janet Newberg at the address set forth in the letterhead.

Respectfully Submitted,

Janet A. Newberg

cc: Robert Haselow, M.D.

Submitter : **Dr. Emily Einsberg** **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
Baltimorc, MD 21244-8018

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

Dcar 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 disproportionatcly 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 : **Robin Ploeger** **Date: 08/31/2007**

Organization : **The University of Tulsa**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer and the director of the athletic training education program at The University of Tulsa. This program prepares students for careers in athletic training, therefore I m concerned about future employment opportunities for these students, which has prompted me to contact you today.
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,
Robin Ploeger, EdD, ATC, LAT

Submitter : Dr. Julie Chen **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)

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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. David Pittman** **Date: 08/31/2007**

Organization : **OrthoLink Physicians Corp**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am both a Physical Therapist and Certified Athletic Trainer with over 30 years of experience. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for "rehabilitation" in hospitals and facilities proposed in 1385-P. I know many excellent, highly qualified ATC's that these changes would negatively affect. But more importantly, this would restrict access to excellent care by many patients that could greatly benefit from these services. I could go on and on, but my purpose is to respectfully request that you withdraw the proposed changes and further investigate the facts for clinical and financial justification.

Respectfully,

David Pittman, PT, AT,C.

Submitter : **Mr. Keith Benson** **Date: 08/31/2007**

Organization : **Sport Specifics**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Keith Benson and I am a certified and licensed athletic trainer and a certified strength and conditioning specialist. I have worked in outpatient sports medicine and now work to prevent injuries and provide post rehabilitation training. My credentials allow me to provide effective health information and training many people. I am concerned that the average person (patient) already receives less effective care and treatment due to constriction of services provided by athletic trainers by the CMS.

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,

Keith Benson, ATC, LAT, CSCS

Submitter : Dr. Ona Kareiva **Date:** 08/31/2007

Organization : Tidewater Anesthesia Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachments

CMS-1385-P-14879-Attach-1.DOC

CMS-1385-P-14879-Attach-2.DOC

14879

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

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

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

Thank you for your consideration of this serious matter.

Ona Kareiva, MD

Submitter : **Dr. mounzer agha** **Date: 08/31/2007**

Organization : **oncology hematology associates**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

please refer to attached comments on photopheresis reimbursement.

CMS-1385-P-14882-Attach-1.DOC

4882

August 30, 2007

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

Subject: RESOURCE-BASED PE RVUs (for PHOTOPHERESIS) (CPT 36522)

Dear Sirs:

I am a hematologist-oncologist with Oncology Hematology Associates. My group operates a physician-directed clinic at the Hillman Cancer Center, which is affiliated with UPMC in Pittsburgh. My colleagues and I have carefully investigated providing photopheresis services for our drug-refractory transplant patients suffering from the multiple serious manifestations of chronic graft-versus-host disease (GVHD) who require this therapy. However, we cannot do so because the reimbursement currently dictated by the practice expense RVUs does not approach the costs we would incur to provide this service.

Our intention to provide photopheresis for our patients is motivated by three objectives. First, we want to reduce the physical stress on our patients associated with traveling to an unfamiliar and congested part of town. We want them to come to our clinic, which is more convenient and easier to access. Many of these patients are weakened or wheelchair-bound.

Second, we want to reduce exposure of our patients to dangerous and potentially fatal infectious risks associated with having to receive their photopheresis treatments at the hospital apheresis unit. These patients are almost invariably maintained on corticosteroids and other powerful immunosuppressive drugs, and frequently contract serious or fatal bacterial or viral infections.

Finally, providing the photopheresis ourselves will also give us an opportunity to more closely monitor the health status of these GVHD patients, who are suffering from one or more cutaneous, mucosal, gastrointestinal, hepatic, pulmonary and ocular manifestations.

Our frustration is that somehow the practice expense RVUs proposed by CMS (37.04) would scarcely cover our costs for just the expensive supply kit, nurse operator's time and mitogenic drug (methoxsalen). Most immediately, we must cover the very considerable clinic overhead connected with the treatment space, as well as the cost of the UVAR XTS photopheresis devices and the annual maintenance contract on those devices.

At our reimbursement rate of about $34 per RVU, those 37 practice expense RVUs amount to about $1,260. We would be paying between $1,015 and $1,100 per disposable procedural kit, depending on the quantity we order, and would incur costs of about $60 for methoxsalen, another $25 for ancillary procedural supplies and at

minimum about $95 for the service time of a trained apheresis nurse specialist ($27 per hour including benefits for 3-1/2 to four hours). Our total cost for just these supplies, the drug and our nurse is *conservatively* about $1,200 – nearly the entire proposed payment rate for the procedure itself. This leaves essentially no contribution toward our clinic operating overhead costs, or the amortized cost of the machine or the annual service contract to maintain the machine.

At a minimum, we will need 45 to 50 practice expense RVUs to afford to provide this procedure, depending on the reimbursement per RVU that Medicare ultimately decides upon for next year.

If it is not already obvious, I want to be clear: our objective in providing photopheresis is *not* to "make money." There are just 1.67 physician work RVUs to compensate me for my time to plan the therapeutic regimen, pre-assess the patient before the procedure and address all procedure-related protocol adjustments or side effects the patient may experience.

Our objective is very straightforward: to provide better care, a better patient experience and ultimately better health outcomes for this small population of clinically complex and unusually compromised patients. We cannot do so with the reimbursement that Medicare pays now or proposes to pay for the technical portion of this procedure.

On behalf of myself and my colleagues and above all our patients, I urge you to examine the information that has been made available to you about costs of this procedure, and revise the RVUs to a level that makes this service financially feasible for us to provide.

Sincerely,

Mounzer A. Agha, M.D.
Director, Stem Cell Transplantation Program
UPMC Cancer Centers

MA:jp

Submitter : **Dr. Brandon Thompson** **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. Jennifer Zieg** **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)

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

Thank you for your consideration of this serious matter.

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

Organization : **Medcenter One**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Raymond Hall. I am Athletic Trainer at Medcenter One Health Systems in Bismarck, ND.
My responsibilities are working in an out-patient physical therapy clinic and outreach setting providing sports medicine coverage to local and rural schools. I recieved my four year degree in Athletic Training from an accredited progarm at North Dakota State University. I am a Certified Athletic Trainer and Licensed in the state of North Dakota.

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

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

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

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

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

Sincerely,

Raymond Hall, M. MGT., L/ATC,CSCS

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

Organization : **Murray State University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

My name is Eric Frederick, MS, ATC. I am a certified athletic trainer at Murray State University in Murray, Kentucky.

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

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

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

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Sincerely,

Eric Frederick, MS, ATC
Doctoral Student, Rehabilitation Sciences, University of Kentucky
Athletic Trainer/Lecturer - Murray State University
217 Stewart Stadium
Murray, KY 42071-3351
270-809-5580
270-809-5526 - Fax
270-293-1690 - Mobile
eric.frederick@murraystate.edu
www.goracers.com

Submitter : Dr. Luz Feldmann **Date:** 08/31/2007

Organization : Luz A. Feldmann MD, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Attatchment

14887

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

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

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please refer to the attached comments.
Thank you.

CMS-1385-P-14888-Attach-1.WPD

14888

Mr. Kerry N. Weems August 24, 2007

Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

PHYSICIAN SELF-REFERRAL ISSUES

Dear Mr. Weems:

I wish to comment on the July 12 proposed 2008 physician fee schedule rule, and in particular the issue surrounding physician self-referral and the "in-office ancillary services" exception. I support the removal of physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.

I have been a licensed Physical Therapist for 29 years and I currently practice in a physical therapist-owned private practice. Since Stark II, I have witnessed a steady erosion of patient choice in physical therapy providers as physicians seek to control the marketplace of a professional service that is not their own.

I have been alarmed by the rapid growth of physician-owned physical therapy practices in Minnesota. Physicians are being encouraged to do so by intense marketing efforts by groups that characterize these practices as "passive revenue streams." Coursework and consulting focuses on maximization of billing, with absolutely no reference to physician involvement or quality of care.

In my particular market, there is only one orthopedic surgeon group that does NOT own its own physical therapy services. These services have been added to the buffet of services from which physicians collect "passive revenues" as a result of their own referrals. Physical therapists who work for our practice have been approached to set up these practices for physicians, and when the offers have been declined, the responses have come in the form of threats that our business will suffer. While we have indeed seen a significant drop in the number of referrals from these physician groups, they continue to send their "complicated" cases to us. Complications can be characterized as medically complex and/or financially undesirable.

Discussions with physician groups who were contemplating ownership of physical therapy assure us that "it's not about access for patients, it's not about quality of care, it's

not personal – it's simply financial." These practices are being set up, by their own admission, solely for profit.

Recently a large family practice group opened its own physical therapy practice one block from ours. They currently employ 5 physical therapists and we have experienced a commensurate loss of business. However the physicians themselves seek services for themselves and for their family members from our practice.

A disturbing number of patients are reporting that they have had a difficult time choosing their own physical therapist. In some cases the patients have been told that if they don't receive physical therapy from the provider of the physician's choice, then they cannot secure a referral for physical therapy.

These clear and avoidable conflicts of interest are pervasive and do not serve the best interest of patients or the payer. Patient control should not be mistaken for patient care. While physician ownership of physical therapy professional services is being defended as giving physicians "a greater role" little evidence exists that supports that intention. In fact, since Stark II most physician-owned practices are taking advantage of the reassignment laws to avoid the "incident to" requirements relating to physician oversight.

Current Medicare regulation does not require direct supervision of the practice of physical therapy. No referral is required. The only requirement that involves physicians is the certification of plans of care, a policy developed in effort to control utilization. As an independent and private practice, we send our care plans for certification to physicians who do not have a financial interest in our practice. On the other hand, physician-owned physical therapy services are certified by the physician who profits from the service – an avoidable conflict of interest.

I emphatically support any efforts to eliminate abusive financing arrangements under the Stark law that are contrary to the best interest of the Medicare beneficiary. I strongly urge the CMS to remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.

I sincerely thank you for your consideration of my comments.

Submitter : **Dr. Leslie Medley** **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
Baltimorc, 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 : Mrs. Jeannen Gulenchyn **Date:** 08/31/2007

Organization : McDonough Orthopaedic

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dcar Sir or Madam:

I am a ccrtified and licensed athletic trainer working in a private Orthopaedic clinic for the past 16 years. I am writing today to voice my opposition to the therapy standards and rcquirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

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

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical expcrience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to 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 thc 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 arc pertinent in ensuring patients receive the best, most cost-effective trcatment available.

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Sinccrely,

Jcannen Gulenchyn, ATC, OT, CSCS

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

Organization : Dr.

Category : Health Care Professional or Association

Issue Areas/Comments

Medicare Economic Index (MEI)

Medicare Economic Index (MEI)

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

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

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

Thank you for your consideration of this serious matter.

Katarzyna Ciesielski

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

Organization : **Tidewater Anesthesia Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1385-P-14892-Attach-1.DOC

14892

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

John Snell, MD

Submitter : **Dr. Paul Hopkins** **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

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter : **Miss. Alison Pulver** **Date: 08/31/2007**

Organization : **Indian Creek Upper School**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am the head athletic trainer at Indian Creek Upper School. We are a private school with 158 students in the upper school population, which of whom all must play a sport as a graduation requirement. I provide all the athletic training needs to all of our after school teams as well as run the health services office during the school day. My educational background consists of a BS in Kinesiological Science, MS in Health Science, teaching certification for k-12 health, Board certification by the NATABOC, board certification by the NSCA, and instructor status for the American Heart Association for CPR and AED.

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,
Alison Pulver, MS, ATC, CSCS

Submitter : **Dr. Brian Hatzel** **Date: 08/31/2007**

Organization : **Grand Valley State University**

Category : **Academic**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Dr. Brian Hatzel and I am a faculty member and Certified Athletic Trainer at Grand Valley State University.

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

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

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

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Sincerely,

Dr. Brian Hatzel, ATC

Submitter : **Dr. William Evans** **Date: 08/31/2007**

Organization : **SWFUA**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Physician Self-Referral Provisions

CMS-1385-P-14896-Attach-1.DOC

14896

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 to 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,

William P. Evans, M.D.

Submitter : **Mr. Brian Farr** **Date: 08/31/2007**

Organization : **The University of Texas**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Brian Farr. I am the Director of the Athletic Training Education Program at the University of Texas at Austin, a Lecturer in the Department of Kinesiology and Health, a certified athletic trainer (ATC) a licensed athletic trainer (LAT), and a certified strength and conditioning specialist (CSCS).

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

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

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Sincerely,

Brian K. Farr, MA, ATC, LAT, CSCS

Submitter : **Dr. Chris Estrada** **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:

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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. Helen O'Keeffe** **Date: 08/31/2007**

Organization : **The Permanente Medical Group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Submitter : Mrs. Judi Tekautz **Date:** 08/31/2007

Organization : Winona Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a Certified Athletic Trainer employed through a community hospital in Winona, MN.

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.

Winona, like many small rural communities, is struggling with the shortage of qualified health care workers, particularly in the areas of nursing and physical therapy.

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,
Judi Tekautz, ATC

Submitter : **Dr. Stephanie Jones** **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:

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

Thank you for your consideration of this serious matter.

Submitter : **Dr. Nihar Patel** **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
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Thank you for your consideration of this serious matter.

Submitter : **Ms. Heather Veal** **Date: 08/31/2007**

Organization : **Ms. Heather Veal**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

August 31, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
Heather Veal
2330 Ridge Road
Opelika, AL 36804

Submitter : **Dr. Roland Flores** **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)

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

Thank you for your consideration of this serious matter.

Submitter : **Dr. Jason Bennett** **Date: 08/31/2007**

Organization : **Chapman University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a professor of athletic training at Chapman University. I have been a practicing certified athletic trainer for 12 years.

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

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

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

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

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

Sincerely,

Dr. Jason Bennett, DA, ATC

Submitter : Dr. Alexander Zonshayn **Date:** 08/31/2007

Organization : AZ Anesthesia

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

attachement

CMS-1385-P-14907-Attach-1.WPD

CMS-1385-P-14907-Attach-2.TXT

#14907.

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,

Alexander Zonshayn, MD
12000 Bustleton Ave, Suite 208
Philadelphia, PA 19116

Submitter : Dr. Kelly Frew **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)

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Thank you for your consideration of this serious matter.

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

Organization : sutherland cardiology clinic

Category : Physician

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Sutherland Cardiology Clinic (17 Physicians) Request:
Nuclear and Echo equipment actual utilization remains below 50%.
The Proposal to increase to 75% would be inaccurate and inappropriate.

Submitter : **Ms. Denise Garris** **Date: 08/31/2007**

Organization : **American College of Cardiology**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

See Attachment

CMS-1385-P-14910-Attach-1.PDF

14910

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Washington, DC 20037-1153
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Linda D. Gillam, M.D., F.A.C.C.
David R. Holmes Jr., M.D., F.A.C.C.
Jerry D. Kennett, M.D., F.A.C.C.
Michael G. Kienzle, M.D., F.A.C.C.
Bruce D. Lindsay, M.D., F.A.C.C.
Charles R. McKay, M.D., F.A.C.C.
Michael J. Mirro, M.D., F.A.C.C.
Rick A. Nishimura, M.D., F.A.C.C.
Steven E. Nissen, M.D., M.A.C.C.
Patrick T. O'Gara, M.D., F.A.C.C.
Miguel A. Quinones, M.D., F.A.C.C.
George P. Rodgers, M.D., F.A.C.C.
Jane E. Schauer, M.D., Ph.D., F.A.C.C.*
James E. Udelson, M.D., F.A.C.C.
C. Michael Valentine, M.D., F.A.C.C.*
W. Douglas Weaver, M.D., F.A.C.C.
Kim Allan Williams, M.D., F.A.C.C.
Michael J. Wolk, M.D., M.A.C.C.
Janet S. Wright, M.D., F.A.C.C.
William A. Zoghbi, M.D., F.A.C.C.
*ex officio

Chief Executive Officer
John C. Lewin, M.D.

August 30, 2007

Mr. Herb Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8018

Dear Mr. Kuhn:

The American College of Cardiology (ACC) is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC is pleased to offer comments on the notice of proposed rulemaking entitled **CMS-1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008** published in the *Federal Register* on July 12, 2007. Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

This letter will focus on CMS's proposals for Physician Payment in 2008, issues with Section A - Practice Expense Values, Section E - Specific Coding Issues related to PFS and section S – Other Issues. We will address other provisions of the NPRM in a separate letter.

MEDICARE PHYSICIAN PAYMENT RATE FOR 2008

Due to the Sustainable Growth Rate, 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 drastic cuts. Payments to physicians today in 2007 are essentially the same as they were six years ago in 2001.

Only physicians and other health professionals face steep cuts under this flawed formula. Other providers, such as hospitals and nursing homes have payment updates that reflect the cost of inflation. In 2008, physicians and other health care practitioners whose payment rates are tied to the physician fee schedule face a 10% payment rate cut. **The ACC 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.**

A. Resource based Practice Expense Relative Value Units

Equipment Usage Percentage Assumptions – Equipment Utilization Data

The ACC commends CMS for its thoughtful and careful response to recommendations that the equipment use percentage assumption now used in calculating practice expense RVUs be changed. We agree with CMS's assessment that there is no empirical evidence upon which to base an alternative equipment use percentage and urge that the agency continue its work with the physician community to obtain the data necessary to make an appropriate decision about this issue. Until better data are available, any decisions to alter the equipment use percentage would be arbitrary and could risk creating unintended, inappropriate incentives for the purchase and use of medical equipment.

Equipment Interest Rate Assumptions – Cost of Capital Assumptions

The College also supports CMS decision with respect to the interest rate used in calculations of equipment costs. Most physician practices are small businesses, so data on loans provided by the Small Business Administration should provide a reasonably accurate reflection of the cost of credit for typical physician practices.

Cardiology Supply information

Tables 1 and 2 in the preamble to the proposed rule identified several supply and equipment items for which CMS needs current price information. Following is ACC's response to this request.

Table 1 Supply items needing specialty input for pricing			
Code	Description	New price	Source
SK 105	Blood pressure recording form	NA	
This item can be deleted. The ambulatory blood pressure monitoring system for which we are providing new price information generates the form, so separate pricing is not necessary.			
SD 140	Pressure bag	$95.00 per 5 unit box	McKesson
SD 213	Tubing, sterile, non-vented (fluid administration)	$47.46 per 50 unit box	McKesson

Table 2 Equipment items needing specialty input for pricing			
Code	Description	New price	Source
EQ 269	Ambulatory blood pressure monitor	$1920	Tiba Medical
EQ 008	ECG signal averaging system	$17,900	GE
System includes ECG cart ($12,500), software for late potential QRS ($3,200), and software for P-wave measurement which is less common ($2,200).			

We have forwarded this information, along with documentation of the prices to the responsible CMS staff.

Physician Practice Information Survey Data

On March 24, 2006, a multi-specialty sign-on letter from the AMA (signed by more than 70 organizations) was sent to CMS with the following recommendation: *We are all in agreement, however, that moving forward, it is imperative that a multi-specialty practice expense survey be conducted to collect recent, reliable, consistent practice expense data for all specialties and health care professionals. We urge CMS to work with the AMA and other physician and health professions organizations to achieve this goal.*

The ACC appreciates that CMS has expressed support of this survey process. The AMA, in coordination with over 70 specialty societies and the Gallup organization, has initiated a survey effort and plans to provide the data from the Physician Practice Information (PPI) Survey to CMS in the Spring of 2008 for implementation for the 2009 Medicare Physician Payment Schedule.

In the interim, the American College of Radiology (ACR) presented information to CMS recommending that CMS alter its practice expense methodology for radiology by weighting the survey data to account for practice size. Based on this recommendation, CMS has proposed to revise the practice expense per hour (PE/HR) associated with radiology using the survey data weighted by practice size. The radiology PE/HR is

proposed to increase 18% under this method, from $174.18 to $204.86 Although we applaud CMS for being amenable to altering its methodology to more accurately reflect specialty societies' practice expenses, the ACC believes that this action is unfair as this weighting methodology has not been done for all specialties. The weighting method is also questionable as the universe of practice sizes by specialty is unknown. CMS has not published a report or the detailed weighting methodology used in this radiology specific modification. We are concerned that this weighting method may not be available to all physician specialties, whose costs may also vary by practice size.

The ACC recommends that CMS utilize recent, reliable, and consistent practice expense data for all specialties and health care professionals.

Inputs for Cardiac Monitoring

The ACC remains concerned that the significantly reduced practice expense RVUs proposed for remote cardiac monitoring services could threaten patient access to these important services. We are pleased that CMS has requested additional practice expense data for these procedures. The ACC concurs with CMS's assessment that remote cardiac monitoring services do not fit the typical physician service model for purposes of developing direct practice expense inputs. Consequently, the current direct practice expense inputs do not capture all practice expenses required to provide remote cardiac monitoring services. **We are supportive of the work that the remote cardiac services providers have completed to date and we look forward to working with CMS and remote cardiac monitoring services providers to gather and review any additional necessary data.**

Home PT/INR Monitoring

The ACC appreciates CMS's attempt at correcting the problem raised when applying the standard Medicare Physician Fee Schedule PE RVU methodology to home PT/INR monitoring—especially the application of the methodology for equipment time in use cost to the PT/INR monitor. We are concerned about increasing the minutes in use from 32 to 1,440 as it does not appear to have a rational basis and does not provide for adequate recoupment of the cost of the device. ***We urge CMS to correct the equipment cost inputs to assure that payment will be adequate to support appropriate use of this technology.***

Anticoagulation Management Services

ACC strongly disagrees with the CMS decision to continue to consider anticoagulation management codes (99363 and 99364) to be bundled into the work of evaluation and management codes. The initial impetus for the creation of this code was the 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 complete range of this

work is not paid under the current system. During the creation of the code, the Current Procedural Terminology (CPT) editorial panel and the Relative Value Scale Update Committee (RUC) were very careful to create protections in the code that would prevent work from anticoagulation management being included in selecting the level of evaluation and management codes. 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. There is still no explanation offered in the 2008 proposed rule.

ACC strongly encourages CMS to not finalize its proposal to consider these services bundled but instead change their status to a covered service. Anticoagulation management services are an important responsibility and CMS should recognize the extensive work involved by paying for this service.

Diagnostic Catheterization – Non-facility Practice Expense Inputs

At the February 2007 RUC Meeting, the Practice Expense Review Committee reviewed a request from CMS to establish non-facility inputs for the family of CPT codes 93501 through 93556 for cardiac catheterization. The ACC, in cooperation with the Society of Cardia Angiography and Interventions and the Cardiovascular Outpatient Center Alliance, developed PE inputs for the nonfacility setting for 13 of the 28 CPT codes in this family. The PERC considered the proposed new or updated PE input recommendations for 13 cardiac catheterization CPT codes.

The specialty societies recommended that the remaining 15 codes in the cardiac catheterization family remain carrier-priced, or be assigned an "NA" for the practice expense in the office setting. ***The ACC would like to thank CMS for their consideration and acceptance of this request.***

Further ACC noted an error in the calculation of the indirect practice expense for the cardiac catheterization injection codes (CPT 93539 – 93545). The PE labor table incorrectly notes "NA" in the facility setting for this code series. As noted in a July 23, 2007 communication to CMS, the site of service indicator should be changed as the PE methodology automatically picks this up in the calculation of indirect practice expenses.

Professional Liability Insurance (PLI) RVUs (TC/PC) Issue

In the July 12, 2007 *Proposed Rule*, CMS indicates that "we would like to better understand how, and if, technicians employed by facilities purchase PLI or how their professional liability is insured. In addition, we are soliciting comments on what types of PLI are carried by facilities that perform technical services."

The ACC believes that in the case of imaging services, this approach results in PLI RVUs that do not accurately reflect the relative professional liability costs associated with the

professional and technical components. Although the technical performance of an imaging service does entail some professional liability risk, the liability risk associated with the physician interpretation of the imaging service is much greater. We urge CMS to develop a more accurate method for distributing the PLI RVUS between professional and technical components. Development of such a method may not be accomplished quickly. ***In the short term, therefore, ACC recommends that CMS reverse the current assignment of PLI RVUs between technical and professional components.***

E. Specific Coding Issues related to PFS

Additional Codes from the Five-Year Review

In May 2007, the RUC submitted recommendations for nine issues identified for review as part of the 2005 Five-Year Review. We thank CMS for accepting the RUC's recommendations for the Insertion of Heart Pacemaker (CPT code 33207).

The ACC was disappointed to learn that CMS rejected the RUC's recommendation to refer CPT code 93325 *Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)* to the CPT Editorial Panel and proposes instead that this service be bundled.

As stated in the ACC' August 10, 2007 letter to CMS, we do not agree with CMS' assertion that color flow Doppler is "intrinsic" to all echocardiography services. Historically, 1-dimensional echo (M-mode) was developed in the 1970's, 2-dimensional echo became common in the early 1980's, spectral Doppler (93320) grew in the late 1980's, and color flow Doppler (93325) became common in the early 1990's. Each new technology required new transducers and new equipment. Over time it has become common to perform routine 2-dimensional echocardiography (93307) with spectral Doppler (93320) and color flow Doppler (93325), but the Doppler services have not become an intrinsic part of any echo service. Every echo case does not require Doppler. In every echo case where Doppler is used, there is a conscious decision to adjust the imaging mode and acquire a different type of information with very different clinical implications. Examples of its use include the assessment of heart murmurs and the assessment of timing and magnitude of systolic and diastolic left ventricular contraction. Color Doppler is critical for differentiating mild degrees of valve regurgitation that do not require surgical intervention from more significant degrees of valve regurgitation that are treated by valve repair or replacement.

The ACC and American Society of Echocardiography (ASE) will present physician work and practice expense recommendations for the new combined echocardiography code at the September 2007 meeting of the RUC. We believe that implementation of the new combined echocardiography code -- with RVUs reflecting the RUC's evaluation of the

physician work and practice expense associated with the code-- will largely address CMS's concerns about separate reporting of 93325.

The ACC strongly urges CMS to allow this issue to be addressed within current processes and not finalize your proposal to bundle 93325 in 2008. We understand that CMS initially brought this issue to the Five-Year Review of the RBRVS and would like to see it addressed promptly. We believe that the specialty has moved forward and CMS should recognize that the process is working to resolve the agency's concerns, while ensuring that the resources required to provide this service are accurately reflected in CPT and the RBRVS.

Cardiac Rehabilitation Reporting

The ACC is concerned with the proposed new Medicare policy to change the definition of session to a unit to per hour. In well over 95% of clinical situations, those sessions are one hour long, so we believe that very little new data, if any, will be gained by a coding shift that changes a unit from a "session" to an hour.

We are also concerned about the inclusion of the term "physician service" in the actual payment tables. Prior to implementation of the revised National Coverage Determination (NCD) for Cardiac Rehabilitation Programs (20.10) the issue of physician proximity during cardiac rehabilitation services was controversial and inconsistently defined by Medicare contractors. The revised NCD addresses the issues and defines requirements for physician proximity and availability. We are concerned, though, that including the term "physician service" in the payment tables could confuse Medicare contractors.

The ACC recommends that CMS remove the term "physician service" from the payment table vernacular as it will unquestionably confuse Medicare contractors regarding physician presence during cardiac rehabilitation. Also, clarify the coding parameters for use of the "hour" timeframe. For example, what documentation is needed in the medical record to ensure appropriate payment? Is the window for one hour from 46 minutes to 74 minutes, or is it from 31 minutes to 89 minutes, or is there some other parameter. And finally, given the fact that "sessions" do equal one hour, we question whether CMS will gain any new data that would be helpful in accurately measuring the services provided.

S. Other Issues

Proposed Elimination of Exception for Computer-Generated Facsimiles

While the ACC agrees that CMS' eventual goal of moving to e-prescriptions is worthwhile, we nevertheless have some concerns that the proposed elimination is perhaps premature at the present time. We also appreciate that CMS is eager to foster a "tipping

point" that incentivizes transition to use of the SCRIPT standard among physicians and providers. The ACC has consistently supported movement toward adoption of an "Electronic Health Record" (EHR) system to help improve both the quality of, and efficiency in providing, health care to our fellow citizens.

Our initial concern is that the proposed change confuses "mandate" for "tipping point" however. The proposed approach may in fact create incentives for current and prospective users to revert back to paper dispensation for prescriptions by forcing the change too quickly on providers—despite the one-year "grace" period. CMS' goal should instead be to set the conditions in place for a true "tipping point" to occur—absent a mandate—so that the incentive to change will be obvious to all, and the cost of non-adoption will be equally prohibitive and apparent.

In reviewing the discussion provided in the section to justify the proposed change, we noted that, while identifying the lack of changeover, no theories or explanations are given to address why the e-prescribing has not changed. We submit for CMS' consideration that since the percentage of SCRIPT non-participants has now been established, efforts should focus next on identifying those factors contributing to non-adoption by providers—perhaps through surveys or other quantifiable methods. Once the underlying factors engendering non-participation are identified, options to address them appropriately—including the possibility of a mandate—can be developed and implemented with the input of all stakeholders in a collaborative effort.

As proposed, the ACC is concerned that this mandate puts a disproportionate financial and administrative burden on smaller physician practices and pharmacies, especially those located in rural areas without reasonably convenient access to technical support. Implementation of the proposal could—for many practices—not just force an upgrade of any currently-employed e-prescribing system using computer-generated faxes, but also require additional staff training that will change office workflows in both smaller and larger practices. Such costs will not be trivial; while a software "upgrade" to accomplish compliant electronic transmission may be provided by the practice's vendor via annual maintenance contracts, substantial work will still be placed on the individual practices to implement the changes and route the e-prescriptions appropriately.

As stated in our comments discussing the effects of a proposed elimination of the exemption, we strongly recommend CMS conduct studies to identify why the SCRIPT standard hasn't reached a "tipping point" toward adoption among providers before issuing any mandates for change. Again, once underlying factors contributing to non-participation are identified, CMS can then engage stakeholders to develop options to address them appropriately.

Recalls and Replacement Devices

While the ACC agrees that CMS' concerns regarding the financial consequences of these product recalls/replacements are justified, the agency's primary criterion while evaluating

a course of action should be consideration of how any policy promotes the best interests of beneficiaries and ensures their access to continuing care for any condition arising out of recalls. Ultimately, should CMS adopt a policy that reduces access for beneficiaries affected by the recall to necessary care, the Medicare program may—in the end—have to

pay higher costs for more catastrophic care later than what would have been expended to monitor patients earlier on in the course of treatment.

It is our belief that adoption of a policy that would restrict access to patient care or reduce physician reimbursement would be very disruptive and will not result in significant savings to the Medicare program. In fact, Medicare may wind up paying higher costs for more catastrophic care than what would have been expended to monitor patients.

The ACC recommends that any actions CMS pursues to address the added physicians' costs for beneficiary diagnostic and other monitoring services not adversely impact—or otherwise place the cost burden on—the physicians providing these necessary services. It would be patently unfair to financially "penalize" physicians who—bearing no fault for the device manufacturers' product defects—are left to address the consequences of the product recalls and the needs of adversely affected beneficiaries. The ACC also requests that CMS defer development of any provisions until the potential outcomes have been thoroughly vetted through the appropriate stakeholders with a vested interest in pacemaker and ICD patient care.

Thank you for the opportunity to comment upon this proposed rule. The ACC appreciates CMS' continued willingness to work cooperatively with the physician community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Rebecca Kelly, ACC's Director of Regulatory Affairs at 202-375-6398 or rkelly@acc.org with any questions.

Sincerely,

James T. Dove, M.D., F.A.C.C.
President, American College of Cardiology

cc: Kenneth Simon, MD - CMS
Edith Hambrick, MD - CMS
Pam West - CMS
Rick Ensor - CMS
Ken Marsalek - CMS
ACC CV-RUC
ACC Advocacy Committee
ACC SLT

Submitter : **Mr. Bryan Renshaw** **Date: 08/31/2007**

Organization : **Mr. Bryan Renshaw**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

RE: Physician Self-Referral Provisions.

I wish to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the in-office ancillary services exception. I have been a physical therapist for nine years. The first four years of practicing physical therapy I worked for a "physician-owned" physical therapy clinic. The last five years I have owned a outpatient physical therapy clinic. I have seen first hand the abuse that can arise by physicians owning a physical therapy practice. Physicians will typically tell their patients that they need to supervise their care by keeping them in the clinic in their facility. I never experienced a physician monitoring their patient's treatment. I have heard direct comments from physicians saying that they wanted to own a physical therapy clinic in order to increase their profit margins. When I was a part of a physician owned clinic I was instructed in the number of visits and units that I needed to have in order to increase the physician's profit margin. I have also heard many comments from my patients in regard to the superior care offerred to them by physical therapist owned clinics. I believe that CMS and medicare beneficiaries would both benefit from changing the provisions for in-office ancillary services to exclude physical therapy. Thank you for your time and consideration.

Bryan R. Renshaw MSPT

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

Organization :

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Amy Whitley and I am a certified athletic trainer. I am currently employed at North Mississippi Medical Center in Tupelo, Mississippi. My job responsibilities require my medical services at Pontotoc and South Pontotoc High School. Along with my athletic training degree, I also have a Masters in Food Science, Nutrition, and Health Promotion.

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

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

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

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

Sincerely,
Amy Whitley, ATC

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

Organization : Emory University Sports Medicine

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Gina Shipman and have recently graduated from undergraduate at Culver-Stockton College. I am a newly Certified Athletic Trainer in the profession, and have a graduate assistantship through Georgia State University working at Emory University (both in Atlanta, GA).

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

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

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

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

Sincerely,

Gina Shipman, ATC

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

Organization :

Category : **Individual**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

I SUPPORT THE ANESTHESIA CONVERSION FACTOR INCREASE.

CMS-1385-P-14914-Attach-1.DOC

#14914

August 31, 2007

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

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

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am from New Bern, NC. I am glad to see that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue. I am concerned that I will have limited access to anesthesia services as a patient. I support the increase in the Medicare payment for anesthesia services to ensure that I have access to anesthesia services for me and my friends The current amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists, like my dad, are being forced away from areas, like New Bern, with disproportionately high Medicare populations.

.

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

Thank you for your consideration of this serious matter.

Sincerely,

Carolyn Panza

Submitter : **Dr. Maneesh Amancharla** **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. Kevin Bolton** **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

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Anesthesia Coding (Part of 5-Year Review)

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

Thank you for your consideration of this serious matter.

Submitter : **Dr. James Borden** **Date: 08/31/2007**

Organization : **SWFUA**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Physician Self Referral

CMS-1385-P-14917-Attach-1.DOC

14917

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,

James D. Borden, M.D.

Submitter : **Mr. Patrick Board** **Date: 08/31/2007**

Organization : **Associated Physicians**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See attachment

CMS-1385-P-14918-Attach-1.PDF

CMS-1385-P-14918-Attach-2.PDF

#14918

COMMENT:
2008 MEDICARE PHYSICIAN FEE SCHEDULE

The overriding goal of the Medicare program is to provide its beneficiaries with access to medically necessary quality healthcare. The proposed rule changes for services "under arrangement" will have a devastating impact on access to quality health delivery by beneficiaries who reside in non-urban regional areas. In regions characterized by populations comprised of less than 250,000 over broad geographic areas, access to the technology incorporated in numerous diagnostic and intervention services is often dependent upon collaborative arrangements among health providers, involving, of necessity, both physician management and investment.

The proposed rules would render illegal fledgling agreements among physicians and hospitals in these small urban communities. These "under arrangements" and provider-based joint ventures, through collaborative investments have brought new technologies and improved services to their communities. "Under arrangements" and provider-based joint ventures are essential to producing efficiency and access for Medicare patients in familiar, easily accessible regional locations. Given the limited populations in these cities, and the resulting smaller pool of trained technicians, and nurses, sources of capital pooling of resources are critical to launching these new services and providing local access. Physicians often represent the most efficient source of capital and the only trained persons to supervise the allied health providers. Outpatient settings often offer more cost effective (even if on the hospital campus) alternatives to certain of these services. Local hospitals in small communities often struggle to find the capital to fund their inpatient technology and service requirements and to recruit the medical staff necessary to serve the health needs of their patients.

Rationale for creating a small urban exception:

A. "Under Arrangements" and Joint Venture Agreements provide access and efficiencies in the smaller urban markets.

In a period of increasing competition and demand for state-of-the-art diagnostic and therapeutic modalities, the regional health-care provider, meaning both hospitals and physicians, has limited opportunities to create productive partnerships that allow for risk sharing, wiser allocation of limited resources, and meaningful management by the physicians who assume management responsibility in a hospital setting. Although excoriated in the preamble of the Proposed Rule, the allegation that "no legitimate reason" for such arrangements exists paints with too broad a brush, especially in the many more remote locales in the United States where millions of Medicare beneficiaries patients prefer to seek and receive treatment within 50 miles of their homes—and certainly not in the intimidating environs of larger cities where such treatment opportunities inevitably will concentrate if the regional provider no longer can compete.

The objectives of the "under arrangements" agreements in these small urban settings permit the hospital and the physician to pool their diverse areas of clinical and management expertise. When the hospital and physician and/or physician groups work together, the much criticized tendency to duplicate services—with the multiple radiology devices, for example—is eliminated, thus reducing the capital expenditures of those providers and, in due course, realizing savings for the patient and the third-party payor. This collaboration extends beyond the financial statement to creating genuine communication and engagement among providers who, while sharing a common commitment to patients, often approach patient care issues from different vantage points and cultures. Who better to manage and oversee a cardiac catheterization laboratory than the very physicians who perform interventions each day? These physicians are postured to evaluate services, personnel, patient needs, equipment and supply utilization, and patient outcomes. And, although certainly not in vogue in the modern era, the physician who has at least some marginal economic interest in the efficiency of the lab (or other facility) has a natural motivation to weigh costs and effectiveness with unprecedented focus. It is this economic efficiency—the emphasis on cost control and collaborative deployment of resources—that the regional provider proposes will result in ultimate benefit to the patients and the payor system.

B. In smaller markets the benefits of physician management outweigh the potential for abuse.

Smaller communities have only a handful of specialists in critical specialty areas such as orthopedics, cardiology, radiology, oncology, neurology and urology. The pool of trained staff is limited. These physicians are highly visible and the potential for abuse is limited given the smaller physician community. When such services are managed by physicians with an eye to increased efficiency, the patient experience is improved as well. The objective is to handle patients with safe and appropriate treatments, of course, but there is yet another motivation to provide a positive experience and a higher level of patient access and convenience. At the heart of such arrangements is a joint commitment by the hospital and the physician manager (or joint venturer) to increase and maximize patient satisfaction with the physicians' professional expertise being at the cornerstone of the clinical oversight and decision making.

The Proposed Rule would invalidate arrangements where physicians directly perform or supervise the services. These are exactly the type of services where, especially in smaller markets, physician involvement is beneficial for both efficiencies and for quality. Abuse is highly unlikely because the physician has a strong incentive that the patient derive satisfaction for the combined service as physicians' major source of referrals are from satisfied patients (or referring generalists who want their patients to be well treated).

Similar benefits are evident in the "under arrangements" services available in provider-based surgery centers. Again, physicians or physician groups bring to bear years of experience in the surgical suite and bring a focused management perspective on such entities. This management experience would extend not only to the daily operation

of such facilities, but also to the management of costs and the pursuit of high patient satisfaction. When there is alignment of business and management of objectives, the tendency to duplicate services—i.e., creation of a competing free-standing ambulatory surgery center—is no longer an issue. Resources are either saved or directed to other initiatives to expand patient care.

C. The financial opportunities are significant to recruit and retain quality physicians into smaller urban markets.

Physician Recruiting in smaller urban markets is becoming increasingly difficult due to the competitive advantages of larger urban markets, in compensation, advancement, and access to technology. Stand alone physician fees which have seen a decrease from Medicare since 2002 and much more dramatic reductions from third-party payers, combined with increased practice operating costs. The 2001 Medicare Conversion factor was $38.2581 and in 2007 the rate is $37.8975. The Medical Group Management Association has long compiled information on physician practice operating costs. For the period 2001-2007 practice operating costs have increased 34%. These challenging economic realities may result in the inability to recruit and retain quality physicians to serve these populations. Compounding this situation is the very high demand for most specialty physicians. According to Merritt, Hawkins & Associates, a large national recruiting firm, over 75% of searches today are for specialty (non-primary care) physicians. An article in *Health Affairs* identified a potential shortage of 200,000 by 2020 if current demographic and medical trends persist. We anticipate the shortage would only be compounded in smaller regional communities where there is simply less of any physician specialty to meet the community's needs.

The foreboding world foreshadowed by the preamble and the Proposed Rule increases the burden of the regional health care provider to compete on all fronts. Retaining a quality pool of physicians requires not only more than the minimum of diagnostic and therapeutic resources for patients, but also the prospect of competitive compensation for that work. The loss of "under arrangements" opportunities will make for hard choices. If capital resources are stretched, or limited capital leads to an unequal focus in the multi-specialty practice, physicians naturally go where their best interests lead them—to larger facilities with the best equipment and the best prospect of a successful practice in all respects. Over time, the talent pools where it is less needed—in the urban, expanding, crowded, and intimidating medical centers—and away from the cities of 100,000 that provide easy access and a comfortable environment for patients in its region. The loss of "under arrangements" means the evaporation of one more tool a regional provider may have to attract quality physicians to outposts distant from medical training hospitals and urban medical centers.

D. The proposed rule would have a disproportionate adverse impact on access to quality medical care in small urban markets of less than 100,000

CMS faces daunting challenges, no doubt, in executing the legislation authorizing the Proposed Rule. The concerns raised in the preamble are not cynical; no doubt, there

are arrangements which offend the intent of Congress and the spirit of these rules. But the prescription for addressing these issues is administered in an identical dosage for all providers in the Proposed Rule—the small regional hospital's alliance with its capable medical staff in the operation of a cardiac catheterization lab or a radiation oncology treatment center is restrained identically to the massive urban health care centers for which such arrangements are less critical. In larger communities, physicians can collaborate and advance technology through educational foundations and grants, the endowments of the not for profit hospitals are generally greater and tied to major universities or not for profit systems.

Given this reality, the Proposed Rule once adopted will condemn smaller communities to one of three negative scenarios that will adversely affect access and quality:

- Recruitment of physician specialists will become increasingly difficult and the availability of such specialists will decline.

- New technologies will be introduced but at suboptimal efficiency and quality due to duplication and lack of qualified personnel.

- These communities will not have access to convenient life saving (and even cost saving) new diagnostic and minimally invasive interventional technologies

Rationale for Personal Services Exception

The Medicare Program has long recognized that physicians' self referral is at the core of the doctor-patient relationship and therefore not subject to abuse so long as services are medically necessary. Physician management agreements, provider-based joint ventures and "under arrangements" services agreements where those services that are personally supervised by physicians who are performing services will not result in over utilization since at the core of the referral decision is the physicians' personal determination of the need to treat. The fact that many of the most effective and therapeutic medical services performed by physicians are supported by technology or by allied health service providers should not preclude physicians from having a financial interest in them.

Obviously, financial interest and management oversight by physicians who are physically present can lead to greater efficiencies and quality. Moreover, physician control will provide greater clinical sensitivity. In smaller communities, the pooling of best practices by using resources from hospital and multiple physician groups may be the only way to provide these services on a cost effective and clinically sound basis. We suggest that any such services be permitted provided that adequate peer review programs are in place.

Rationale for Group Practice Exception

Group practices offer:

- substantial patient convenience and coordination of medical records to avoid unnecessary duplication of tests and enhance the quality of care to patients
- convenient access to specialty consults and physician scheduling and continuity of care
- resources for joint investment in technology, and
- critical mass to support better administration, physician education, information systems, improved purchasing and to support improved benefits and efficiencies for nursing and allied health staff

Group practices have overhead that could be amortized over the provision of ancillary services under the supervision of the physicians and administrators in the group practices. This will lower costs by providing incentives for convenient and timely ancillary services to be provided by those practices. Often times, collaboration with hospital and other service providers in joint ventures or "under arrangements" services have been structured so as to avoid duplication and to bring to the table the best resources from both organizations. Group practices should have the flexibility to work with other physicians and hospitals to bring new technologies and services to their communities. In smaller communities the benefits of this exception are even greater as the group practices that are permitted to participate in these ancillary service ventures would be better position to recruit and retain quality specialists.

Conclusion

We urge CMS to weigh carefully the unintended consequences of its Proposed Rule and the potential collateral damage it portends for the regional health care community which provides critical care to millions of Medicare recipients across the country. In addition to the obvious adverse impact on health delivery it will also adversely affect the local economies of these communities as the large group practices and hospitals are some of the largest employers in the region and the local economies will suffer if these professionals and allied health providers concentrate in large urban markets.

We suggest the Proposed Rule have three well delineated exceptions:

1. **Small Urban Exception.** The Rules would not prohibit arrangements among physicians and hospitals under the provider based joint rules or under arrangements where the facilities are located in counties having an aggregate population of less than 150,000 persons.

2. **Personal Services Exception.** The Rules would not prohibit arrangements where the physicians personally perform services at the facilities they manage or provide services either as hospital based joint ventures or under arrangements.

3. **Group Practice Exception.** These arrangements would be permitted among physicians in a community so long as at least 70% of the control and ownership of the management services provider was held by not more than two group practices (or specialist physicians within such practices).

Dated: August 31, 2007

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Category : Local Government

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

See attached comment in pdf format.

CMS-1385-P-14919-Attach-1.PDF

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Hon. Edward W. Pliska
(1935-2006)
Xenophon Tragoutsis (Ret.)

August 29, 2007

Via Electronic Submission

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

Re: Comments on CMS-1385-P
"GEOGRAPHIC PRACTICE COST INDICES (GPCIs)"

To Whom It May Concern:

This office represents the following counties in the State of California: County of Santa Cruz, County of Sonoma, County of San Diego, County of Marin, County of Santa Barbara, and County of San Luis Obispo. Each of our clients is a "supplier" of medical services as that term is defined in 42 U.S.C. § 1395x (d). The following responses are submitted on behalf of each of those California counties.

I. General Comments

Generally speaking, the proposed rule does too little, too late. There have been no updates to the geographic localities used to calculate payments under the physician fee schedule since 1997 and this has resulted in significant underpayments being made to our clients as well as to numerous other suppliers in over 440 counties nationwide. (*See* Geographic Areas Used to Adjust Physician Payments for Variation in Practice Costs Should Be Revised, GAO-07-466, June 2007 ["GAO Report"], p. 5.)

There is currently a significant need for a uniform revision of the locality structure and that revision should be applied to all states, not just to California. Suppliers in more urbanized counties across the country are not the only ones being affected by Medicare's failure to revise the locality structure. Beneficiaries in urban counties that are part of large multi-county localities have seen their access to health care reduced as suppliers increasingly eliminate Medicare patients from their practices. In addition, beneficiaries and/or their supplemental

insurance carriers in rural counties that are part of large multi-county localities are paying more than they should because the payment levels in their localities are artificially inflated by the inclusion of urban counties (and their higher county GAFs) in those localities.

Perhaps the most significant defect of the Proposed Rule is the failure to provide for periodic revisions of the locality structure using defined criteria. This was a central recommendation of the Government Accountability Office in its recent report which was specifically addressed to the issue of the adjustment of localities:

> "Regarding our second recommendation – that CMS examine and, if necessary, update the payment localities on a periodic basis – the agency stated that it considers payment locality issues when concerns are raised by interested parties and based on its own initiative, an approach that it believes is more flexible and efficient than examining the payment localities every 10 years. Reviewing payment localities in response to concerns raised by interested parties, however, could result in CMS examining only selected physician payment localities, rather than examining all payment localities using a uniform approach. Updating the payment localities at least every 10 years when new decennial census data become available would ensure that Medicare appropriately accounts for chances in the geographic distribution of physicians' costs of operating a private medical practice." (*See* GAO Report, p. 41.)

Medicare has not demonstrated any ability to modify payment localities consistently with significant demographic changes over the last eleven years. In the 1996 Final Rule, Medicare stated a position similar to its response to the GAO's recommendation on updating localities:

> "While we do not plan to routinely revise payment areas as we implement new GPCIs, we will review the areas in multiple locality States if the newer GPCI data indicates dramatic relative cost changes among areas." (Final Rule, 11/22/1996, 61 FR 59497.)

Rather than addressing the significant demographic changes that it recognizes have occurred in the years since 1996, Medicare has repeatedly refused to implement any locality changes at all. (Proposed Rule, 8/15/2003, 68 FR 49044; Final Rule, 11/7/2003, 68 FR 63214; Proposed Rule, 8/5/2004, 69 FR 47504; Final Rule, 11/15/2004, 69 FR 66263; Proposed Rule, 8/8/2005, 70 FR 45784; Final Rule, 11/21/2005, 70 FR 70152-70153; Proposed Rule, 8/22/2006, 71 FR 48994; Final Rule, 12/1/2006, 71 FR 69655.)

Medicare's demonstrated inability to implement needed locality modifications on its own initiative underscores the absolute necessity of adopting a rule under which Medicare is required to update localities based on uniform criteria at specific intervals of time. It is our clients'

position that the 10-year period proposed by the GAO is too long and would suggest that a 3-year period would be more appropriate. That would make the updating of localities under Part B consistent with the period for updating localities under Part A.

II. Discussion of Specific Issues

A. Errors in the Data Tables Make Them Unreliable

We find ourselves unable to effectively comment on any of the three options presented in the Proposed Rule (72 FR 38137-38142) primarily because the data contained in the explanatory tables in unreliable in the following ways:

(a) the tables for Options 1-3 contain inaccurate calculations of percent change due to locality changes;

(b) the tables for Options 1-3 show inconsistent values for county GAFs for 6 counties;

(c) the tables for Options 1-2 appear to have been derived from methodologies that are inconsistent with prior practice;

(d) the table for Option 3 appears to have been derived from a methodology that is inconsistent with the methodology laid out in the descriptive text for Option 3; and

(e) the table for Option 3 appears to contain incorrect GAFs for San Diego County, Santa Clara County, San Benito County, and perhaps other counties.

These inconsistencies and apparent errors call all of the data shown in the tables into question. On July 17, 2007, we submitted a FOIA request for, *inter alia*, data underlying each of the GAFs and GPCIs shown on the tables. Our FOIA request included a request to expedite the response so that we would be able "to submit a timely and complete response to the Proposed Rule published by CMS in 72 FR 38122." To date, we have not received a response to that request and are therefore unable to submit a complete response to the Proposed Rule.

Following are descriptions of the specific statistical deficiencies that are apparent on the face of the Proposed Rule.

Given the number and magnitude of the statistical errors, we request that the Proposed Rule be republished, the comment period reopened, and all requested underlying data be made available to allow the public to make full and informed comments.

1. Inaccurate Percentage Change Figures

As shown on the attached Exhibits A through C, each of the percentage change figures shown on Tables 7 through 9 are incorrect.

All but one of the percent change figures on Tables 7 and 8 are off by less than one percent and such differences may admittedly be due to rounding of data in the tables.

However, the difference between the percent change shown for Rest of California in Table 8 (-0.049%) and the actual percent change (-0.49%) cannot be so explained. Similarly, the errors in the percent differences in Table 9 range from -11.9% to 10.23%, and differences of such magnitude cannot be explained by rounding. The source of these errors is not apparent and may result from data errors, data entry errors, or formulaic errors.

Given the magnitude of the errors, we believe that the Proposed Rule should be republished with the errors corrected, the data we requested should be provided, and the comment period reopened.

2. Inconsistent Values for County GAFs

As shown on the attached Exhibit C, the 2009 County GAFs for six counties (Santa Cruz, Monterey, Sonoma, Marin, Solano, and Napa) are not consistently shown on Tables 7 through 8.

The reason for the inconsistencies is not apparent. Given the magnitude of those inconsistencies, we believe that the Proposed Rule should be republished with the inconsistencies resolved, the data we requested should be provided, and the comment period reopened.

3. Incorrect Use of the 5% Iterative Method in Options 1 & 2

Although Options 1 and 2 purport to use the 5% iterative method used by Medicare in redefining the localities in 1996, the method described in the Proposed Rule is considerably different from that used in 1996 and was expressly rejected by Medicare in 1996.

In 1996, Medicare described the 5% iterative method it adopted ("Option 1i") as follows:

> "Under this [rule], current localities are used as building blocks. The 22 existing statewide localities remain statewide localities. [The rule] sets new localities in the remaining 28 States by comparing the area cost differences as represented by the locality GAFs within a State. An area's GAF is a weighted composite of the area's work, practice expense, and malpractice GPCIs and allows a comparison of

> overall costs among areas. Briefly, a State's localities are ranked from the highest to the lowest GAF. ***The GAF of the highest price locality is compared to the weighted average GAF of all lower-price localities.*** If the percentage difference exceeds 5-percent, the highest-price locality remains a distinct locality. If not, the State becomes a statewide locality. If the highest-price locality remains a distinct locality, the process is repeated for the second highest-price locality. Its GAF is compared to the statewide average excluding the two highest-price localities. If this difference exceeds 5-percent, the second highest price locality remains a distinct locality. This logic is repeated, moving down the ranking of localities by costliness, until the highest-price locality does not exceed the combined GAFs of all less costly localities by 5-percent and does not remain a distinct locality. No further comparisons are made, and the remaining localities become a residual rest-of-State locality. ***The GAF of a locality always is compared to the average GAF of all lower-price localities.*** This ensures that the statewide or residual State locality has relatively homogeneous resource costs. [Emphases added.]" (Final Rule, 11/22/1996, 61 FR 59494.)

The GAO used a similar methodology to develop the "county-based iterative" and "MSA-based iterative" options it described in its recent report. (*See* GAO Report, p. 24.)

In contrast, Options 1 and 2 of the current Proposed Rule compares a county's GAF to its locality's GAF. This methodology (referred to in 1996 as "Option 1") was expressly rejected by Medicare in 1996 for two reasons:

> "First, some mid-sized metropolitan areas in large States such as California and Texas do not remain distinct FSAs despite their considerably higher input prices than in the rural and small city areas of their States with which they would be combined into a single residual area. Second, some large metropolitan areas in small States, such as Baltimore, Maryland, do not remain distinct FSAs. This is because the State GAF to which all locality GAFs are compared contains the high cost area GAFs. This makes it difficult for the mid-sized areas in large States to exceed the State GAF, even though their own GAFs may substantially exceed the GAF of all other localities in the residual area to which they would be assigned under Option 1. In large States with a wide range of GAFs, the mid-sized cities and metropolitan areas tend to be combined with the residual rest-of-State area. Their GAFs are sharply reduced, lessening the accuracy of input price tracking and creating large boundary differences in GAFs between large and mid-sized cities and at rural State boundaries that are not reflective of true input price differences." (Proposed Rule, 7/2/1996, 61 FR 34618.)

We believe, but cannot state with certainty because Medicare has not provided us with the underlying data, that using the methodology it had previously rejected accounts for the fact that certain counties (including San Diego, Santa Barbara, San Luis Obispo, Sacramento, El Dorado, and Placer Counties, among others) were not – but should have been – included in the list of new localities in Options 1 and 2.

Given the unexplained use of a methodology that Medicare had previously rejected, we believe that the Proposed Rule should be republished with the proper methodology employed in Options 1 and 2, the data we requested should be provided, and the comment period reopened.

4. Conflict Between the Value for the County GAF for San Benito County Shown in Proposed Rule and the Value Shown by GAO

There is a significant difference between the value for the county GAF for San Benito County shown in the Table 9 (0.971) and the value shown by the GAO (1.081). (*Compare* 72 FR 38142 with GAO Report, p. 54.)

We believe the difference must lie in the census and/or housing data used by Medicare and the GAO. The magnitude of the difference calls all data in Tables 7 through 9 into question. Therefore, we believe that the tables in the Proposed Rule should be checked for error, the Proposed Rule should then be republished, the data we requested should be provided, and the comment period reopened.

5. Conflicts Between Table 9 and Option 3 Description

There are discrepancies between description of Option 3 and the locality configuration shown in Table 9 resulting from the failure to correctly employ the methodology as described.

The methodology for Option 3 is described as follows:

> "[W]e sorted the counties by descending GAFs and compared the highest county to the second highest. If the difference is less than 5 percent, the counties were included in the same locality. The third highest is then compared to the highest county GAF. This iterative process continues until a county has a GAF difference that is more than 5 percent. When this occurs, that county becomes the highest county in a new payment locality and the process is repeated for all counties in the State." (72 FR 38141.)

In contrast, the groupings of the five proposed localities shown in Table 9 appear to have been defined at times by an absolute differential of 0.05 and at times by a relative 5% differential.

If a 5% differential is uniformly employed as described in the text of the Proposed Rule, six localities would result, not five as shown in the table.

The attached Exhibit E shows the localities created by the use of a relative 5% differential. Exhibit E assumes that most of the "Current County GAFs" shown in Table 9 are correct, a fact which, as discussed above, is open to question. As noted on Exhibit E, the county GAF for San Benito as calculated by the GAO Report is used, and the county GAFs shown in Table 8 for Marin, Napa, Solano, Santa Cruz, Sonoma, and Monterey Counties are used as we tentatively believe those values to be more accurate than those shown in Table 9.

For these reasons, we believe that the proposed localities shown in Table 9 need to be corrected, the Proposed Rule needs to be republished, the data we requested needs to be provided, and the comment period needs to be reopened.

B. The Declines in Certain County GAFs Are Not Supported by Changes in HUD Rental Data

The Proposed Rule states: "Rent data produce the most significant changes because they are based on annual changes in HUD rents and are therefore more volatile than the wage (Census) data." (72 FR 38138.)

In our FOIA Request of July 17, 2007, we asked to be provided with:

> "The source file for Practice Expense GPCIs for the years 1999 to 2009, including documents sufficient to show: (a) the rent data, wage data, and other expense data used for all counties and localities; (b) the methodology used to modify any HUD rent data employed in the calculations, including which percentile and type (number of bedrooms) used; and (c) the actual calculation used for all counties and localities in order to arrive at the peGPCI for each (this should include all components of the peGPCI)."

As previously noted, we requested that the response be expedited so that we could effectively respond to the Proposed Rule, but no response was forthcoming.

We made the request after noting that several counties, including San Diego and Santa Clara, show declines in their county GAFs between 2006 and 2009 that do not appear to be supported by changes in the most volatile component of the GAF formula – fair market rental ("FMR") data supplied by HUD.

The attached Exhibit F illustrates the issue with respect to San Diego County. Between 2006 and 2009, the GAF for San Diego County will decline by 1.83%. In contrast, the FMR for

2-bedroom units is set to increase by 21.40%. The fact that the GAF is declining when the FMR is increasing and the magnitude of the FMR increase when compared to the GAF decrease leads us to believe that the 2009 county GAF for San Diego County shown in Table 9 is incorrect. The data we sought in our FOIA request would have confirmed or negated that belief.

The attached Exhibit G illustrates the issue with respect to Santa Clara County. Santa Clara County dropped from No. 1 nationally (with highest rate of repayment by Medicare to physicians) to No. 3 between 2007 and 2008. The significant percentage changes as between Santa Clara, San Mateo, and San Francisco Counties in their respective repayment rates, or Geographic Adjustment Factors ("GAF") cannot be explained by the respective changes in the factors that most affect the formulaic outcome -- namely, FMR data and the Practice Expense Geographic Practice Cost Index ("peGPCI").

Between 2007 and 2009, the county GAF for Santa Clara County is set to decline by 9.25%. In contrast, the FMR for 2-bedroom units is set to increase by 0.70%. The contrasts between changes in the county GAF and the FMR for Santa Clara County leads us to believe that the 2009 county GAF for Santa Clara County shown in Table 9 is incorrect.

Additional information was available for Santa Clara County that we lacked for San Diego County, and that additional information gives additional support to our belief that the county GAF for Santa Clara County is incorrect. The attached Exhibit G contrasts the changes in the county GAF, peGPCI, and FMR data for Santa Clara, San Mateo, and San Francisco Counties between 2005-2007 and 2007-2009. The changes between San Mateo and San Francisco Counties are highly correlated – probably because they are part of the same MSA and share many of the same data that are used to calculate the peGPCI. In contrast, there is a complete of a direct correlation between the changes in the county GAF, peGPCI, and FMR data for Santa Clara County between 2005-2007 and 2007-2009 when contrasted with the same changes for San Mateo and San Francisco Counties. These contrasts lead us to believe that some or all of the 2009 county GAFs for Santa Clara, San Mateo, and/or San Francisco Counties may be incorrect.

For these reasons, we believe that the proposed localities shown in Table 9 need to be corrected, the Proposed Rule needs to be republished, the data we requested needs to be provided, and the comment period needs to be reopened.

C. Vital Importance of Medicare Providing Underlying Data

The multitude of errors and inconsistencies contained in the Proposed Rule underscore the vital importance of Medicare producing the data we requested in our FOIA Request of July 17, 2007. Having this data will allow us to cross-check Medicare's data and provide support for modeling of alternative methods of configuring localities now and in the future.

D. The Proposed Rule Makes Use of Unauthorized Adjustments to Impose Statewide Budget Neutrality

Options 1 and 2 contain GAFs that are based on GPCIs that have been modified in an unspecified manner in order to result in aggregate payments to California remaining the same. (72 FR 38139.) According to the Proposed Rule, "changes to GPCIs must be applied in a budget neutral manner (and under the current locality system, BN results in aggregate payments within each State remaining the same), there are significant redistributive effects to any change." (72 FR 38139.)

It is our belief that there is no statutory authority for modifying the payment formula to impose statewide budget neutrality for the following reasons:

(1) Such a modification would not allow accurate an accurate comparison to be made between costs in the different fee schedule areas and the national average of costs as required by 42 U.S.C. § 1395w-4(e).

(2) Nothing in the statutory scheme allows for modification of the physician fee schedule to create statewide budget neutrality following locality changes. (*Compare* 42 U.S.C. § 1395w-4(c)(2)(B)(ii).)

(3) Medicare's own statement of the payment formula under Part B does not include a statewide budget neutral adjuster: "Payment = $[(RVU_{work} \times GPCI_{work}) + (RVU_{practice\ expense} \times GPCI_{practice\ expense}) + (RVU_{malpractice} \times GPCI_{malpractice}) \times CF]$." (*See* Proposed Rule, 8/22/2006, 71 FR 48985.)

(4) Medicare has expressly (and correctly) stated in the past that the physician fee schedule is budget-neutral on a national basis and not on a statewide basis: "The physician fee schedule is budget-neutral on a national basis. If a State with multiple payment areas converts to a statewide payment area using population-weighted State GPCIs after the physician fee schedule became effective, the change may not be budget neutral within the State. . . . There is no statutory requirement that the physician fee schedule be budget neutral within a State." (Proposed Rule, 7/14/1993, 58 FR 38002.)

In addition, under Options 1 and 2, the imposition of a statewide budget neutrality requirement, one which is not statutorily authorized, will inequitably affect California physicians and beneficiaries in counties outside the ones which will be made part of the new localities described in those options. The redistributive effects of the locality changes must, by statute, be spread across the entire Medicare system and not localized in the State of California.

We request the CMS justify its belief that statewide budget neutrality is authorized by statute, regulation, or rule by identifying the source of its belief. Failing that, we request that the Proposed Rule be corrected to remove the effects of any statewide budget-neutral adjustments that have been made to the data, the Proposed Rule be republished, and the comment period reopened.

E. The Proposed Rule Does Not Discuss Promised Efforts to Work With Other Agencies to Study and Develop Alternative Options

In December 2006, CMS stated that it intended to work with MedPAC and the GAO "to study our current methodology and develop alternative options [for locality changes]." (Final Rule, 12/1/2006, 71 FR 69655.)

The Proposed Rule does not contain any discussion of any such efforts. The Proposed Rule should be modified to identify the nature and extent of any efforts CMS undertook to work with MedPAC and the GAO, the results (if any) of those efforts, the Proposed Rule should be republished, and the comment period should be reopened.

F. The Proposed Rule Fails to Give Due Consideration to an Option Based on MSAs

The Proposed Rule fails to give due consideration to a fourth option, one based on MSAs. The GAO Report concluded that an MSA-based locality structure was one of three alternatives that would improve payment accuracy (i.e., reduce overpayments and underpayments to physicians) without a significant increase in administrative expense. (GAO Report, pp. 23-44.)

The GAO's conclusions appear to be supported by statements CMS has made on the issue. In the past, CMS has recognized the need for a "national classification system built on clear, objective standards." (Proposed Rule, 8/8/2005, 70 FR 45794.) In addition, CMS has concluded that "the MSA system (developed by OMB) is the only one that meets the requirements for use as a classification system in a national payment program." (Proposed Rule, 8/8/2005, 70 FR 45794.) As such, CMS uses the MSA system for purposes of, *inter alia*, classifying hospital payment areas, and establishing local wage and rental data for purposes of calculating payments to both hospitals and physicians. Further, CMS admitted to the GAO that "they did not anticipate that significant modifications to the payment localities would require a substantial amount of additional ongoing administrative burden." (GAO Report, p. 37.)

Currently, CMS uses an MSA-based locality structure to make payments to hospitals under Part A. The following table shows the effects of the disparate methods employed by Medicare in defining geographic payment localities as between Part A and Part B:

HOSPITALS (*Under "Part A"*)	SUPPLIERS (*Under "Part B"*)
Annual Payments Appr. $150 Billion	Annual Payments Appr. $60 Billion
Payment Schedule Updated Every Year	Payment Schedule Updated Every 3 Years
Geographic Localities Based on Metropolitan Statistical Areas ("MSAs") Usually Revised Every 3 Years by OMB	Geographic Localities Established in 1966 by Insurance Companies and Revised Only Once by Medicare in 1996
Medicare Does Not Administer Boundaries of Geographic Localities	In 1991, Medicare Assumed the Responsibility to Administer Boundaries of Geographic Localities But Has Not Made Revisions Since 1996
433 Geographic Localities Based on Demographically Homogeneous MSAs	89 Geographic Localities Based Primarily on Counties and Combinations of Counties Which Are Often Demographically Diverse
Geographic localities understandable and fair	Geographic localities poorly understood and inequitable
Comprehensive Regulatory Provisions for Reclassification of Hospitals into Different Geographic Localities for Reimbursement Purposes	No Regulatory Provisions for Reclassification of Suppliers into Different Geographic Localities for Reimbursement Purposes
Payment System Accurately Reflects Costs Within Small, Well-Defined, Homogeneous Geographic Localities	Payment System Does Not Accurately Reflect Costs Within Demographically Diverse Multi-County Geographic Localities

Given these facts, it is simply inconceivable that CMS did not include a study of an MSA-based locality structure in the Proposed Rule. We recommend that CMS republish the Proposed Rule including a study of an MSA-based locality structure, and reopen the comment period.

G. CMS Should Identify and Quantify Additional Administrative Burdens When Analyzing Modifications to the Locality Structure

No attempt was made to identify or quantify additional administrative burdens that might result from the implementation of any of the three proposed options on a single-state or national level.

In the past, CMS has justified the reduction in the number of localities under Part B to 89 based on reduction in administrative burdens. In contrast, as shown in the above table, Medicare bases its payments to hospitals under Part A using an MSA-based locality system in which there are 433 localities. Clearly, the administrative costs of using the MSA-based locality system under Part A (with almost five times the number of localities as used for Part B) must be justified or else CMS would not have implemented it.

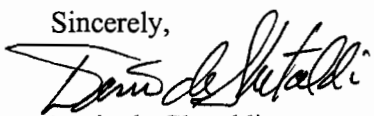
If administrative costs are to be considered as a significant factor in choosing one locality proposal over the other, generalized conclusions that one alternative might somehow prove more expensive or burdensome are not sufficient. Instead, in order for the public to make informed comments on proposed locality changes under Part B, Medicare needs to identify and quantify the comparative administrative costs of each alternative.

We recommend that CMS republish the Proposed Rule including a study of the nature and extent of additional administrative burdens resulting from any proposed option, and reopen the comment period.

III. Conclusion

For all of the foregoing reasons, we are unable to select a proposed alternative for modification of the locality structure under Part B. We recommend that CMS: (a) republish the Proposed Rule with the inclusion of the corrections, additional information, and consideration of the other proposed alternatives we have requested; and (b) reopen the comment period.

Sincerely,



Dario de Ghetaldi

DEG/drj
Enc.

EXHIBIT "A"

OPTION 1 -- ERRORS IN CALCULATION OF PERCENTAGE CHANGE

Figures as Shown in Table 7 -- Option 1						
Locality Name	**County Name**	**New CY 2009 GAF, No Locality Change**	**New CY 2009 GAF With Locality Change**	**Percent Change Due to Locality Change [sic]**	**Actual Percent Change Due to Locality Change**	**Error**
Santa Cruz	Santa Cruz	1.017	1.100	7.59%	**7.545%**	**-0.59%**
Monterey	Monterey	1.017	1.080	5.83%	**5.833%**	**0.06%**
Sonoma	Sonoma	1.017	1.076	5.51%	**5.483%**	**-0.49%**
Marin	Marin	1.112	1.173	5.19%	**5.200%**	**0.20%**
Napa/Solano	Solano	1.112	1.066	-4.33%	**-4.315%**	**-0.34%**
Napa/Solano	Napa	1.112	1.066	-4.33%	**-4.315%**	**-0.34%**
Rest of California	Rest of California	1.017	1.012	-0.49%	**-0.494%**	**0.82%**

EXHIBIT "B"

OPTION 2 -- ERRORS IN CALCULATION OF PERCENTAGE CHANGE

Figures as Shown in Table 8 -- Option 2							
Locality Name	**County Name**	**CY 2009 County GAF**	**New CY 2009 GAF, No Locality Change**	**New CY 2009 GAF With Locality Change**	**Percent Change Due to Locality Change [sic]**	**Actual Percent Change Due to Locality Change**	**Error**
Marin	Marin	1.173	1.112	1.173	5.19%	**5.20%**	**0.199%**
Napa/Solano	Napa	1.080	1.112	1.066	-4.33%	**-4.32%**	**-0.343%**
Napa/Solano	Solano	1.053	1.112	1.066	-4.33%	**-4.32%**	**-0.343%**
Santa Cruz/Monterey/Sonoma	Santa Cruz	1.100	1.017	1.082	6.03%	**6.01%**	**-0.376%**
Santa Cruz/Monterey/Sonoma	Sonoma	1.076	1.017	1.082	6.03%	**6.01%**	**-0.376%**
Santa Cruz/Monterey/Sonoma	Monterey	1.080	1.017	1.082	6.03%	**6.01%**	**-0.376%**
Rest of California	Rest of California	1.017	1.017	1.012	-0.049%	**-0.49%**	**90.082%**

EXHIBIT "C"

OPTION 3 -- ERRORS IN CALCULATION OF PERCENTAGE CHANGE

Figures as Shown In Table 9 -- Option 3								
County	Current Medicare Locality	Current County GAF	Proposed Medicare Locality	Proposed Locality GAF	Current Locality GAF	Percent Difference	Calculated Percent Difference	Error
San Mateo	San Mateo, CA	1.204	1	1.197	1.204	-0.60%	-0.585%	-2.600%
San Francisco	San Francisco, CA	1.201	1	1.197	1.201	-0.30%	-0.334%	10.225%
Marin	Marin/Napa/Solano, CA	1.170	1	1.197	1.112	7.60%	7.101%	-7.026%
Santa Clara	Santa Clara, CA	1.148	2	1.119	1.148	-2.50%	-2.592%	3.534%
Contra Costa	Oakland/Berkeley, CA	1.134	2	1.119	1.131	-1.00%	-1.072%	6.750%
Alameda	Oakland/Berkeley, CA	1.129	2	1.119	1.131	-1.00%	-1.072%	6.750%
Orange	Anaheim/Santa Ana, CA	1.128	2	1.119	1.128	-0.80%	-0.804%	0.533%
Ventura	Ventura, CA	1.121	2	1.119	1.121	-0.20%	-0.179%	-11.900%
Los Angeles	Los Angeles, CA	1.112	2	1.119	1.112	0.60%	0.626%	4.086%
Santa Cruz	Rest of California	1.098	3	1.061	1.012	4.90%	4.618%	-6.100%
Napa	Marin/Napa/Solano, CA	1.077	3	1.061	1.112	-4.60%	-4.807%	4.302%
Monterey	Rest of California	1.077	3	1.061	1.012	4.90%	4.618%	-6.100%
Sonoma	Rest of California	1.074	3	1.061	1.012	4.90%	4.618%	-6.100%
San Diego	Rest of California	1.053	3	1.061	1.012	4.90%	4.618%	-6.100%
Santa Barbara	Rest of California	1.053	3	1.061	1.012	4.90%	4.618%	-6.100%
Solano	Marin/Napa/Solano, CA	1.051	3	1.061	1.112	-4.60%	-4.807%	4.302%
Sacramento	Rest of California	1.047	4	1.023	1.012	1.20%	1.075%	-11.600%
El Dorado	Rest of California	1.033	4	1.023	1.012	1.20%	1.075%	-11.600%
San Bernardino	Rest of California	1.023	4	1.023	1.012	1.20%	1.075%	-11.600%
Placer.	Rest of California	1.021	4	1.023	1.012	1.20%	1.075%	-11.600%
Riverside	Rest of California	1.017	4	1.023	1.012	1.20%	1.075%	-11.600%
San Luis Obispo	Rest of California	1.015	4	1.023	1.012	1.20%	1.075%	-11.600%
San Joaquin	Rest of California	1.006	4	1.023	1.012	1.20%	1.075%	-11.600%
Yolo	Rest of California	0.995	5	0.962	1.012	-4.90%	-5.198%	5.724%
Stanislaus	Rest of California	0.979	5	0.962	1.012	-4.90%	-5.198%	5.724%
Mono	Rest of California	0.977	5	0.962	1.012	-4.90%	-5.198%	5.724%
Nevada	Rest of California	0.975	5	0.962	1.012	-4.90%	-5.198%	5.724%
Kern	Rest of California	0.973	5	0.962	1.012	-4.90%	-5.198%	5.724%
San Benito	Rest of California	0.971	5	0.962	1.012	-4.90%	-5.198%	5.724%
Sierra	Rest of California	0.967	5	0.962	1.012	-4.90%	-5.198%	5.724%
Amador	Rest of California	0.967	5	0.962	1.012	-4.90%	-5.198%	5.724%
Fresno	Rest of California	0.963	5	0.962	1.012	-4.90%	-5.198%	5.724%
Mendocino	Rest of California	0.960	5	0.962	1.012	-4.90%	-5.198%	5.724%
Madera	Rest of California	0.960	5	0.962	1.012	-4.90%	-5.198%	5.724%
Tuolumne	Rest of California	0.959	5	0.962	1.012	-4.90%	-5.198%	5.724%
Alpine	Rest of California	0.957	5	0.962	1.012	-4.90%	-5.198%	5.724%
Mariposa	Rest of California	0.956	5	0.962	1.012	-4.90%	-5.198%	5.724%
Tulare	Rest of California	0.950	5	0.962	1.012	-4.90%	-5.198%	5.724%
Butte	Rest of California	0.950	5	0.962	1.012	-4.90%	-5.198%	5.724%
Merced	Rest of California	0.949	5	0.962	1.012	-4.90%	-5.198%	5.724%
Calaveras	Rest of California	0.949	5	0.962	1.012	-4.90%	-5.198%	5.724%
Humboldt	Rest of California	0.947	5	0.962	1.012	-4.90%	-5.198%	5.724%
Lake	Rest of California	0.947	5	0.962	1.012	-4.90%	-5.198%	5.724%
Imperial	Rest of California	0.945	5	0.962	1.012	-4.90%	-5.198%	5.724%
Plumas	Rest of California	0.945	6	0.938	1.012	-7.30%	-7.889%	7.468%
Lassen	Rest of California	0.944	6	0.938	1.012	-7.30%	-7.889%	7.468%
Sutter	Rest of California	0.942	6	0.938	1.012	-7.30%	-7.889%	7.468%
Yuba	Rest of California	0.942	6	0.938	1.012	-7.30%	-7.889%	7.468%
Colusa	Rest of California	0.940	6	0.938	1.012	-7.30%	-7.889%	7.468%
Del Norte	Rest of California	0.940	6	0.938	1.012	-7.30%	-7.889%	7.468%
Modoc	Rest of California	0.938	6	0.938	1.012	-7.30%	-7.889%	7.468%
Shasta	Rest of California	0.937	6	0.938	1.012	-7.30%	-7.889%	7.468%
Kings	Rest of California	0.935	6	0.938	1.012	-7.30%	-7.889%	7.468%
Inyo	Rest of California	0.935	6	0.938	1.012	-7.30%	-7.889%	7.468%
Siskiyou	Rest of California	0.934	6	0.938	1.012	-7.30%	-7.889%	7.468%
Trinity	Rest of California	0.933	6	0.938	1.012	-7.30%	-7.889%	7.468%
Tehama	Rest of California	0.932	6	0.938	1.012	-7.30%	-7.889%	7.468%
Glenn	Rest of California	0.930	6	0.938	1.012	-7.30%	-7.889%	7.468%

EXHIBIT "D"

INCONSISTENT COUNTY GAFs

	2009 County GAFs		
County Name	Option 1: "New CY 2009 GAF With Locality Change"	Option 2: "CY 2009 County GAF"	Option 3: "Current County GAF"
Santa Cruz	1.100	1.100	1.098
Monterey	1.080	1.080	1.077
Sonoma	1.076	1.076	1.074
Marin	1.173	1.173	1.170
Solano	1.066	1.053	1.051
Napa	1.066	1.080	1.077

EXHIBIT "E"

OPTION 3 USING CORRECTED COUNTY GAFS AND UNIFORM 5% DIFFERENCE

County	Current Medicare Locality	Corrected Current County GAF	Locality 1 "Option 3" 5% Difference	Locality 2 "Option 3" 5% Difference	Locality 3 "Option 3" 5% Difference	Locality 4 "Option 3" 5% Difference	Locality 5 "Option 3" 5% Difference	Medicare's Proposed "Option 3" Locality
San Mateo	San Mateo, CA	1.204	0.00%					1
San Francisco	San Francisco, CA	1.201	0.25%					1
Marin	Marin/Napa/Solano, CA		2.57%					1
Santa Clara	Santa Clara, CA	1.148	4.65%					2
Contra Costa	Oakland/Berkeley, CA	1.134	5.81%	0.00%				2
Alameda	Oakland/Berkeley, CA	1.129		0.44%				2
Orange	Anaheim/Santa Ana, CA	1.128		0.53%				2
Ventura	Ventura, CA	1.121		1.15%				2
Los Angeles	Los Angeles, CA	1.112		1.94%				2
Santa Cruz	Rest of California			3.00%				3
San Benito	Rest of California	*1.081*		4.67%				*5*
Monterey	Rest of California			4.76%				3
Napa	Marin/Napa/Solano, CA			4.76%				3
Sonoma	Rest of California			5.11%	0.00%			3
Solano	Marin/Napa/Solano, CA				2.14%			3
San Diego	Rest of California	1.053			2.14%			3
Santa Barbara	Rest of California	1.053			2.14%			3
Sacramento	Rest of California	1.047			2.70%			4
El Dorado	Rest of California	1.033			4.00%			4
San Bernardino	Rest of California	1.023			4.93%			4
Placer.	Rest of California	1.021			5.11%	0.00%		4
Riverside	Rest of California	1.017				0.39%		4
San Luis Obispo	Rest of California	1.015				0.59%		4
San Joaquin	Rest of California	1.006				1.47%		4
Yolo	Rest of California	0.995				2.55%		5
Stanislaus	Rest of California	0.979				4.11%		5
Mono	Rest of California	0.977				4.31%		5
Nevada	Rest of California	0.975				4.51%		5
Kern	Rest of California	0.973				4.70%		5
Sierra	Rest of California	0.967				5.29%	0.00%	5
Amador	Rest of California	0.967					0.00%	5
Fresno	Rest of California	0.963					0.41%	5
Mendocino	Rest of California	0.960					0.72%	5
Madera	Rest of California	0.960					0.72%	5
Tuolumne	Rest of California	0.959					0.83%	5
Alpine	Rest of California	0.957					1.03%	5
Mariposa	Rest of California	0.956					1.14%	5
Tulare	Rest of California	0.950					1.76%	5
Butte	Rest of California	0.950					1.76%	5
Merced	Rest of California	0.949					1.86%	5
Calaveras	Rest of California	0.949					1.86%	5
Humboldt	Rest of California	0.947					2.07%	5
Lake	Rest of California	0.947					2.07%	5
Imperial	Rest of California	0.945					2.28%	5
Plumas	Rest of California	0.945					2.28%	6
Lassen	Rest of California	0.944					2.38%	6
Sutter	Rest of California	0.942					2.59%	6
Yuba	Rest of California	0.942					2.59%	6
Colusa	Rest of California	0.940					2.79%	6
Del Norte	Rest of California	0.940					2.79%	6
Modoc	Rest of California	0.938					3.00%	6
Shasta	Rest of California	0.937					3.10%	6
Kings	Rest of California	0.935					3.31%	6
Inyo	Rest of California	0.935					3.31%	6
Siskiyou	Rest of California	0.934					3.41%	6
Trinity	Rest of California	0.933					3.52%	6
Tehama	Rest of California	0.932					3.62%	6
Glenn	Rest of California	0.930					3.83%	6

County GAFs Shown for Option 2
GAF for San Benito as Calculated by GAO (compare: 0.971 per Medicare)
Localities Under Option 3 Using Uniform 5% Threshholds
Localities Shown by CMS Under Option 3

EXHIBIT "F"

THE SAN DIEGO COUNTY GAF ISSUE

	GAF	Change	Prior Year FMR*	Change
2005	1.07825		$1,183	
2006	1.07225	-0.56%	$1,065	-11.08%
2009	1.05300	-1.83%	$1,355	21.40%

*HUD FMR data from the prior year is used to calculate the current year peGPCI. The rental figures shown are for 2-bedroom units.

EXHIBIT "G"

THE SANTA CLARA COUNTY GAF ISSUE

	Santa Clara			San Mateo			San Francisco		
	GAF	National Rank	Year-Year Change	GAF	National Rank	Year-Year Change	GAF	National Rank	Year-Year Change
2003	1.184	3		1.119	2		1.221	1	
2004	1.184	3	0.00%	1.201	2	7.33%	1.223	1	0.16%
2005	1.224	3	3.38%	1.230	2	2.41%	1.239	1	1.31%
2006	1.265	1	3.35%	1.259	2	2.36%	1.256	3	1.37%
2007	1.265	1	0.00%	1.259	2	0.00%	1.256	3	0.00%
2008	1.206	3	-4.66%	1.231	1	-2.22%	1.228	2	-2.23%
2009	1.148		-4.81%	1.204		-2.19%	1.201		-2.20%
	2005- 2007 Delta		3.24%	2005- 2007 Delta		2.30%	2005- 2007 Delta		1.35%
	2007- 2009 Delta		-9.25%	2007- 2009 Delta		-4.37%	2007- 2009 Delta		-4.38%

	Santa Clara		San Mateo		San Francisco	
	peGPCI	Delta	peGPCI	Delta	peGPCI	Delta
2005	1.551		1.547		1.554	
2007	1.543	-0.52%	1.539	-0.52%	1.546	-0.51%
2009	1.292	-16.27%	1.431	-7.02%	1.439	-6.92%

	HUD FMR*	Delta	HUD FMR*	Delta	HUD FMR*	Delta
2004	$1,821		$1,775		$1,775	
2006	$1,284	-29.49%	$1,536	-13.46%	$1,536	-13.46%
2008	$1,293	0.70%	$1,592	3.65%	$1,592	3.65%

*HUD FMR data from the prior year is used to calculate the current year peGPCI.
The rental figures shown are for 2-bedroom units.

Submitter : **Dr. Jonas Hatkin** **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 : Mr. Steve Lieber **Date:** 08/31/2007

Organization : HIMSS

Category : Other Association

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

HIMSS Submits the attached pdf file for consideration. The following section from the pdf file highlights recommendations by the organization:

The current landscape provides a broad number of challenges for clinician and pharmacies, including a widespread need for contingency planning; uncertainty on incentives and reimbursements for clinicians employing HIT solutions; and the potential impact on providers and pharmacies. Recognizing these challenges and necessary solutions are still being developed, HIMSS and our members recommend that CMS delay the elimination of the exception, allowing the future action to include the following components:

" Implement all required changes for E-Prescribing on a schedule under one final rule: HIMSS members are concerned that providers and pharmacies will be confused by the elimination of the exemption for computer-generated facsimiles just months prior to the overarching changes to E-Prescribing requirements from the Medicare Modernization Act of 2003 that must be promulgated by April 2009.

" HIMSS recommends a consolidated rule that adheres to the April 2009 deadline, allowing time for implementation and testing to occur: When the timeline is complete, HIMSS members suggest CMS consider an implementation period of 6-12 months before the exemption is eliminated.

" Allow for fax prescriptions as a fail over measure in the event of network requirements or failure. This will ensure the timeliness of medication dispensing especially at the community level.

CMS-1385-P-14921-Attach-1.PDF

#14924

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www.himss.org

August 31, 2007

Herb Kuhn, M.D.
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Dr. Kuhn:

The Healthcare Information and Management Systems Society (HIMSS) is pleased to submit our comments regarding the CMS' Proposed Rule *"Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions."* CMS **Reference Number: CMS-1385-P posted on July 12, 2007**). For the purpose of our response, we will be directing our comments changes to the **PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER GENERATED FACSIMILES.**

HIMSS is the healthcare industry's only membership organization exclusively focused on providing leadership for the optimal use of healthcare information technology and management systems for the betterment of healthcare. HIMSS represents more than 20,000 individual, 300 corporate members, and 47 chapters nationwide. HIMSS seeks to shape healthcare public policy and industry practices through its educational, professional development, and advocacy initiatives designed to promote information and management systems' contribution to quality patient care.

As you are well aware, HIMSS has responded to several CMS requests for public comment on E-Prescribing. HIMSS has leveraged the subject matter expertise of the members of our E-Prescribing Work Group and the Electronic Health Record Vendor Association, and recently incorporated input from our Life Sciences Roundtable to ensure that our response reflects the broadest level of industry experience. The viewpoints of these groups, along with their industry colleagues, ensure that HIMSS fulfills its requirement to offer a coordinated voice to the national discussion on these important healthcare issues. We are also aware that HIMSS member organizations, such as SureScripts, and RxHUB are submitting responses, and suggest that their unique perspectives should be considered in the promulgation of the final rule.

HIMSS appreciates CMS' effort to initiate steps to increase provider implementation of electronic healthcare solutions, and commends the department's interest in eliminating the "exemption [for] computer-generated facsimiles from strict adherence to the NCPDP SCRIPT Standard for communication of prescription or certain prescription-related information between prescribers and dispensers" in Section 423.160(a)(3)(i) of the November 2005 final rule (70 FR 67571). As an organization, we are committed to supporting the development and distribution of information and management systems, across the healthcare continuum, to achieve greater patient safety, improved office efficiency, better quality of care, and more cost effective care delivery. E-Prescribing and the broader adoption of Electronic Health Records foster an environment where these improvements can be maximized.

The current landscape provides a broad number of challenges for clinician and pharmacies, including a widespread need for contingency planning; uncertainty on incentives and reimbursements for clinicians employing HIT solutions; and the potential impact on providers and pharmacies. Recognizing these challenges

and necessary solutions are still being developed, HIMSS and our members recommend that CMS delay the elimination of the exception, allowing the future action to include the following components:

- **Implement all required changes for E-Prescribing on a schedule under one final rule:** HIMSS members are concerned that providers and pharmacies will be confused by the elimination of the exemption for computer-generated facsimiles just months prior to the overarching changes to E-Prescribing requirements from the Medicare Modernization Act of 2003 that must be promulgated by April 2009.
- **HIMSS recommends a consolidated rule that adheres to the April 2009 deadline, allowing time for implementation and testing to occur:** When the timeline is complete, HIMSS members suggest CMS consider an implementation period of 6-12 months before the exemption is eliminated.
- **Allow for fax prescriptions as a fail over measure in the event of network requirements or failure.** This will ensure the timeliness of medication dispensing especially at the community level.

The following sections support HIMSS observations:

Potential Impact on Providers and Pharmacies

Like our industry colleagues, HIMSS members are concerned about the impact of eliminating the exception for computer-generated faxes that occur under two scenarios – for clinicians who have E-Prescribing capabilities, and for clinicians who use more limited technologies. First, for clinicians who have adopted HIT solutions to include EHRs and E-Prescribing capabilities, HIMSS concurs that the 15-20% implementation rate referenced in the proposed rule is unacceptable, particularly when a provider already possesses solutions that are NCPDP SCRIPT compatible. Our members relate experiences in which they or their customers have not, in fact, maximized their HIT solutions. We are encouraging our members to raise their levels of implementation, with the goal of 100% utilization of the system. We caution CMS that the out-of-pocket expenses for seemingly simple upgrades, or for "turning on" existing capabilities, may prohibit some providers from advancing their implementation levels; and an abrupt change in the requirement may cause some providers to revert to paper-based solutions. Given the patient safety and healthcare quality concerns related to the paper-based prescription, we suggest CMS work with HIMSS and our industry colleagues to ensure that we minimize the likelihood of such backward steps. In addition, upgrades often require IT resources at the practice end that they might need to pay additional costs to implement. In addition, even if office-level resources are available, time needs to be allocated in order for an organization to test, retest, migrate, and mitigate change.

E Prescribing initiatives are not simply a matter of turning on a module at a particular computer and utilizing the software with the touch of a mouse. The key to effective automated prescribing habits begins with a well thought through workflow analysis in the provider site that is completed before the automation is installed. The costs and time involved in implementing this key step can easily be half or more of the cost of any e-prescribing installation. Further more, when e-prescribing alternatives are provided at no cost, the significant effort (and cost) involved in the reengineering still remains. We strongly encourage CMS to adopt an implementation process that takes these important workflow changes into consideration and allows for sufficient time to identify and cover the cost involved, and to ensure successful implementation of this technology.

Second, HIMSS has the most concern over eliminating the exemption for computer-generated faxes, for clinicians and pharmacies that use more limited technologies. HIMSS members are concerned that CMS' attempt to foster adoption of E-Prescribing will widen a capability gap for providers who have not begun using NCPDP SCRIPT compatible equipment. We are vocal supporters of increasing adoption and implementation rates for HIT solutions; however, this requirement could create an unnecessary burden on providers who have not yet adopted more advanced HIT solutions. If in fact this were to result in a slowing of HIT adoption rates, the associated risks to patient safety and the quality of healthcare delivery would persist. In this regard, HIMSS members believe that the final specification for any E-Prescribing system should incorporate fax fail over capability as a necessary back-up to SCRIPT. HIMSS expects that future efforts to certify E-Prescribing systems, such as the kind performed by the Certification Commission for Healthcare Information Technology (CCHIT), will recognize fax fail over as a necessary requirement. Thus, for CMS to eliminate electronic faxing now would be counterproductive.

Contingency Planning

HIMSS encourages CMS to permit provider offices and pharmacies to develop contingency plans for circumstances that would require the office to revert to computer-generated faxing. As we are reminded every day, even with the best of systems in place, situations may arise that will preclude providers and pharmacists from using E-Prescribing capabilities. Addressing these circumstances in the final rule, and affording providers and pharmacies the opportunity to develop achievable alternative solutions, will foster practical and effective clinical and business processes.

Varying Federal and State Requirements

HIMSS members have become increasingly concerned about the inconsistencies from state to state regarding if or how E-Prescriptions can be utilized. While HIMSS is encouraged by the recent announcement of the passage of Electronic Prescription transmission provisions in all 50 states, HIMSS members remain concerned about wide-ranging inconsistencies in E-Prescribing rules, formats, and processes that exist between states and also within states. The laws and regulations that govern prescriptions, such as requirements for handwritten signatures in certain cases, often conflict with E-Prescribing enabling rules. Even within a given state, prescription requirements may differ depending on the payor involved. These inconsistencies create a confusing environment which is burdensome to providers, pharmacists, and ultimately, patients. HIMSS encourages CMS to leverage its relationship with the states, through Medicaid and other state-based programs, to develop a common framework for E-Prescribing overall, including electronic authorization. Providers and pharmacists need an E-Prescribing process that incorporates common parameters. HIMSS members believe that if states were to adopt laws that would enable E-Prescribing standards, such as electronic signature as a replacement for handwritten signature, the ultimate benefit would outweigh the burden of change for all parties.

More specifically, CMS's proposed rule cites the statistic that only 20 percent of independent pharmacies are capable of sending and receiving SCRIPT transactions. HIMSS' members believe that an important reason for the slow rate of adoption is directly related to costs. While readiness for connectivity may in fact be widespread, readiness for implementation is much less prevalent, especially for small, non-chain pharmacies. The costs of installing and implementing e-prescribing are significant: software must be purchased, software upgrades will be needed, and transaction fees will apply. Also significant are the costs associated with making the necessary changes to workflow and resource deployment within the pharmacy organization. HIMSS members suspect that these cost burdens may account for the lower adoption rate among small pharmacies. In fact, if small pharmacies lost their ability to receive electronically-faxed prescriptions, they would be at a disadvantage when competing for business. The current electronic fax exception allows patients and providers to work together to select from a wider range of available pharmacies. While HIMSS supports the eventual full adoption of E-Prescribing capabilities in all pharmacies, large and small, it would be counterproductive, to change the rule at this point in time.

Incentives:

HIMSS also encourages CMS to address the issue of incentives to participate in the E-Prescribing program. As we mentioned in our comments to CMS prior to the adoption of the current final rule, a number of organizations within the healthcare continuum will participate based on community empowerment and federal regulation. However, HIMSS anticipates that a significant number of providers and organizations will not participate until they receive adequate reimbursement through implementation funding, deferential reimbursement, or pay-for-performance. In keeping with the HIMSS mandate for providing practical solutions for our membership and industry, HIMSS members on the Ambulatory Information Systems Steering Committee have developed a user-friendly white paper, entitled, "Stand-Alone E-Prescribing: Ready or Not?," to assist providers as they prepare for E-Prescribing. As ambulatory care providers with an affinity for information technology solutions, the group provides an unique perspective of the issues surrounding E-Prescribing. HIMSS encourages CMS to consider this document and supportive information before developing the final rule, as it pertains to the exemption.

Controlled Substances

Finally, HIMSS and our members are concerned that the federal government has not reached a conclusion on the matter of the Electronic Prescribing of controlled substances. Our members have been instrumental in providing insight into the discussions between the various federal agencies and the healthcare industry. While we understand that technology solutions exist that can address the Drug Enforcement Agency's (DEA) concerns

about provider authentication; we are concerned that all details in this regard have not been addressed. HIMSS and our members encourage CMS to continue working with other DHHS agencies and the DEA to develop procedures that and capitalize on HIT (to include NCPDP fill-status requirements) and the subsequent improvements in supply tracking and drug dispensing patterns that Electronic Prescribing enables. HIMSS looks forward to continuing this dialogue throughout the year.

Conclusion:

In conclusion, HIMSS and our members are encouraged by CMS' interest in eliminating the exception for computer-generated facsimiles. The benefits associated with E-Prescribing and broader HIT solutions for patients, clinicians, and the overall healthcare system are well documented. HIMSS looks forward to increased adoption rates and a time in the very near future when we will have reached a critical mass of providers and pharmacies that can exchange electronic prescriptions. Given the current state of HIT adoption in the provider community, HIMSS strongly encourages CMS to take into account all the aforementioned factors before eliminating the exemption for computer-generated facsimiles of prescriptions. HIMSS asks CMS to incorporate the following recommendations into the final rule:

- **Implement all required changes for E-Prescribing on a schedule under one final rule**
- **Promulgate a consolidated rule that adheres to the April 2009 deadline, allowing time for implementation and testing to occur.**
- **Allow for fax prescriptions as a fail over measure in the event of network requirements or failure.**

HIMSS and our members support the advancement of E-Prescribing and applaud CMS efforts to expand the use of more effective technologies. If you have any additional questions please contact Mr. Thomas M. Leary, Senior Director, Federal Affairs, tleary@himss.org, or 703.562.8814.

Sincerely,

H. Stephen Lieber, CAE
HIMSS President & CEO

John Wade, FCHIME, FHIMSS
VP, Executive Director KC REE, and Former CIO,
Saint Luke's Health System
HIMSS Chairman of the Board

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

Organization : **Aplastic Anemia and MDS International Foundation**

Category : **Consumer Group**

Issue Areas/Comments

TRHCA-Section 110: Anemia Quality Indicators

TRHCA-Section 110: Anemia Quality Indicators

RE: TRHCA, SECTION 110: ANEMIA QUALITY INDICATORS

Centers for Medicare and Medicaid Services

7500 Security Boulevard

Baltimore, MD 21244

The Aplastic Anemia and MDS International Foundation, a non-profit organization that serves patients with rare bone marrow failure, is writing in support of the proposal described in Section 110 Reporting of Anemia Quality Indicators within the proposed rule CMS-1385-P Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008. If implemented, this requirement would mandate that all providers who submit a request for payment of erythropoiesis-stimulating agents (ESAs) administered for any reason include information about the beneficiaries' hemoglobin or hematocrit levels. This proposed policy affects many of our constituents with the diagnosis of myelodysplastic syndromes (MDS) who are also Medicare beneficiaries: ESAs are often administered to address MDS symptoms.

The Foundation believes that requesting this information of providers will not be unduly onerous and that this proposal represents reasonable clinical care. Moreover, while current science supports the use of ESAs in MDS patients, we are interested in any knowledge on the use of ESAs in MDS patients that may be gathered through this requirement.

Thank you for your consideration. If the Foundation or our medical advisory board can be of any assistance, please do not hesitate to call on us.

Sincerely,

Christin L. Engelhardt
Health Professionals Program Director

Submitter : Dr. Glenn Davis **Date:** 08/31/2007

Organization : Dr. Glenn Davis

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am pleased at the awareness of the inadequate conversion factor for anesthesia services and would welcome the $3.30 increase per unit.

Serving in an area with a overwhelming Medicare/ Medicaid burden makes any increase a step towards continued viability of anesthesia services for the eldery. The enactment of CMS-1385-P would be a help greatly.

Please consider this message an indication of my overwhelming support for your consideration of CMS-1385-P

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

Organization : **Ron Gaines**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Sincerely,

RonGaines

Submitter : **Dr. Ruth Grissom** **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.

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

Thank you for your consideration of this serious matter.

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

Organization : Kaiser Permanente

Category : Health Plan or Association

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Kaiser Permanente, Colorado, was informed on August 27, 2007, of the proposed rule that would eliminate the exemption for computer generated faxes from the Medicare Part D ePrescribing requirements by January, 2009.

While Kaiser Permanente strongly supports the pursuit of standard electronic prescription writing, we believe that this deadline is premature. We believe that a date of January, 2010, would remove undue hardship while fully implementing ePrescribing solutions. We respectfully request that even after the final ePrescribing requirement date, that computer generated faxes still be allowed as back-up for communicating prescriptions in the event that the fully electronic system fails for any reason for a particular transaction.

Thank you for your consideration of these recommendations.

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

Organization : **Orthopedic Fitness and Therapy**

Category : **Other Practitioner**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I direct a fitness/therapy center geared to assisting active people of all ages with musculoskeletal challenges. CMS has a tremendous amount of power to help types of professionals while harming others in the wake of their decisions. This personally impacts my ability to help my clients, as their interactions with their health insuranec providers often mimic CMS decisions.

I am writing today to voicc my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposcd 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 thcsc proposed rulcs will creatc 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 experiencc, 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 comc 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,
Thomas Kiff, MA, ATC
Director, Orthopedic Fitness and Therapy
www.orthopedicfitness.com
763.694.6167 (o)

Submitter : **Mr. David Grauer** **Date: 08/31/2007**

Organization : **Squire, Sanders**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please accept the attached comment.

CMS-1385-P-14928-Attach-1.DOC

#14928

SQUIRE SANDERS | LEGAL COUNSEL WORLDWIDE

SQUIRE, SANDERS & DEMPSEY L.L.P.
1300 Huntington Center
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Office: +1.614.365.2700
Fax: +1.614.365.2499

Direct Dial: +1.614.365.2786
dgrauer@ssd.com

August 31, 2007

VIA ELECTRONIC SUBMISSION

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

Re: CMS-1385-P
- **Comment on the Physician Self-Referral Provisions Unit-of-Service Payments**

Ladies and Gentlemen:

Squire, Sanders & Dempsey L.L.P. appreciates the opportunity to comment of the proposed rules identified above. Specifically, we would like to offer the following comment with respect to the section entitled: "Unit-of-Service (Per-Click) Payments on Space and Equipment Leases."

The proposed changes to space and equipment leases prohibiting unit of service based payments to physician lessors by hospital lessees is bad policy. The rule conflicts with previous OIG opinions that correctly determined similar payments, when subject to a cap, do not present a risk of abuse. Moreover, the rule will impair investments in new technology and thereby negatively impact patient care while increasing health care costs. Finally, the per-click restriction contradicts clear Congressional intent.

In OIG Advisory Opinion No. 01-17 (October 17, 2001), the OIG determined that a unit-based payment with a monthly cap does not increase the risk of abuse of health care programs. In that opinion, the OIG found it important that the medical director agreement was consistent with fair market value, based upon a specified hourly rate, subject to a monthly payment cap, and paid only with written documentation of the hours and services provided. The OIG reached this conclusion despite the agreement's failure to comply with the personal services and management contract safe harbor because it did not specify an "exact schedule, precise length and exact charge for the intervals and the requirement that the aggregate compensation paid over the term of the contract be set in advance." *Id.* at p. 8; citing 42 C.F.R. §§ 1001.952(d)(3), (d)(5).

Similar to medical director and other personal service agreements, the risk of abuse is significantly decreased when a per-click equipment lease contains a monthly cap. The agreement could be certified as at fair market value and be paid only with proper documentation of the use of the equipment. The same reasoning that compelled the decision in the aforementioned opinion applies here. The proposed prohibition represents an economically and medically inefficient method of attempting to control the risk of overutilization.

Furthermore, the alternative to unit of service based compensation is a lease set at a fixed monthly rate, but that alternative raises the likelihood of abuse. If the lease rate, despite being set at a theoretical fair market value, is set prior to any experience amongst the parties in the actual usage of the equipment, it is a certainty that one party will make a windfall. Either the hospital or physician will prosper due to the over or under use, respectively, of the equipment. This certainty may encourage abuse by the parties, most likely by markedly increasing the use by hospital of equipment beyond the capacities anticipated as a result of the unbalanced economic structure of the arrangement. This utilization will result in a hospital windfall and an increased cost to Federal health care programs.

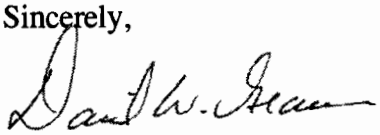
The elimination of per-click equipment leases will also impair the ability of providers to obtain cutting edge technology. Many hospitals do not have the capital budget to purchase such equipment in the absence of physician investment. The restrictions to per-click leases may cause physicians to discontinue the purchase of the newest and best technology since such purchase would involve unacceptable financial risk. To the extent that the proposed rule disincentifies investment in new technology, quality of care will suffer and more costly less effective treatment options will be utilized.

Finally, the prohibition on per-click equipment rental contradicts Congressional intent. House Conference Report No. 103-213, at 814 (1993) states that:

> The conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of services furnished, so long as the amount of the time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement.

Thus, Congress clearly intended that per-click rates would satisfy the Stark law and regulations. The current attempt to prohibit such arrangements is, therefore, outside the authority of CMS.

Sincerely,



David W. Grauer, Esq.

SQUIRE, SANDERS & DEMPSEY L.L.P.

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

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am a Physical Therapist working in a private Phyiscal Therapy Office- that has earned a good reputation in our community for 12 years. Recently, I worked with a patient referred to us for shoulder pain from an orthopedist. This orthopedist is part of a physician owned office that has their own physical therapy services. We had seen her for 11 visits and she was pleased with her care at our private clinic. The patient was educated with her options for continued therapy as a patient after surgery. She had a follow up appointment with the orthopedist and was scheduled for surgery. She called to discontinue further treatments.
Two weeks later, the Physician Owned Physical therapy office called our office to see the number of visits the patient had with us for insurance purposes. I called the patient at home to inquire about her surgery. She had reluctantly stated that she was now going to the Physician Owned Physical Therapy office.
This is one of many examples of our patients' that are persuaded towards Physican Owned Physical Therapy offices. The frequency of events like this is increasing at a disturbing rate. To the point where it is affecting our practice. Often times when a patient requests to come to our clinic, or one of the other independant practices in our area, they are told that they do not really need physical therapy. It would appear that the Pyhsician Owned Practices are trying to drive the Independant Practices out of business with self referrals. Thank you for your attention to this matter. Our existence hangs in the balance of stopping physcian self referrals.

Submitter : Dr. MARK HELD **Date:** 08/31/2007

Organization : Dr. MARK HELD

Category : Physician

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

I SUPPORT AN INCREASE IN THE ANESTHESIA CONVERSION FACTOR

CMS-1385-P-14930-Attach-1.DOC

#14930

August 31, 2007

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

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

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am a surgeon from New Bern, NC. I am glad to see that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue. I am concerned that I will have limited access to anesthesia services as a surgeon. I support the increase in the Medicare payment for anesthesia services to ensure that I have access to anesthesia services for my patients The current 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, like New Bern, with disproportionately high Medicare populations.

.

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

Thank you for your consideration of this serious matter.

Sincerely,

Mark C. Held, MD

Submitter : **Dr. Ruth Grissom** **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

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

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

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

Thank you for your consideration of this serious matter.

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

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

August 30, 2007

Attn: CMS Rulcmaking Board

Rc: Stark Rcferral for Profit Loophole

I am an outpaticnt physical therapist in Huntsville, Alabama. It has become quite obvious that this loophole has opened another avenue for physicians to pad thcir pockcts. I would like to share a few examples based on reports from a local patient and a therapist who works for a physician owned clinic.

Physicians have required their patients who need therapy to go to the clinic in which the physician is receiving profits/bonuses. Example: A patient was ordered to go to Physical Therapy and when she told the doctor that she would rather go to another clinic the physician simply tore the referral up and said well, you really don t need therapy anyway . Thus taking away the patient s right to choose clinics, even if they aren t happy with the services at that clinic.

In recent conversation with a PT working for a physician owned orthopaedic clinic, he stated whenever our patient numbers are down, all we do is just go next door and tell the docs and they load us up because they know if we aren t busy they aren t making as much on their bonus checks .

These are just a few examples of the unethical use of this loophole. As medical professionals, isn t it our job to do what s best for each and every patient, not to mention keeping medical cost down for the patient and third party payers. Removing physical therapy from the in-office ancillary services exception would definitely improve patient care as well as save patient and CMS/Medicare dollars.

Sincerely,

Huntsville Physical Therapist
35806

Submitter : **Dr. Letty Liu** **Date: 08/31/2007**

Organization : **American Society of Anesthesiologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Letty M. P. Liu, M.D.

Submitter : **Dr. Alice Oswald** **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

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

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

Organization : **SWFUA**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Physician Self-Referral Provisions

CMS-1385-P-14935-Attach-1.DOC

#14535

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,

Paul R. Bretton, M.D.

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

Organization : charles locl

Category : Physician

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Oppose bundling of 93325 doppler color flow to other separately identifyable echo codes.

93325 is not intrinsic to other non 93325 codes, nor do the other echo code rvu reflect the nature of 93325

Coding--Reduction In TC For Imaging Services

Coding--Reduction In TC For Imaging Services

Oppose 32% reduction in technical component for left heart caths.
Odd how ASC APC 0080 (which equates to left heart cath 93510,93555,93556)get an 11% increase.

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

Organization : **Karla Gaines**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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

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

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

Thank you for your consideration of this serious matter.

Sincerely,

Karla Gaines

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

Organization : Looper, Reed & McGraw, P.C.

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please see attachment.

CMS-1385-P-14938-Attach-1.PDF

#14938

LooperReed & McGraw
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August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS – 1385 – P

Dear Ms. Norwalk:

We are writing in response to the concerns CMS has expressed regarding under arrangement services agreements between physicians and hospitals. CMS' position that such arrangements are nothing more than sham relationships which increase the risks of over-utilization clearly ignores the fact that many of the arrangements improve patient access to services including new and innovative services, provide a means for physicians and hospitals to coordinate care and provide it in the most cost effective setting and that these services are all provided under the professional responsibility of the hospital. Additionally, CMS has ignored the fair market value requirement for these type arrangements to meet the indirect compensation exception under the Stark Law.

Specifically, CMS' proposal to revise the definition of an "entity" under the Stark Law and replace the bright line definition it adopted in the Stark II Final Rule with an ambiguous definition will add to confusion in the industry rather than help clarify the issue. Further, and though MedPAC's proposed revision would be clear, its adoption would impact many other types of arrangements between physicians and hospitals, such as an equipment lease arrangement structured in accordance with the equipment rental exception under the Stark Law and which, as so structured, does not present an incentive for over-utilization or abuse.

If adopted these changes would impact numerous relationships which were legitimately analyzed and structured in accordance with the indirect compensation arrangement as CMS specifically directed. CMS' proposed reversal of its position clearly punishes these legitimate relationships. Further, and of greater importance, the failure to grandfather existing

Submitter : Ms. Denise Garris **Date:** 08/31/2007

Organization : American College of Cardiology

Category : Physician

Issue Areas/Comments

IDTF Issues

IDTF Issues

See Attachment

CMS-1385-P-14940-Attach-1.PDF

#14940

Helping Cardiovascular Professionals Learn. Advance. Heal.

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Charles R. McKay, M.D., F.A.C.C.
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Rick A. Nishimura, M.D., F.A.C.C.
Steven E. Nissen, M.D., M.A.C.C.
Patrick T. O'Gara, M.D., F.A.C.C.
Miguel A. Quinones, M.D., F.A.C.C.
George P. Rodgers, M.D., F.A.C.C.
Jane E. Schauer, M.D., Ph.D., F.A.C.C.*
James E. Udelson, M.D., F.A.C.C.
C. Michael Valentine, M.D., F.A.C.C.*
W. Douglas Weaver, M.D., F.A.C.C.
Kim Allan Williams, M.D., F.A.C.C.
Michael J. Wolk, M.D., M.A.C.C.
Janet S. Wright, M.D., F.A.C.C.
William A. Zoghbi, M.D., F.A.C.C.
**ex officio*

Chief Executive Officer
John C. Lewin, M.D.

August 30, 2007

Mr. Herb Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8018

Dear Mr. Kuhn:

The American College of Cardiology (ACC) is pleased to offer our comments on Sections II(I) and (M) of the notice of proposed rulemaking entitled **CMS-1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008** published in the *Federal Register* on July 12, 2007 (72 Fed. Reg. 38122 – 38395).

The ACC is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments on Sections II(I) [*IDTF Issues*] and II(M) [*Physician Self-Referral Provisions*] in support of that goal.

§II(I) Independent Diagnostic Testing Facility (IDTF) Issues—

Insurance Coverage:

CMS is proposing to clarify that IDTF suppliers are required to report to their Medicare contractor only certain significant (not all) changes to the enrollment application within 30 days and all others within 90 days. Currently, any changes to the enrollment form (e.g. ownership, location, etc.) are required to be reported to CMS within 30 days.

ACC Recommendation: The ACC welcomes this relaxation of an administrative requirement, and thanks CMS for its responsiveness to provider needs.

Beneficiary Complaints:

CMS is proposing to require IDTF suppliers to "answer, document, and maintain documentation of beneficiaries' questions and responses to their complaints at the physical site of the IDTF." Previously, IDTF suppliers were only required to ". . . answer beneficiaries' questions and respond to their complaints." In addition, the proposed revisions describe the exact records and documentation process CMS intends to impose as its standard, including: the complainant's name; address; phone number, health insurance claim number; a summary of the complaint; name of the person receiving the complaint; a summary of the actions taken to resolve the complaint; and, where an investigation of the complaint was not conducted, the IDTF supplier must record the name of the person making that decision and the reason behind it. CMS does clarify however that mobile IDTFs are to maintain such records at the "home office."

ACC Recommendation: The ACC recommends that CMS not adopt this proposal at this time without providing stakeholders additional opportunities to work with the agency to develop mutually acceptable improvements to the processing of beneficiary complaints. In the alternative, the College recommends that CMS develop a standardized complaint form and/or perhaps an electronic/web-based platform for submitting complaints regarding an IDTF.

Discussion: This proposal introduces significant new administrative burdens for IDTF suppliers, which in turn will add significant implementation and maintenance costs to current operations. While many of these data fields are part of most standard medical record software, collection, entry, and maintenance of this data will consume significant staff-hours for completion and maintenance that will add to administrative costs for IDTF suppliers. Further, IDTF suppliers will have to ensure that any new data collected per this revised standard are stored and secured pursuant to HIPAA requirements. It is unclear whether the burden of implementing this proposal would be exceeded by the benefit such documentation would produce.

Overall Supervisory Responsibility of the IDTF:

CMS is deleting the current ambiguous standard making the IDTF supervisory physician responsible for the overall operation and administration of the IDTF(s) etc.

ACC Recommendation: The ACC generally welcomes this clarification of an administrative requirement, and thanks CMS for its responsiveness to IDTF supplier and provider needs. We request however, that CMS clarify in the final rule how the proposed change would affect a supervising physician who works outside of a written IDTF protocol? In addition, please clarify who would be responsible for signing off on written protocols for testing when the supervising physician is a specialist.

leased space and equipment. We believe that emphasis should be placed on appropriate use—using appropriateness criteria and clinical guidelines for reference—regardless of who receives payment, not additional regulatory proscriptions.

Discussion: The ACC is concerned that CMS' proposal approaches this issue from a position that is critical of such arrangements based on "inherent susceptibility" to fraud and abuse, even if the arrangements meet the standards of leasing requirements described in the regulation. We think this approach to reviewing such arrangements misses the opportunity to evaluate the potential cost savings realized through competition between available providers of space and equipment that previously were only offered by larger providers.

It is our understanding that the proposed change would only apply to individual physician lessors and would not apply to arrangements between the "physician group and the hospital," and in arrangements where the hospital (or other DHS entity) is the lessor. The proposed limitations could ultimately result in reduced competition and cost savings through increased inefficiency in any given market for the services provided through space/equipment leases using this method of payment.

Revisions to Address Potentially Abusive "Set in Advance" and Percentage-Based Compensation Arrangements:

CMS is proposing to clarify that such arrangements may be used only for: 1) paying for personally performed physician services, and 2) must be based on the revenues directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department—which is not directly or indirectly related to the physician services provided.

ACC Recommendation: While the College strongly supports efforts to reduce fraud, waste, and abuse in the Medicare program, we believe that the proposed changes are premature without additional information to be provided by CMS on the problems with certain arrangements that the agency seeks to address specifically.

Discussion: The ACC again expresses concern regarding CMS' assumption that such arrangements are "potentially abusive" without also considering the potential benefits inherent to them. Is it CMS' intention to eventually require all contractual arrangements—excepting personal services—follow a "flat-fee" model? If so, we are unclear as to whether there are any distinctive advantages inherent to flat-fee arrangements to reduce the potential for abuse that are not also apparent in other variable fee-type arrangements. Especially if both types of arrangements follow the usual

through the NPRM process. This implies a rush to approve the change, which in turn raises stakeholder concerns that adoption of the proposal is a foregone conclusion irrespective of public comment. Further stoking our concern is the warning provided in the proposal for commenters to bear in mind the risk of self-incrimination while preparing comment submissions. This warning could have an unintended "chilling effect" on public responses, in that by lowering the level of factual detail shared (out of fear of self-incrimination), the quality of dialog between stakeholders and CMS on this important proposal would also be diminished. We believe this approach to soliciting comment runs counter to the perception that CMS seeks to work constructively with all stakeholders in the interest of continuing to improve the Medicare program.

Alternative Criteria for Satisfying Certain Exceptions—Involving Trivial or Innocent Violations of Stark Rules:

In response to public comments received with regard to risk of disproportionately severe penalties for minor or inadvertent violations of the self-referral statute—especially where the non-complying entity was attempting to meet an exception in good faith—CMS is requesting comments on how it may amend certain exceptions of the rules to permit an "alternative criteria" for satisfying the exceptions.

ACC Recommendation: The ACC commends CMS for this initiative seeking to moderate imposition of sanctions related to low-level, inadvertent violations of the physician self-referral statute.

Services Furnished "Under Arrangements:"

For purposes of services furnished "under arrangements" (e.g. where a physician-owned entity supplies DHS to a provider—e.g. hospital, etc.—under an "arrangement," and the provider then bills Medicare for the DHS) CMS is proposing to redefine "entity" so that a DHS entity includes both the person/entity performing the DHS, as well as the person/entity submitting claims, or causes claims to be submitted to Medicare for the DHS.

ACC Recommendation: The ACC recommends CMS not adopt this proposed change to the self-referral rules, as we believe the arrangements targeted by the proposal do not operate within the scope of statute and, more importantly, ultimately may benefit the Medicare program.

Discussion: It is unclear why CMS believes it is necessary to regulate activities that do not directly furnish—or otherwise bill Medicare directly for providing—DHS to beneficiaries. Specifically, it is our understanding that with this proposal CMS seeks to prohibit arrangements that are structured such that referring physicians own leasing,

Submitter : **Ms. janet moore** **Date: 08/31/2007**

Organization : **american association of nurse anesthetists**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES

Dear Administrator:

As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

This increase in Medicare payment is important for several reasons.

? First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
? Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
? Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.

Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).

America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.

Sincerely,

Name & Credential
__Janet Moore
Address
_____4700 orchard Ave. No.
City, State ZIP Crystal Minnesota 55429

Submitter : **Mr. Jim Ramsay** **Date: 08/31/2007**

Organization : **New York Rangers Hockey Team**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

08/31/2007

Dear Sir or Madam:
My name is Jim Ramsay and I am the Head Athletic Trainer for the New York Rangers Hockey team. I have been an Athletic Trainer in the National Hockey League for 20 years and am proud of my profession and the impact it has on healthcare management.
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,
Jim Ramsay
Head Athletic Trainer
New York Rangers

Submitter : Dr. Bhupinder Saini **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14943-Attach-1.DOC

=14943

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

Kerry Weems
Centers for Medicare & Medicaid Services
Department of HHS
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.**

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

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

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

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

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,

Bhupinder Saini, MD
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Mr. Robert Tarpey** **Date: 08/31/2007**

Organization : **Toronto Blue Jays**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I work for the Toronto Blue Jays as a minor league Athletic Trainer.

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

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

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

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

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

Sincerely,

Robert M. Tarpey, MS, ATC, PES
Athletic Trainer
Toronto Blue Jays

Submitter : **Mr. William Johnson** **Date: 08/31/2007**

Organization : **Triangle Orthopaedics**

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Willy Johnson; I am a state certified athletic trainer working in North Carolina. Over the past 10 years, I have been in the elinieal setting. During this time pcriod, I have gained important knowledge to better provide for the patients that I see.
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 concernecl 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 experiencc, 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,

Willy Johnson, ATC-L

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

Organization : The Society of Thoracic Surgeons

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1385-P-14946-Attach-1.DOC

#14946

August 31, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue
Washington, DC 20201

Submitted Electronically at CMS e-rulemaking website

RE: CMS 1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008

Dear Mr. Kuhn:

On behalf of The Society of Thoracic Surgeons (STS), we appreciate the opportunity to comment on the CMS proposed rule published in the Federal Register on July 12, 2007.

The STS appreciates the amount of work on the part of CMS required to determine appropriate and accurate payment policies across the wide range of codes and procedures provided by over 700,000 physicians to Medicare beneficiaries. In particular, we strongly applaud the administration's movement toward data-driven methodologies and increased transparency and reliance on objective evidence to determine appropriate utilization and payment policies. We will stress the value of data-driven approaches to both payment methodologies and quality measurement and recommend several additional areas where data could guide the agency in refining specific areas of physician payment, quality and efficiency policies in this regard.

To provide context regarding the impact of Medicare payment policies on cardiothoracic surgery since the implementation of the RBRVS, we believe it is again imperative to comment that the specialty of cardiothoracic surgery is facing a devastating shortfall of applicants to our residency positions. While several training programs have closed due to lack of applicants, and hence, the number of residency positions available has declined slightly, from over 140 per year to fewer than 130 per year, the number of applicants to those positions has fallen by over 50 percent in the past 12 years. For the past four years, there have been fewer applicants than positions, and for the past three years in a row, at least one-third of residency positions have remained vacant due to lack of applicants. There is strong evidence that this residency shortfall is a direct result of the cumulative effect of Medicare payment policies. In fact, Medicare payment rates for the most common cardiothoracic surgery procedures are currently reimbursed at nearly 35% of their 1987 levels in CPI-adjusted dollars. It has become clear that these government-set Medicare reimbursement rates are lower than the market will bear.

These continual reductions in reimbursement rates are creating a certain and severe shortage of surgeons available to treat Medicare beneficiaries in the future. It is worth

noting that the two primary disease conditions treated by CT surgeons are coronary artery disease, and lung cancer; the number one and two killers of American citizens. The incidence of both of these conditions increases with age. We strongly urge CMS to take note of the harmful cumulative effects of decades of payment reductions in both work and practice expense, and guide policy to help prevent this shortage before the access problem becomes more acute. In fact, AMA workforce studies have shown that **cardiothoracic surgery is the only medical specialty that is not only not growing, but is actually declining in number of physicians** at a time when the Medicare beneficiary demand for these services is predicted to skyrocket as the Medicare population grows.

Resource Based Practice Expense Relative Value Units

A. Practice Expense Direct Inputs for Clinical Staff

STS must once again comment that the continued exclusion of the clinical staff that cardiothoracic surgeons employ (and who work in the hospital with the surgeons) from the practice expense calculation is a violation of the BBA statute of 1997. This situation hampers quality improvement, fosters unnecessary complications and costs, and has had a significant deleterious effect on the practice of surgery and upon our patients. Data from the HHS OIG show that it is indeed typical practice for surgeons to employ these clinical staff; that hospitals are not paying for these staff; and that the implementation of this change in 1999 has shifted hundreds of millions of dollars in PE costs in the formula from CT surgeons who incur them to all E&M codes inappropriately. To correct this misallocation would cost nothing, and would have minimal effect on the PE RVUs for E & M codes (less than 5 cents per visit). The costs of these clinical staff must either be required to be paid by hospitals, or reimbursed under practice expense, but the decision by CMS to do neither, is both contrary to the statute and a major contributor to the problems experienced by the specialty. **We strongly recommend that the costs of clinical staff included in the original CPEP data, be removed from the E&M code pool where they have been inappropriately shifted, and restored to the CT practice expense pools where they belong. We remind you that this change is budget neutral and would have a trivial impact on the reimbursement for E&M services (less than $.05 per visit).**

STS notes that many of the changes proposed in the area of practice expense relate more to paying costs for the business of medicine rather than costs required for the practice of medicine. This is especially true with regard to the low equipment utilization assumptions as well as the high interest rate assumptions upon which CMS bases PE payments for equipment financing. These are examples of profit centers for physicians which are optional, and not necessary costs of direct patient care. The participation of our clinical staff delivering essential perioperative care not provided by hospital staff following cardiothoracic surgical procedures is a requirement for quality care, and yet is currently disregarded by CMS.

Similarly, the costs attendant to clinical data collection for quality improvement purposes should be considered an allowable practice expense by Medicare. Several decades of experience in quality improvement has shown that the collection of data for quality measurement, feedback, and improvement is the best way to improve quality in medicine. The specialty of cardiothoracic surgery has employed this method for nearly two decades and in doing so, we have reduced mortality rates in coronary artery bypass surgery by 70% below previously expected mortality rates. At the same time, we have reduced costly complications significantly. To participate in these efforts each surgeon participant site spends between $50,000 and $100,000 per year for the costs of software, data managers, and database participation to learn where they have opportunities for improvement. Yet despite all the dialogue in CMS about value based purchasing, quality measurement and improvement costs remain completely uncompensated. **We strongly recommend that costs directly related to data collection, analysis and feedback for quality improvement be included as allowable practice expense costs under Medicare, or that CMS develop an additional "quality improvement cost" element to be incorporated into the fee schedule calculation that would not drain the current, inadequate pool of practice expense funds.**

STS supports CMS continuing to implement the transition to bottom-up methodology despite the negative impact of the implementation on our specialty. The bottom-up methodology is an appropriate methodology and captures most of the actual PE costs, but there will inevitably be legitimate practice expenses that are not captured with a bottom up methodology. While we are appreciative of the improved acquisition of data to support the bottom up methodology, we are concerned that there are some aggregate costs that may not be captured under this method. Therefore, data on total practice expenses must still be part of the calculations of practice expense RVUs. Nevertheless, the acceptance of the survey data from several specialties using differing methodologies will continue to cause distortions in the relative accuracy of the PE formula, until new and uniformly acquired data can be utilized.

The practice expense inputs will be more accurate if they are based upon consistent data with standardized definitions and statistically significant number of sources. The all-specialty practice survey undertaken by the Gallup Organization with support from STS, AMA, and most other specialties should yield such consistent data source, and would go a long way toward improving the equity of the allocations in the future. We recommend that CMS accept new data in 2009 for 2010 fee schedule or as soon as feasible.

B. Equipment Utilization Percentage Assumptions & Data

The decision to purchase and utilize technological medical equipment in a medical office is one made often for the convenience of the patient, but also, in the case of high-tech imaging and other diagnostic equipment, is a business decision to use the purchase of equipment as an additional profit center in the practice. These practice expenses are seldom mandatory, and are commonly quite lucrative. We are surprised that CMS would set payment policies that create such strong incentives to purchase and utilize these devices with such low utilization assumptions and high interest rate payment amounts. As

mentioned previously, the STS believes the best policies are those derived from sound data. The data on utilization rates of equipment to determine practice expense costs have come from two sources: from ABT Associates, who were contracted by CMS to determine the original usage rates, and from MedPAC, which analyzed actual equipment utilization rates in a small study to inform Congress. Both of these sources of data found that equipment usage rates were well above the 50% assumption utilized by CMS for PE payment. ABT recommended that 70% be established as an appropriate assumption, and MedPAC found actual usage rates in excess of 100% in some instances.

The fact that the 50% utilization rate chosen by CMS is based upon no data whatsoever would appear to be indefensible when there are two sources of data in existence. Moreover, equipment utilization rates are eminently measurable, and could easily be established using actual data. **STS recommends that CMS undertake a study of utilization rates of specific equipment in representative settings, or use data from existing sources to determine the appropriate utilization rate.**

C. Equipment Interest Rate Assumptions

Similar to above, the interest payment of 11% for large equipment financing shifts scarce Practice Expense resources from the true costs of providing care to the "business aspect" of medicine which are often profit centers for physicians. STS believes that there are differing considerations for the financing of equipment of differing sizes and costs. Each of these prevailing rates can be measured with a simple survey. As suggested by the AMA's RUC, **STS recommends that CMS review the prime interest rate and either update interest assumptions annually or use a rolling average rate.**

Specific Coding issues related to PFS

A. Application of Budget Neutrality to Conversion Factor

The proposed application of budget neutrality adjustments to the work values creates distortions and an inequitable redistribution of resources that is punitive to services and procedures that require more physician work. Unless the intent of CMS is to favor non-work services, it would be both more logical and equitable to apply budget neutrality adjustments in an across-the-board manner that does not take resources from one set of services and redistribute it to others. **STS recommends that CMS apply the budget neutrality adjustments to the conversion factor.**

B. Recommendation on bundling of services for Echocardiography

STS disagrees with the CMS decision to bundle 93325 with the entire family of echocardiography codes, without changing the work and practice expense values of those affected base codes. In reviewing Medicare claims data submitted to the RUC, it is clear that the employment of 93325 with another base echocardiography code is only typical for 99307.

Since a code bundling 93307 with 93325 and 93320 has already been approved by CPT and will be valued by the RUC in September 2007, we recommend that CMS consider the RUC recommendations from that meeting in the Final Rule. Since 93325 clearly results in additional physician work, and is not typically performed with the other echocardiography base codes, we recommend that CMS permit the concomitant use of 93325 with the remaining echocardiography base codes.

TRHCA - - Section 101(b): Physician Quality Reporting Initiative (PQRI)

A. Recommended Measures for 2008

For 2008 PQRI, the Society believes that while helping physicians learn to measure and report data on the care they provide is a critical first step, it is perhaps more important to speed the evolution of measures toward both areas of high priority, and measures that have the greatest impact on quality improvement and costs to the Medicare program.

Several recently published studies have highlighted the tenuous link between compliance with simple process measures, and either improvement of patient health outcomes or reductions in cost areas such as hospital admissions or occurrence of complications. The PQRI as currently structured does little to focus on high-cost, high incidence, or chronic disease areas. Nor does the current PQRI weigh or prioritize measures based upon the strength of the link between the processes measured and improvement of beneficiary outcome. Nearly all of the PQRI measures are static process measures, which tend to reward compliance with one process rather than to reward attainment of the desired result. The focus exclusively on process compliance will stifle innovation in health care as rewards for compliance provide powerful disincentive to try new approaches. Rewarding outcome attainment would have the opposite effect of stimulating innovation to find the most effective way to achieve the best result for the patient. We are surprised that CMS has apparently not considered any incentive that would reward the attainment of outcome improvements, and has continuously rebuffed our efforts to share cost and quality data to measure and improve overall value in Medicare.

Measurement of patient outcomes is certainly much more difficult given the necessity of risk adjustment and the high premium on data accuracy, but improved outcomes is likely the only place where significant reductions in unnecessary care as well as leaps in prevention and innovation could produce major cost savings through continuous quality improvement in Medicare.

Moreover, the PQRI, either as currently structured, or as proposed in this rule, is completely unable to measure health outcomes of beneficiaries with any meaningful risk adjustment. It has been established by decades of experience and published studies that without adequate risk adjustment, beneficiary outcomes measurement and reporting can have serious negative consequence for not only access to care for the sickest patients, but

also could increase costs for the program as has resulted from such data collection and publication in some states.

Conversely, attempts to measure provider costs (or efficiency) will be equivalent to strict rationing of care without significant safeguards that measure results achieved for the patient. No Medicare beneficiary wants their choice of heart surgeon (or any other provider) to be made on the sole basis of cost. Unless risk adjusted outcomes can be held constant, profiling or other judgments made based upon costs are wholly inappropriate, will be detrimental to beneficiaries, and will likely increase program costs in the longer term. In short, the Medicare program must utilize clinical data and develop accurate risk adjustment in order to begin measuring outcomes, and to ultimately and appropriately reduce unnecessary costs. The Society of Thoracic Surgeons has already done all of this, and is eager to work with CMS to develop the appropriate quality and efficiency improvement systems even further.

The STS is proposing additional measures for PQRI 2008 that would begin to move beyond claims-based data, which lack the accuracy and granularity for appropriate risk adjustment, toward enabling CMS to utilize clinically valid, audited, and risk-adjusted data to determine outcomes and efficiency within the program. We are already involved with multiple major private payers in similar efforts, and we hope that Medicare will not lag too far behind the private sector.

1. Participation in a multi-institutional database

The first measure, which we strongly recommend be adopted for PQRI 2008, is a structural measure that will facilitate all future data collaboration efforts. This measure has been approved by the NQF as part of the cardiac surgery performance measure set in 2004, as measure number one. It is: *Participation in a Systematic Database for Cardiac Surgery.* This one structural measure is possibly more valuable than the other 20 measures in the NQF approved cardiac surgery measure set. This is the case because it *enables* the collection of standardized clinical data on every other performance measure, be they structural, process, or outcome measures. STS has unequivocally shown that participation in database is associated with improvement in outcomes. We believe this is one of the reasons the TRHCA statute encouraged the Secretary to select measures for 2008 that include structural measures. The STS recommends that the NQF endorsed measure – *Participation in a Systematic Database for Cardiac Surgery* – be included by CMS in the 2008 PQRI measures.

The Society of Thoracic Surgeons also recommends that a similar measure be adopted for General Thoracic surgery. We are proposing that *Participation in a Systematic National Database* be included in the measure set adopted by CMS as a structural performance measure that is available for general thoracic surgeons and congenital heart surgery as well, since standardized national databases exist in these areas of specialty.

Moreover, we recommend that this structural measure be adopted or available for all physicians, with appropriate standards and safeguards for data standardization, validity,

audit, and privacy protection. Through adoption of this one simple measure, CMS could allow and encourage the medical specialties to develop the appropriate clinical measures collection, analysis, feedback, and risk adjustment methods for their clinical discipline, while CMS could benefit greatly from the reduced administrative burden, increased physician buy-in, clinical relevancy and timely update of elements and risk algorithms. Ultimately, CMS could utilize the physician-consensus risk adjusted outcomes, and couple them with Medicare cost data to improve both quality and cost: which equates to value for the Medicare beneficiary and the taxpayer. We are aware of dozens of medical specialties that are in the process of developing national clinical registries or databases. This one simple step would send the message that CMS is engaging the professional responsibility of medical societies to measure and improve the care they deliver.

2. General Thoracic Surgery

In addition to the critical structural measure of database participation, STS recommends that CMS adopt a set of measures for General Thoracic surgery. These measures are currently being considered by AMA's PCPI as well as the AQA and NQF. We propose the following measures be adopted for 2008 PQRI:

1. Participation in a Systematic National Database for General Thoracic Surgery.
2. Recording of Performance Status (Zubrod, Karnofsky, WHO or ECOG Performance status) Prior to Lung or Esophageal Cancer Resection.
3. Recording of Clinical Stage for Lung Cancer and Esophageal Cancer Resection.
4. Screening for Smoking Status – Surgical Procedures.
5. Pulmonary Function Test Prior to Major Anatomic Lung Resection.

3. Adult Cardiac Surgery

There are currently 3 NQF-endorsed / AQA-approved performance measures dealing with discharge medications following CABG. The measures specify that patients are discharged on anti-platelet medication (NQF measure 13), beta-blocker medication (NQF measure 14), and anti-lipid medication (NQF measure 15).

For the 2008 PQRI measures for adult cardiac surgery, we recommend that a technical change in the specification for discharge medications be made to bring them more into conformance with other measures in PQRI, and to avoid delays in our physicians' ability to submit claims on a timely basis. We request that the adjustments be made to the adult cardiac measures to indicate that these discharge medications were ordered, rather than administered. This minor technical modification will make these measures significantly less onerous to report in a claims-based protocol. The spirit, intent, and evidence for these measures will not be affected by reporting them in this way.

With regard to the consensus organizations acceptable to approve or endorse physician quality measures, we agree and support CMS in the determination that only the NQF meets the requirements of NTTAA of 1995 as well as OMB circular A-119, and hence is at present the only organization that is qualified to endorse consensus quality measures.

We also agree that once NQF endorsed, measures may go through the AQA for coordination of implementation, but that this need not be a requirement for CMS adoption of measures for PQRI. We further agree that where no NQF endorsed measures exist, measures that have been approved by the AQA or comparable process may be used. We believe that a straightforward process such as this is necessary to bring together the myriad quality measures and ensure standardization, harmonization, and consensus. CMS is right to allow measure development to flow from many different organizations, without restricting the source. The consensus process at NQF is sufficiently rigorous to discern between measures that are not appropriate or relevant to patient care, and those that will be more meaningful to quality improvement.

Nevertheless, it is imperative that measures evolve rapidly from the current measurement of many simple processes where questionable gaps exists (i.e. routine screenings, patient history, counseling smoking cessation) to measures which are most directly related and linked to improved results. In addition, priority disease conditions must be established to allocate scarce resources where the near-term impact will be greatest. Moreover, the "one size fits all" approach of requiring measures for every specialty or disease group has caused somewhat of a lowest common denominator approach, which has stymied groups with advanced measurement and improvement capabilities. Instead, we suggest an incentive approach, which would reward rapid improvement and serve as a model for other groups, which may be just beginning the process of quality measurement and improvement.

B. Registry-based Reporting for PQRI

As we have commented earlier in this section, the current construct of PQRI, which collects administrative claims based data designed for billing purposes, is wholly inadequate for a continuous quality improvement system. The ultimate goal of value based purchasing should not be simple "box-checking," or static compliance with rudimentary processes of care. We believe CMS shares that goal of moving toward an approach that can determine the level of quality of the care delivered, in a risk-adjusted construct that relates directly to the outcomes achieved for Medicare beneficiaries. Claims based data is not sufficiently robust or sufficiently accurate to allow adequate risk adjustment to determine patient outcomes satisfactorily. The PQRI is a fine beginning step to allow providers to begin collecting, measuring, and communicating information on the care that they provide. But, without any understanding of the ultimate goals and future evolution of such a system, Medicare runs the risk of establishing a static system where process compliance is improved at additional cost to the program, with no attendant improvement in outcomes nor efficiency or effectiveness of that care. This has been shown to be the result of static process measurement systems under many demonstrations and in multiple recently published studies. Furthermore, we caution against measuring cost or "efficiency" of providers without adequate data on clinical outcomes. If cost is measured against process compliance alone, it is very likely that providers that use more resources in the short term to prevent complications or further costs down the road, and achieve superior outcomes – will be penalized. Such a

construct with be damaging to the credibility of the program, to physician trust, and runs the very real risk of harming Medicare beneficiaries.

It is therefore imperative that CMS design and communicate a system, which is capable of evolving toward collecting clinically detailed information on patient conditions, co-morbidities, and results achieved in both acute and chronic illness, and primary and specialized care. CMS must also communicate such an evolving process in advance so that Medicare providers can design systems that capture the relevant data, and can be aware of how the system can ultimately help improve care.

Clinical registry, or database based collection and reporting of clinically rich data elements is the best way to achieve this goal. Several highly sophisticated data registries are in existence that can supply the information needed to measure and communicate compliance with structural, process, and risk-adjusted outcomes measures today. Dozens of physician and non-physician specialties are in the development phases of such data registries as well. However, the lack of database standards is an impediment to interoperability, standardized definitions, and measurement of care across disciplines and disease states.

The systematic collection of standardized clinical data is both difficult and expensive. The STS National Cardiac Database (NCD) captures 100 percent of the procedures performed by each participant at over 85% of the cardiac surgery programs in the country. Each participant must purchase software, employ a trained data manager, and pay participation fees to help offset costs of warehousing and analysis of our data at the Duke Clinical Research Institute (DCRI). The STS has expended approximately $15 million in the development and maintenance of this database, and participants have expended tens of million of additional dollars which have been completely uncompensated by CMS or most other payers. Nevertheless, we have reduced observed over expected mortality rates in cardiac surgery by about 70 percent over the nearly two decades of data collection and feedback. This equates to the saving over nearly 100,000 American lives!

The NCD now contains over 3 million patient records, measures each participant's compliance with many process measures as well as the rates of mortality and complications with sophisticated risk adjustment. We can also measure the effectiveness of many procedures on different populations as well as effectiveness of devices and new innovations. We have developed a composite measure that measures and appropriately weights 11 of the NQF endorsed measures for cardiac surgery and yields one composite score for each participant. We are working with many major private payers to utilize this information in the improvement of care and efficiency. Despite such advances, we have been unable to convince CMS to work with us to undertake similar initiatives in Medicare, and have been hampered by the one-size fits all approach to rudimentary quality measurement. While we seek to accelerate our quality improvement efforts, and share these methods with many other willing specialties, the current regulatory approach has served to impede progress. The lack of cooperation or assistance (much less remuneration) from CMS has been disheartening to say the least.

We recommend that CMS look beyond 2008 PQRI and articulate a more iterative approach that will allow providers to understand and implement data collection systems with shared endpoints and ultimate goals in mind.

The Society of Thoracic Surgeons has approached CMS repeatedly over the past several years asking CMS to utilize our objective clinical data, and match it with cost data, to measure and improve both quality and value. It is particularly important to note that this data link, when paired with the STS composite model, can immediately produce cost-of-care measures. Furthermore, the ability to collect longitudinal data based on the STS clinical information will permit unprecedented analyses of episodes of care and long-term sequelae of treatment strategies.

With the above concerns and recommendations as prelude, we recognize that for 2008 PQRI, STS members must continue to submit CPT II codes through the Medicare claims process. This information is already being submitted to the STS Database, so the present PQRI protocol creates an undue administrative burden that is both time-intensive and redundant. It should be emphasized that this duplication of effort is clearly recognized by physicians and serves as a powerful deterrent to clinical data collection. **In its present format, PQRI actively discourages the use of clinical registries and therefore impedes national quality improvement.**

While our surgeons must submit duplicative and less sophisticated data through a claims process to help CMS determine their compliance with IMA use and beta blockade, we could give that information to CMS today with much greater accuracy for all patients through the STS NCD. In short, we have already achieved the end result of PQRI of feedback to each participant their compliance rates with each measure (as well as many additional and more relevant measures) to help improve care, yet we are required to participate in a rudimentary and less accurate system to collect a small bonus under Medicare. This system is suboptimal and quickly losing the confidence of America's cardiothoracic surgeons.

Given CMS's interpretation of the statutory requirement that; "...the Secretary shall address a mechanism whereby an eligible professional may provide data on quality measures through an appropriate medical registry (such as the Society of Thoracic Surgeons National Database)...." to mean the testing of options for 2008 at minimum, the STS is prepared to participate with CMS in the exploration and testing of data submission options.

Of the five options outlined for data submission to CMS, we find one option, Option 3, to be most appropriate and effective for data collection and submission for PQRI in 2008, but also seems to be the approach, which most readily lends itself to evolution to measuring more sophisticated performance metrics such as those that require risk adjustment. This is because only Option 3 allows the registry to perform the necessary calculations to be able to submit completed numerator and denominator information to

CMS. This is important as we move toward measures, which require additional clinical data not captured in CPT category II or G-code data.

STS recommends, and would like to utilize, Option 3 in the collection and transmission of quality data to CMS in 2008 PQRI.

Additionally, though the STS National Database is rigorously validated and audited by the Iowa Foundation for Medical Care, STS would seek some indemnification or protection from liability in our role as a "data submission vendor" for information that is reported through our database that may be erroneous as submitted from the participant. We would like to discuss this concern with CMS as we believe it will be shared by any or all registry data submission entities. The STS NCD, as well as the databases for general thoracic surgery and congenital cardiac surgery, are HIPAA compliant.

While these comments have been focused on the STS NCD, we should emphasize that there are global implications for the entire field of medicine. Most would agree that the STS NCD is one of most mature and effective databases in existence today. If this database is not used as a data entry platform for upcoming CMS programs, it will send a clear message that CMS does not value high quality clinical registries. That, in turn, will serve as a major deterrent to those medical societies now considering the development of a clinical registry. Clearly, this message will be one that universally discourages data collection, which is the most important element in quality measurement. If this approach is taken, CMS may well be embarking on a path that will create a sense of nihilism in physicians, make a mockery of existing databases, and actually reduce the quality of care.

Alternatively, the use of the STS Database in upcoming CMS initiatives will demonstrate a strong and tangible advantage of clinical registries. This approach will strongly encourage others to develop meaningful clinical registries, which will accelerate data collection to improve patient care and reduce cost.

Conclusion

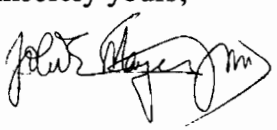
The proposed rule for the Medicare Physician Fee Schedule for 2008 would reduce payments for cardiothoracic procedures by an additional 2% on top of the scheduled 9.9% reduction under SGR beginning on January 1st. This continued reduction in payment is untenable, and will exacerbate and accelerate the growing shortage of cardiothoracic surgeons just as the baby boomers need care the most. While our specialty has made revolutionary strides in quality measurement and quality improvement saving tens of thousands of additional lives, Medicare reimbursement has decimated our ranks. The coming access crisis for cardiothoracic care under Medicare cannot be avoided at this point due to the long training period required to train a cardiothoracic surgeons. The shortage, while now inevitable, can be mitigated if CMS immediately recognizes the problem, and takes steps to prevent further unwarranted devaluation of services and exclusion of legitimate costs from practice expense. A clear area, which could simultaneously mitigate the effects of the shortage while spurring quality improvement,

would be to recognize and compensate for significant strides in outcomes improvement and efficiency.

We ardently urge the agency to consider these recommendations and implement policies that may help prevent the continued decline in practicing cardiothoracic surgeons and the access crisis, which will face Medicare beneficiaries in need of critical care for heart, lung, and esophageal disease in the near future.

Thank you for your consideration of our comments.

Sincerely yours,



John E. Mayer, Jr., MD
President

Submitter : Mr. Lonnie Scott **Date:** 08/31/2007

Organization : Mr. Lonnie Scott

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#14947

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Ms. Denise Garris **Date:** 08/31/2007

Organization : American College of Cardiology

Category : Physician

Issue Areas/Comments

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

See Attachment

CMS-1385-P-14948-Attach-1.PDF

new measures into the quality reporting system by providing consensus review for implementation of a measure prior to NQF endorsement. The ACC supports CMS's proposal to exclude from the final set of 2008 PQRI Quality Measures any any measure that NQFhas specifically considered , but declined to endorse as of November 15, 2007. The ACC appreciates the description of the differences between the NQF and the AQA. The NQF meets the National Technology Transfer and Advancement Act (NTTAA) requirements for a voluntary consensus body and its endorsed quality measures constitute voluntary consensus standards within the meaning of the NTTAA. The AQA utilizes certain essential practices of a voluntary consensus standards body under NTTA, but does not have a defined organizational structure intended to meet the requirements of the NTTAA.

The ACC's experience with the AQA has been that implementation policies and processes receive the most attention and input from stakeholders, while performance measure adoption input has been minimal and typically defaults to the specialty developer of the measure. We note that the AQA conditionally adopts a measure on a consensus basis, but withdraws the measure for implementation after one year if the measure is not endorsed by NQF. The ACC is concerned that using an organization like AQA, which was originally established to develop policies and process around implementation of measures endorsed by the NQF and has become an organization that adopts measures contingent on NQF endorsement, sets a precedent for bypassing established methodological vetting processes in order to rush measures to market.

The ACC strongly recommends that adequate federal funding be provided to the NQF to ensure that evidence-based performance measures are vetted and endorsed at a pace that meets market demand. The administrative burden on CMS, commercial payers, and physician practices to create systems and processes for reporting on measures that may be revoked seems counterintuitive and counterproductive to the mission of value-based purchasing.

In summary, the ACC strongly recommends that

- ***NQF be recognized as the endorser of measures;***
- ***participation in the PQRI remain voluntary; and***
- ***physicians retain the ability to self-select at least three performance measures relevant to their practice.***

The ACC is disappointed that the short timeline for the implementation of PQRI mandated by the Tax Relief and Health Care Act prevented a more detailed consideration of the methodology required to adapt measures designed for ambulatory performance measures for cardiovascular care to the inpatient setting. The ACC and the AHA, through the PCPI, worked cooperatively to develop measures and specify them for the PQRI; we are discouraged that the measures as specified during the development process will not benefit from the testing process that the PQRI affords.

The ACC respectfully requests that the inpatient discharge codes for measures 5-7 be removed from the PQRI in 2008. We believe that the approach of using inpatient codes for these particular measures undermines their validity.

Regarding Measure 8, Beta blocker therapy for LVSD, the ACC strongly encourages CMS to limit beta blockers to metoprolol, bisprolol, and carvedilol, as there is no evidence of benefit from others, and some evidence to suggest there is not benefit from atenolol.

In reviewing other measures for cardiovascular implications, the ACC advises CMS to consider the following regarding technical specifications:

> **Measure 1:** Hemoglobin A1c in Type II DM is not an important determinant of cardiovascular outcomes. The use of A1c as a PQRI measure should be restricted to Type I DM, where there is evidence that supports it.
>
> **Measure 9:** Antidepressant medication during acute phase is unsupported by data. Studies on depression among post-MI patients show that many acute-phase symptoms resolve spontaneously and rapidly. Data showing benefit come from patients whose depression persisted at least 1 month.
>
> **Measure 30:** Electrocardiogram performed for syncope should be qualified by clinical situation. There is no meaningful role for EKG in evaluation of obvious orthostasis in young healthy individuals.

<u>AMA/PCPI Measures</u>

Given that the three PCPI measures developed in collaboration with the ACC and the American Heart Association (AHA) have not been endorsed by the NQF, the ACC respectfully recommends that they be removed from the list of measures for use in 2008 PQRI. Specifically:

Chronic Anticoagulation in Patient with AF
Assessment of Thrombo-embolic Risk Factors in Patients with AF
Monthly INR Measurement in patients with AF

The ACC does support the use of PCPI/ACC/AHA measures that are NQF-endorsed for inclusion in PQRI 2008 as follows:

HF: Left Ventricular Function (LVF) Assessment
CAD: Lipid Profile
CAD: Drug Therapy for Lowering LDL-Cholesterol
HF: Warfarin Therapy for Patients with Atrial Fibrillation (AF)
CAD with DM and/or LVSD: ACE or ARB Therapy
CAD: Smoking Cessation

Other proposed measures with cardiovascular implications that require close attention to technical specifications are:

ACE/ARB for Chronic Kidney Disease needs to be qualified. ACE and ARB are not indicated for patients with sufficiently severe disease.

Non-physician Measures Currently under Development by PA-QIO

There is no evidence of benefit for universal depression screening. This has proven to be of limited validity in primary care. It is controversial and unproven in the primary care setting, and has no place in a quality measure at this time.

Structural Measures Currently under development by PA-QIO

These measures are not ready for implementation. The assumption that e-prescribing and EHRs improve care has finally been subjected to actual study, and the results have not been as hypothesized. E-prescribing and electronic order entry have had very mixed results with current generation systems, even increasing error rates in some cases, and a recent large study of EHRs demonstrated that they fail to improve quality of care in ambulatory primary care settings. No quality measures should be conditioned upon these use of e-prescribing and EHRs unless and until sound data, not merely good intentions and faith in technology, supports their benefit.

Additional AQA Starter-Set Measures

The measure regarding Beta Blocker Therapy persistent for six months or more post-MI seems redundant of the current 2007 PQRI Measure 7: CAD with prior MI: Beta blocker therapy. How would the technical specifications differ?

Other NQF-endorsed measures

As stated above in #2, the ACC supports the use of AMA/PCPI/ACC/AHA measures that are NQF-endorsed for inclusion in PQRI 2008 as follows:

HF: Left Ventricular Function (LVF) Assessment
CAD: Lipid Profile
CAD: Drug Therapy for Lowering LDL-Cholesterol
HF: Warfarin Therapy for Patients with Atrial Fibrillation (AF)
CAD with DM and/or LVSD: ACE or ARB Therapy

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

The ACC agrees in principle with the use of registries for PQRI reporting. Specifically, the ACC agrees that the ideal process for reporting on PQRI measures should be directly from a registry to CMS on behalf of the eligible professional, and that eligible professionals should provide explicit authorization or permission to the registry to provide such reporting.

In evaluating which registries are appropriate for the testing phase of this mechanism, the ACC encourages CMS to consider the following registry requirements:

- The registry should demonstrate HIPPA and CHI compliance.
- The purpose of the registry should be to improve quality of care and patient outcomes.
- The registry should demonstrate a scientifically rigorous and unbiased methodology for developing data elements that is valid for practicing clinicians and is nationally recognized by appropriately qualified groups.
- The registry should require data submissions be of sufficient size to be statistically and clinically relevant.
- The registry should collect and report back data in a timely manner to physicians to support self assessment and quality improvement activities.
- The registry should demonstrate systems for data collection, data element structure, data personnel training and inter-rater reliability, data storage, monitoring, and review.

- The registry should demonstrate processes and procedures for ensuring data completeness (both at the individual element and the overall composite levels), data consistency (e.g., alpha characters in numeric fields), and data validity (e.g., values outside a normal or expected range)

These considerations are in addition to a registry's technical capability to interface with a CMS clinical warehouse electronic data exchange interface (EDI).

The ACC makes these recommendations based on its experience over the past 10 years with the National Cardiovascular Data Registry (NCDR). NCDR is an initiative of the American College of Cardiology Foundation, with partnering support from the following organizations: CathPCI Registry™; ICD Registry™ - Heart Rhythm Society; CARE Registry™ - the Society for Cardiovascular Angiography and Interventions, the Society of Interventional Radiology, the American Academy of Neurology, the American Association of Neurological Surgeons / Congress of Neurological Surgeons, and the Society for Vascular Medicine and Biology. The NCDR registries are created under the leadership of cardiovascular experts with critical input from NCDR participants regarding the scientific validity, feasibility of implementation, and the burden of data collection.

The NCDR has a rigorous data quality program including an automated Data Quality Report (DQR) to the participant on overall completeness of quarterly data submissions that must pass high thresholds in order to be accepted into the data warehouse. The DQR provides the participant with a confidential analysis of their data submission's completeness and consistency, and is used by the participant to help prioritize data cleaning efforts and to assess the necessity for resubmission. Upon receipt of the DQR, participants are encouraged to resubmit at any time during the Call for Data period to improve the overall completeness of their data.

To be included in a registry, a participant must pass all composite category inclusion thresholds established in the threshold report. This report presents the threshold result for all core elements, as well as the number of unique records, percent valid values, percent invalid values, and percent missing values. Inclusion threshold criteria were chosen for their clinical and structural pertinence. In order for a data submission to be included in the NCDR, each data element must be 95% to 100% complete. In other words, no element may have more that 5% missing data or the submission will be excluded from each specific registry's NCDR averages.

The NCDR also implements a national Data Audit Program. The purpose of this program is to ensure that data submitted to the NCDR fulfill the criteria of consistency and accuracy. Performing systematic, onsite medical record reviews and blinded abstraction of participants' data allows the NCDR to closely monitor the quality of data submitted to the registries. High quality data allows the NCDR to provide complete

statistics to participating institutions and interested third parties and guarantees that all information used for analyses are accurate and complete.

In reviewing the options proposed as possible mechanisms, ACC strongly encourages CMS to test the option identified as number 3, in which registries calculate the reporting and performance rates for Medicare beneficiaries only and submit these rates to CMS with no sharing of beneficiary-level information This option presents the best use of registry data for PQRI reporting and provides CMS with the most current data available. This option also engages physicians and other members of the scientific community in partnering with CMS to appropriate report data for the identified performance measures for PQRI.

If CMS plans to test more than one mechanism, the ACC encourages CMS to consider the option identified as number 5, in which registries would provide a "data dump" of all information in the registry for Medicare beneficiaries only for the service period of interest. In fact, the NCDR has been approached by a number of private payers interested in similar mapping of registry data to claims data to begin to analyze quality improvement for episodes of care. In addition, a description of a probabilistic match methodology that is has as high as 99% probability of correctly linking beneficiary data to patient registry data was described to the NCDR by an analytic center. The ACC cautions that the limitations of using claims data for quality improvement purposes, specifically the lag time in receiving claims data, still exist with this option.

The options identified as 1, 2, and 4 included a number of billing specific elements as examples of data elements needed from a registry in order to meet the proposed mechanism's design. These elements included CPT codes, ICD-9 procedural codes, HCPCS codes, beneficiary claim account number (CAN), beneficiary identification code (BIC), line item and claims expense codes and charges, etc. The ACC has the following concerns with the inclusion of these types of elements:

- These elements add to data collection burden or the expense in integrating software to map claims data to registry data for eligible professionals.
- These elements increase the staff training burden as registry data collection personnel have different skill sets, usually clinical, from billing and coding personnel, or it increases the opportunity for data reporting errors by requiring multiple data entry personnel for a single patient record.
- These elements create potential process problems for data collection resulting in a delay in reporting to registries, which ultimately impacts timely reporting for quality improvement purposes.
- These elements add to the data quality monitoring and data storage burden for registries.

The ACC recommends that CMS eliminate options 1, 2, and 4 from testing for 2008.

Finally, the ACC encourages CMS to evaluate the impact of timeliness of data received through registries rather than claims data in improving efficiency as part of PQRI, and to evaluate whether reporting through registries by eligible professionals results in improvement in performance measures.

Thank you for the opportunity to comment upon this proposed rule. The ACC appreciates CMS' continued willingness to work cooperatively with the physician community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Rebecca Kelly, ACC's Director of Regulatory Affairs at 202-375-6398 or rkelly@acc.org with any questions.

Sincerely,

James T. Dove, M.D., F.A.C.C.
President
American College of Cardiology

cc: Kenneth Simon, MD - CMS
Edith Hambrick, MD - CMS
Pam West - CMS
Rick Ensor - CMS
Ken Marsalek - CMS
ACC CV-RUC
ACC Advocacy Committee
ACC SLT

Submitter : Dr. Siraj Bhadsavle **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 : **Date: 08/31/2007**

Organization : **Medical Group Management Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-14951-Attach-1.PDF

#14957

MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008

Dear Mr. Kuhn:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the proposed rule entitled the "Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for Calendar Year 2008," as published in the July 12, 2007 *Federal Register*. We appreciate the Centers for Medicare & Medicaid Services' (CMS) outreach to the provider community and their willingness to participate in constructive dialogue to improve the Medicare program. We look forward to continuing to collaborate on this and other administrative simplification issues. For these reasons, MGMA offers the following critiques and recommendations related to this rule, as outlined below.

MGMA, founded in 1926, is the nation's principal voice for medical group practice. MGMA's nearly 21,000 members manage and lead 12,500 organizations, in which almost 270,000 physicians practice. MGMA's core purpose is to improve the effectiveness of medical group practices and the knowledge and skills of the individuals who manage and lead them. Individual members, including practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

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Physician reimbursement

The proposed physician fee schedule unfortunately confirms the Medicare Payment Advisory Commission's (MedPAC's) forecast of a 9.9 percent reduction in Medicare physician reimbursement levels for services rendered on or after Jan. 1, 2008. MedPAC estimates that payment will be cut every year for the foreseeable future, a trend that will have grave consequences for the entire health care system. If CMS does not take possible administrative actions and Congress does not act, physicians will receive payment rates lower than those of 1999 – yet, according to MGMA data, their costs have increased by 42.5 percent since that time.

MGMA has conducted extensive surveys of medical practice costs for more than 50 years. Our data demonstrates that the cost of operating a group practice rose by an average 4.8 percent per year over the last 10 years. In fact, between 2001 and 2006, operating costs increased more than 34 percent.

This past June MGMA conducted a poll of members regarding the effects of a 9.9 percent reduction in Medicare payment. Under such a threat, more than 41 percent of respondents said they may have to limit the number of Medicare patients they see. More than 19 percent of respondents to MGMA's questionnaire said they would be forced to stop accepting new Medicare patients.

Beyond restricting access, medical groups also said:

- 57 percent would have to reduce staff health care benefits coverage to remain financially viable;
- 44 percent would cut administrative staffing levels;
- 33 percent would cut clinical staffing levels; and
- 9 percent would cut the number of physicians in their practice.

Lagging Medicare reimbursement updates have simply failed to keep pace with practice costs. If this trend continues, providers will face difficult decisions as they evaluate the economic practicality of caring for Medicare beneficiaries. MGMA data show that practices nationwide have cut costs where they can in staff, housekeeping, maintenance and health information technology expenses. In spite of these measures, nonhospital-owned multispecialty groups reported a 7 percent increase in operating costs in 2005 – more than twice the Medicare update amount. In the face of significant costs associated with professional liability insurance, implementation of the Health Insurance Portability and Accountability Act (HIPAA) and new technology, Medicare reimbursement does not reflect the actual costs of delivering services to Medicare beneficiaries.

While the impact of insufficient Medicare payments is severe, this issue alone does not fully reflect the extent of the program's impact on the American health care system. Most of the nation's private health insurance companies use the Medicare physician fee schedule as a benchmark for their fee schedules. Thus, failure of Medicare payments to keep pace with operational costs is magnified across the nation and affects access to health care for both Medicare and non-Medicare populations.
Our poll indicated that nearly 63 percent of respondents said private insurance companies with which they had contracts made changes to their 2006 payment rates based on the Medicare fee schedule. Of those affected practices:

- 51 percent experienced up to a 5 percent reduction in reimbursements;
- 22 percent experienced up to a 10 percent reduction in reimbursements; and
- Nearly 9 percent experienced up to a 25 percent reduction in reimbursements.

CMS chose not to take administrative steps to soften this crippling blow, even though MGMA and 85 other national medical associations recommended several actions in an April letter to the agency. MGMA urges CMS to work with Congress to eliminate the SGR and develop a methodology that will accurately reflect the increase in the cost of practicing medicine.

Medicare Economic Index

Another component of the Medicare physician reimbursement formula that requires immediate attention is the Medicare Economic Index (MEI). Congress established the MEI in 1973 to measure the rising cost of practicing medicine. However, the MEI calculation today fails to incorporate all of the costs a physician group practice bears to care for patients.

The proposal to apply a 0.65 productivity adjustment to the MEI on the other Medicare providers, while imposing a 1.5 percent productivity offset on physician services is unfair. MGMA strongly believes that the 1.5 percent productivity offset is too high. Physicians face the impossible task of increasing their productivity in treating Medicare patients while complying with burdensome regulatory requirements that did not exist when the MEI was created, including:

- Complying with constantly changing rules concerning referrals and financial relationships;
- Tracking new or altered local and national coverage policies;
- Managing advanced beneficiary notices and certificates of medical necessity;
- Tracking regulations governing patients' eligibility for Medicare and other programs;
- Compliance with limited English proficiency requirements;
- Medicare audits, including Recovery Audit Contractors, compliance with HIPAA and the Clinical Laboratory Improvement Act (CLIA);
- Navigating and resubmitting billing errors; and
- Learning about and participating in quality monitoring and improvement programs such as the Physician Quality Reporting Initiative (PQRI).

Yet again, the agency ignored requests by MGMA and other national provider associations to apply equal productivity rates to all Medicare providers. Using a productivity adjustment just for physicians that is more than double that applied to other providers is both unfair and against CMS' supposed goals of value-based purchasing and pricing transparency.

The MEI should also reflect the modern level of support staff. Of particular concern to MGMA is that employee wages used in the MEI formula do not capture highly skilled professionals now considered essential for the delivery of medical services. These professionals include nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, computer professionals, transcriptionists and certified coders. As CMS encourages adoption of electronic medical records and other types of health information technology systems, practices must often hire staff capable of installing and operating them. MGMA urges CMS to measure accurately all physician group practice costs incurred to care for patients.

Definition of "Physician Services"

MGMA believes CMS could have significantly reduced the cost of a long-term solution to the sustainable growth rate (SGR) formula by retroactively removing physician-administered drugs from physician expenditure targets in previous years thus budgeting more accurately for physician services. The statutory language of the Social Security Act that defines the payment update formula requires CMS to assess the allowed and actual expenditures of the Medicare program. MGMA maintains that the definition CMS uses for "physician services" in the SGR formula is inappropriate because it includes the cost of physician-administered outpatient prescription drugs.

A significant factor in the growth of Medicare expenditures has been the program's coverage of costly new prescription drugs administered in the physician's office. Since the SGR base year, spending for physician-administered drugs has more than doubled. These expenses reflect the acquisition of products rather than services rendered by a medical professional; therefore, they differ from physician services. The inclusion of drugs in the definition of physician services is inaccurate and runs counter to CMS' stated goal of paying appropriately for drugs and physician services. MGMA asserts that the definition of physician services, as required by the statute, does not include the cost of prescription drugs. Congressional leaders have repeatedly urged the agency to retroactively remove increases in Medicare spending attributable to physician-administered drugs when calculating the SGR.

CMS adopted a separate definition of physician services that clearly distinguishes physician-administered outpatient prescription drugs from services rendered by physicians in the Dec. 12, 2002, "Inherent Reasonableness" rule (67 FR 76684). The definition of physician services must be applied consistently for fair and equitable administration of the Medicare program. Furthermore, the recently proposed rule to reform the payment system for physician-administered prescription drugs established a separate venue to address the use and costs of drugs.

Because CMS lumps together the costs of provider services with Medicare Part B drugs, a wider gap between SGR targets and actual provider spending occurs. This limits the reimbursements that physicians could receive. A revised definition of physician services that excludes drugs would more appropriately represent Medicare physician payment costs. MGMA strongly urges CMS to remove prescription drug expenditures from the definition of physician services used to calculate the physician payment update factor.

Full impact of law and regulation

CMS again disregarded multiple requests to classify new national coverage decisions (NCDs) as a change in law and regulation for SGR accounting purposes. The SGR calculation excludes the impact of administrative coverage decisions, even though those decisions have a great impact on patient demand for services as a statutory change. Unfortunately, the CMS proposal to continue funding new NCDs out of existing and limited Part B funds leads to more medical visits and generates additional tests and treatment. If CMS were to accept MGMA's recommendations, new NCD costs would not compete with limited Part B funds. MGMA believes CMS has the administrative authority to better account for the full impact of such changes to law and regulation, and vigorously urges CMS to assert this authority.

Sec. 101(d) – Physician Assistant and Quality Initiative (PAQI) Fund

The 2006 Tax Relief and Health Care Act (TRHCA), which created the Physician Assistance and Quality Initiative (PAQI) Fund, allocated $1.35 billion to this fund and gave the Secretary of Health and Human Services authority to spend it "for physician payment and quality improvement, which may include application of and adjustment to the update of the conversion factor..." MGMA and 85 other national provider associations, as well as MedPAC, strongly urged CMS to use the PAQI fund to decrease the 9.9 reduction to the conversion factor for 2008. Disregarding these recommendations, CMS proposes to allocate the PAQI fund toward bonus payments for the 2008 PQRI. MGMA urges CMS to reconsider this proposal and allocate this funding toward the conversion factor.

Practice Expense relative value unites (PE RVUs)

MGMA brings a particularly valuable perspective to this issue because we have collected practice expense data since 1955. Our data collection involves group practices which range in size from two to several hundred physicians. As such, we understand the magnitude and complexity of CMS' task. In addition, MGMA represents an equal proportion of primary and specialty care practices. Consequently, we are able to detach ourselves from the "outcome" and focus primarily on the "methodology" applied.

Methodology

MGMA supports CMS' decision to implement a bottom-up methodology as opposed to the previous *top-down* approach. While the results of both approaches depend on the quality of the medical practice expense data collected, MGMA believes the bottom-up approach has a greater likelihood of resulting in accurate values. History has shown that calculating practice expenses using a data based methodology is more accurate when compared to a method that uses estimates of actual inputs.

Data Source

As in previous comments, MGMA maintains its concern that the practice expenses methodology is based on the American Medical Association's (AMA) Socioeconomic Monitoring System (SMS) data, which is dated, and the Clinical Practice Expert Panel's (CPEP) data, which is extremely subjective. The SMS data used to calculate practice expenses is from 1995-1999. MGMA is aware of and supports the effort by the AMA to conduct a new survey in order to provide more up-to-date information for this calculation. Given the AMA's experience with surveys of this nature, MGMA is hopeful that the data collected will provide CMS with current and accurate information about the cost of practicing medicine in this country. MGMA appreciates CMS' support for this effort and looks forward to the inclusion of this data in future proposals.

Budget neutrality adjustor

MGMA believes that CMS should reconsider applying the budget neutrality adjustment factor to work RVUs. CMS does not provide an adequate rationale for shifting the budget neutrality adjustor to the work RVUs. In the past, CMS has made the same proposal, and the provider community responded negatively. By placing the budget neutrality factor on the work RVUs, the affect to specialties is varied because of the different levels of work involved. Constant variation in the work RVUs due to budget neutrality adjustments hinders the process of establishing work RVUs for new and revised services. MGMA recommends that CMS apply the budget neutrality adjustor to the conversion factor in order to make the calculations more equitable and understandable to the provider community. MGMA believes that applying the budget neutrality to the conversion factor will have less impact on other payers who use the Medicare Resource-Based Relative Value Scale (RBRVS) and be consistent with the notion of budget neutrality.

CMS is moving towards making pricing information for physicians, hospitals and other providers more transparent. MGMA recommends that CMS apply the principles of transparency to the Medicare policy that govern these prices. By applying the budget neutrality adjustment to the conversion factor, pricing information to the provider community will be more transparent. Transparency of the financial effect of these changes will enable physicians and policymakers to more easily understand the impact of the cuts. In order to achieve CMS' goal of transparency of pricing information, the budget neutrality adjustments should be made to the conversion factor.

Equipment usage assumption

CMS's equipment usage assumption is currently set at 50 percent. While CMS does not put forth a specific proposal, it has indicated that both MedPAC and the AMA RUC support increasing this percentage. MGMA requests that, if CMS changes the current assumption, that it do so based on empirical data that reflects actual usage, including variations based on categories of equipment, geographic considerations, and other appropriate factors.

Geographic practice cost indices (GPCIs)

As noted in our previous comments, MGMA remains opposed to CMS using inappropriate data sources to calculate the GPCIs. This includes the use of census data to calculate GPCI values. The very nature of the data render the values outdated by the time CMS is able to use the information. Additionally, although the statute mandates updating the GPCI values every three years, they are in essence updated only every 10 years since the census is collected once every decade. MGMA maintains that this is unacceptable. A separate source with more timely data must be identified to adhere to the three year update schedule that Congress intended. MGMA recommends that CMS work with other government agencies, including the

Bureau of Labor Statistics, and private organizations to identify alternative data sources. Alternatively, CMS should work with these groups to identify an appropriately indexed data source to meet the statutory requirements.

Of particular concern to MGMA is that employee wages used in the GPCI formula do not capture highly skilled professionals now considered essential for the delivery of medical services. These professionals include nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, computer professionals, transcriptionists and certified coders. While it remains true that the 2000 census definitions of certain medical professionals are more expansive than the 1990 definitions, limited improvements result for the updated GPCI values. The wages of several prominent professions continue to be excluded, including physician assistants, occupational and physical therapists, certified practice managers, information technology professionals, transcriptionists and certified coders. MGMA recommends that CMS revise the GPCIs to include these employees to ensure that the occupations used in the formula reflect the numerous categories of medical workers found in modern practices.

As in years past, the office rental indices used to calculate the practice expense GPCIs are based on the Department of Housing and Urban Development's (HUD) residential apartment rent data. While MGMA is sympathetic to the difficulty CMS has in identifying alternative sources for pricing medical office space, MGMA remains opposed to the use of residential and not commercial data for this purpose. Such use is inconsistent with the core objective of the Balanced Budget Act of 1997 to make Medicare payments resource based.

Professional liability insurance (PLI) RVUs

The law requires CMS to conduct a review every five years of the PLI RVUs in order to reveal marketplace changes in the physician community's ability to acquire PLI. There are approximately 600 technical services with assigned PLI RVU values that are not included in the review process; therefore, they have not been revised since their initial assignment. As a result of the lack of revision, these services have a technical component PLI RVU that is greater than the professional component PLI RVU. The RUC initially asked CMS to change the technical component PLI RVUs because if physicians have to pay the larger PLI premiums, there should be higher RVUs associated with the professional portions of these services.

MGMA would like to assist CMS in developing a resource-based methodology for the technical portion of the PLI RVUs. We believe that our research capabilities can help CMS collect data from a large pool of individuals.

Coding – reduction in the technical component for imaging services under the PFS to the outpatient department (OPD) payment amount

Sec. 5102 of the Deficit Reduction Act of 2005 reduces the technical component of imaging services under the physician fee schedule to the hospital OPD payment amount. Within the statutory language of § 5102, CMS has discretionary authority to define the procedures affected by the payment reduction and to either expand or reduce the application of the provision based on its interpretation of the statutory language. MGMA believes that CMS should use its discretionary authority to limit the application of this provision. To this end, MGMA opposes CMS's proposal to further expand the reach of this ill-conceived law to 6 ophthalmologic procedures. By expanding application of this provision, CMS is exacerbating the impact of this ill-advised law.

End-stage renal disease (ESRD) provisions

Hospital data used

MGMA remains concerned about the appropriateness of using acute care hospital wage index data in the calculation of the ESRD-Composite Payment Wage Rate Index. This index is used to determine payment to both hospital-based and independent ESRD facilities. The use of only hospital data in this calculation would indicate that wages in hospital-based and ambulatory facilities are the same or similar in nature; however, no such determination has been made. In fact, the costs for hospital-based facilities and ambulatory centers vary greatly. The ESRD-Composite Payment Wage Rate index needs to take into consideration wages paid in independent facilities, in addition to those paid in acute care hospital inpatient settings. MGMA urges CMS to locate an alternative data source that reflects information directly tied to ESRD facilities.

Use of Floor/Ceiling Values

CMS has, for the third year in a row, proposed reducing the wage index floor for the ESRD-Composite Payment Wage Rate Index. This decrease will penalize ESRD facilities that have already faced cuts from the transition to the average sales price drug reimbursement methodology. These cuts to facilities' reimbursement will make it even more difficult to recruit and retain qualified personnel in areas affected by the removal of this floor.

Independent diagnostic testing facility (IDTF) issues

Most MGMA members provide diagnostic and other ancillary services "in office" and not through independent facilities. However, some groups also participate in collaborative arrangements with hospitals or other practices, some of which may be licensed as IDTFs. Others may lease space or equipment, particularly mobile equipment, from or to an IDTF or from third party leasing companies that also serve IDTFs and hospitals. These arrangements are structured to comply with Medicare billing and self-referral requirements. We believe they avoid duplication of expensive equipment, while providing flexibility and expanding access to services at locations convenient to patients.

With respect to the many proposals in the physician fee schedule, MGMA has the following comments:

Of primary concern is CMS's proposal to prohibit IDTFs from sharing space, equipment or staff or to sublease its operations to another individual or organization. CMS's rationale for this proposal is that commingling "may allow an IDTF to circumvent Medicare enrollment and billing requirements." CMS does not state, however, how this sharing of space, equipment or staff interferes with carrier review of IDTF requirements. This clear expansion of the existing standards interferes with the flexibility noted above and will likely lead to more duplication of equipment and services. It would also be highly disruptive to arrangements entered into in good faith reliance on existing IDTF standards and Stark rules. MGMA recommends that CMS reconsider this proposal.

Second, MGMA objects to CMS's proposal to reverse its policy with respect to the effective date of IDTF CMS-855 enrollment applications. Under the proposal, the effective date of an IDTF's enrollment would be the later of 1) the date of filing an application that is eventually approved; 2) the date an IDTF begins providing services in a new location; or 3) the filling date of the Medicare enrollment application or the date that the Medicare fee-for-service contractor receives a signed provider enrollment application that it is able to process for approval. This represents a significant change from CMS's current policy, which allows IDTFs to bill for services rendered up to 27 months prior to enrolling in Medicare.

MGMA has engaged in an ongoing dialogue with CMS on issues relating to provider enrollment and appreciates CMS' willingness to engage with us on this issue. On multiple occasions, MGMA has brought concerns regarding existing delays and problems with the enrollment process to CMS's attention. We are concerned about using the date on which a "Medicare fee-for-service contractor receives a signed provider enrollment application that it is able to process for approval" as the date an IDTF receives billing privileges. While CMS carriers are required to prescreen enrollment applications for errors or omissions within 15 days after an application is filed, it is MGMA's understanding that this pre-screening requirement has not been implemented by all of the carriers. Instead, applications may not even be reviewed for a lengthy period of time after receipt by the Medicare carrier. MGMA is aware that CMS is working with Medicare carriers to decrease the length of processing time and appreciates the effort by CMS; however, the problems are not yet resolved. This requirement will only add additional pressures on an overburdened enrollment system.

In addition, we have also received complaints about the complicated and confusing nature of the Medicare enrollment application process, which has led to inadvertent application errors and carrier confusion regarding the completeness of an application, as well as lost materials and other difficulties. Any of these problems could result in an IDTF's enrollment being delayed and the IDTF being unable to bill for services provided during the enrollment period. MGMA has repeatedly requested that additional educational materials be made available to providers to address problems providers have encountered in the application process and reiterates that request here. The proposal indicates that CMS intends to penalize those IDTFs that have difficulty understanding the excessively complicated Medicare enrollment applications if they make errors on that application. Given the large number of applications CMS claims are submitted with errors, it is unfair to penalize providers for what would appear to be a problem with CMS' overall enrollment process.

This policy would also create unnecessary hardships for new IDTFs that need to secure a physical facility and the necessary personnel prior to submitting an enrollment application to CMS. Because supervising physicians are now limited to supervising three IDTFs, CMS's new policy will make it difficult for an IDTF to secure a supervising physician willing to commit to providing services at a facility before its Medicare enrollment is completed. While MGMA appreciates CMS's revision of its previous proposal on this issue, contained in the rescinded Transmittal 187, Change Request 5449, we urge that CMS maintain its current policy with respect to the effective date of enrollment.

Finally, while we applaud CMS's decision to delete the language of 42 C.F.R. § 410.33(b)(1) relating to the requirements of supervising physicians, MGMA reiterates its concerns that CMS is increasing the number of administrative burdens under the already burdensome regulatory scheme imposed on IDTFs and health care providers in general.

Competitive acquisition program (CAP)

MGMA applauds the apparent steps CMS has taken to increase provider participation in the CAP, though MGMA ultimately maintains that the CAP program remains administratively complex and burdensome. MGMA commends the proposal to allow CAP vendors to pay CAP participating physicians for administering a CAP drug without the physician first submitting an administration code to the CAP vendor. But by allowing the vendor authority to verify administration of the drug through a post-payment review process, the entire CAP program remains unappealing and onerous. Requiring the CAP physician to provide medical records to the CAP vendor within 30 days upon request and allowing the vendor to call the practice to verify the administration of the drug only adds to the administrative burden on the physician practice.

MGMA commends CMS for allowing practices recently enrolled in the CAP program to leave the program within 30 days if they demonstrate that their "good faith" efforts to participate led to financial hardship.

Immunoglobulin

MGMA approves of the CMS proposal to continue paying for pre-administration services associated with intravenous immune globulin (IVIG). Ensuring patient access to IVIG and fairly reimbursing providers for administration costs aligns with the agency's goals of accurately paying for appropriate services.

2008 Physician Quality Reporting Initiative (PQRI)

MGMA supports quality improvement activities that focus on patient care, outcomes, satisfaction and the cost-effective use of resources. In the proposed rule, CMS discusses the measurement development process and the need for "consensus organizations" to exhibit openness, balance of interest, due process and an appeals process. MGMA supports the CMS definition of "consensus" as "general agreement – not necessarily unanimity – and includes a process for attempting to resolve objections by interested parties." MGMA does support the proposed rule's discussion of the NQF and AQA roles. While the discussion in the proposed rule of consensus organizations appears valid, we remains concerned that the Physician Consortium for Performance Improvement (the Consortium) was not discussed. Since the Consortium represents over 100 national medical specialties and state medical societies as well as other key organizations, the Consortium certainly has an important role in the development of quality measures before NQF and AQA approval. MGMA urges CMS to clarify in the final rule the Consortium's role in the measure development process.

Physician self-referral (Stark) provisions

MGMA has a long-standing interest in CMS's regulation of group practices and, in particular, CMS's regulation of group practices through the Stark prohibition against physician self-referral. Since the Stark law was first proposed in Congress, prior to its passage in 1989, MGMA has been an active participant in the dialogue to craft a balanced statutory framework and fair and workable regulations. MGMA has two primary objectives. First, we seek to preserve the right of group practices to compete with hospitals and other providers and suppliers in the provision of ancillary services that are integral to the diagnosis and treatment of patients served by group practice physicians. Second, and closely related, we urge lawmakers and regulators to provide flexibility in structuring clinical and business relationships that enhance patient care while avoiding unnecessary duplication of services and facilities.

CMS's proposals to modify the Stark regulations jeopardize both of these objectives. In its attempt to root out fraud and abuse, the Stark proposals paint with too broad of a brush and, if implemented, will undermine legitimate relationships that health care providers have invested resources and energy to develop and that provide beneficial services to patients.

At the outset, we recognize that CMS has specific concerns with respect to the provision of designated health services (DHS) by outside contractors, specifically in arrangements that can be described as "pod" or "condo" labs. We applaud CMS for reconsidering many of its complex proposals from the 2007 Proposed Physician Fee Schedule that would have introduced a new level of micromanagement to an already nightmarishly complicated set of regulations. MGMA is still concerned, however, about the impact of CMS's 2008 proposals on group practices and the ability of providers to understand and implement these changes by Jan. 1, 2008.

In addition, MGMA was astonished that CMS chose to release – unofficially – its Stark III final regulations less than a week before final comments on this rulemaking are due. It is virtually impossible for MGMA and others in the provider community to adequately absorb the full impact Stark III changes will have on this rulemaking. We urge CMS to reopen the comment period on these provisions, permitting the affected regulated community to thoroughly respond to issues in Stark III that affect the proposals contained in the physician fee schedule.

"Under arrangements" contracts (42 C.F.R. § 411.351)

Under arrangements contracts serve an important role in the provision of health care in certain communities. CMS itself made clear that under arrangements contracts can be used "to obtain specialized health care services that [a provider] does not itself offer, and that are needed to supplement the range of services that the provider does offer its patients." 67 Fed. Reg. 49,982, 50,091 (Aug. 1, 2002). When a group practice is the under arrangements supplier to a hospital, it is generally because the services and equipment at issue are used by the group for its own ambulatory patients, while also being made available to patients requiring the same services in connection with an inpatient stay or a hospital outpatient visit. To the extent Medicare reimbursement and self-referral policies accommodate such arrangements, providers avoid the duplication of either highly expensive or highly specialized services or equipment. In addition, providers are able to share expensive equipment when separate purchase of such equipment by any one provider would not be feasible. Patients have greater access to needed health care services, particularly in smaller or more remote markets, and providers are able to allocate their resources to optimize available services. Under arrangements contracts allow medical groups to offer equipment and services that may otherwise only be available to providers with greater resources (like hospitals), which are generally more expensive to the Medicare program, or not at all.

The laws governing under arrangements contracts, found in the Social Security Act, the Stark regulations and CMS' manuals, provide detailed rules that both a hospital and an under arrangements contractor must meet. Whether through the indirect compensation exception, the personal services exception or another Stark exception, these arrangements are required to be at fair market value independent of the volume or value of referrals, to be set out in a written document that contains all of the services to be performed under the agreement and to be reasonable and necessary, among other requirements. Medical groups that structure under arrangements contracts with hospitals do so not in an attempt to circumvent the Stark law, but in an attempt to comply with its strict requirements. Any attempt to further regulate these arrangements runs the danger of prohibiting (or making unduly burdensome) arrangements that serve the important purposes outlined above.

MGMA believes that the current rules governing under arrangements contracts are sufficient to protect the integrity of the Medicare program and opposes CMS's proposal to include within the definition of an entity the person or entity that performs the DHS. This proposal would make it a prohibited referral for a physician to refer a patient to a hospital for DHS if the physician or an entity in which the physician has an ownership interest performs the DHS for the hospital through an under arrangements contract. Outside of a rural setting, no Stark exception would apply to permit these referrals.

Most disturbing about this proposal is that it does not protect services performed by medical group practices in their own facilities. Group practices often provide under arrangements services in their offices under the protections of an under arrangements contract. When a physician has a hospital patient (either inpatient or outpatient) who requires services that the hospital provides under arrangements with another provider, it is beneficial to all parties and improves the continuity of care when that patient receives such DHS services in his or her physician's office. Under CMS's proposed language, this type of arrangement would not be permitted.

In lieu of the current proposal, MGMA believes that better possibilities are available if CMS is determined to make changes to the under arrangements exception. MGMA recommends that CMS either revise the regulatory language of 42 C.F.R. § 411.355(b)(3) or simply change its interpretation of the existing statute and regulation to protect physicians providing DHS in their offices to group patients who also happen to be hospital patients at the time of service. MGMA maintains, as it has previously brought to CMS's attention, that physicians or group practices could provide services under arrangements with a hospital in their own offices under the in-office ancillary services exception. Sec. 1877(b)(2)(B) of the Social Security Act does not require that a group practice submit a bill to Medicare in order to meet the requirements of the in-office ancillary services exception. Rather, Sec. 1877(b)(2)(B) requires that services are billed by a physician, group, or wholly-owned subsidy under a billing number assigned to the group practice, among others. The language of 42 C.F.R. § 411.355(b)(3) mirrors this requirement. CMS currently interprets this requirement as requiring a physician or group to bill Medicare. CMS should allow a physician or group practice to meet the in-office ancillary services test when they bill a hospital for the services provided under arrangements and meet the other requirements of the in-office ancillary services exception (i.e., the site of service and supervision requirements). If an arrangement meets the in-office ancillary services exception in all respects except for the requirement to bill Medicare, it is virtually indistinguishable from the types of "in-office" services Congress clearly intended to protect, and it is unlikely to have the potential for Medicare program abuse. By fairly interpreting the statutory language, CMS would protect services provided under arrangements in the offices of group practices.

CMS also solicited comments on an alternative approach that would use the Stark law to limit under arrangements contracts between hospitals and other providers. The proposed alternative approach would require establishing a definition of an entity that derives a substantial proportion of its revenue from DHS. We believe CMS would have difficulty establishing a definition of "substantial proportion of its revenue" that would be fair in all circumstances. CMS is clearly concerned with certain arrangements that it feels abuse the Medicare system by promoting the unnecessary provision of DHS. Since the group practice definition includes built-in protections against abusive referrals, a better approach would be for CMS to focus its energies on entities that do not meet the definition of a group practice.

If CMS does finalize its current proposal, MGMA requests that CMS clarify, preferably in regulatory language but certainly in the commentary to the 2008 Final Physician Fee Schedule, that the new restriction will not impact the exception available for rural markets. It would indeed be an ironic result – and an unfortunate policy – if a physician's referral to a rural hospital were prohibited because of an under arrangements contract between the hospital and an entity in which the physician had an interest, when the same physician's referral directly to the same entity would be clearly protected. CMS should also make clear that the new provision will not apply to companies that merely lease equipment.

Burden of proof (42 C.F.R. § 411.353)

MGMA opposes CMS's proposed regulatory language that would place the burden of proof on providers when CMS denies payment for a claim it alleges was pursuant to a prohibited referral. At its basis, placing the burden of proof on providers is contrary to accepted notions of due process. Given the complexity of the Medicare system and the amount of resources required to appeal a claim denial, we urge CMS not to adopt this proposal.

Percentage-based compensation (42 C.F.R. § 411.354(d)(1))

MGMA objects to CMS's proposed changes to the percentage-based compensation on the principal that continually changing the scope of permissible arrangements is very disruptive to established, long-term arrangements. In order to comply with the Stark law requirements, providers and their medical groups enter into contracts. It is harmful to the stability of provider relationships to continually fear being out of

compliance with CMS's ever-changing requirements. In its commentary, CMS references potential abuse associated with percentage-based compensation for leases. Before making this change, MGMA requests that CMS provide a more detailed and reasoned analysis of its perceived abuses.

Unit-of-service (per-click) payments in space and equipment leases (42 C.F.R. § 411.357)

As stated above, MGMA objects to the continual tweaking of the regulatory text, which results in disruption and added expense for providers. As CMS states in its accompanying commentary, Sec. 1877(e)(1) of the Social Security Act and 42 C.F.R. § 411.357 already impose detailed requirements for space and equipment leases. Given that providers have entered into agreements based on these detailed requirements, MGMA requests that CMS not adopt this proposal.

Antimarkup provisions (42 C.F.R. § 414.50)

MGMA is concerned with CMS's proposal to expand the antimarkup provision, historically applied to the technical component (TC) of diagnostic tests performed by outside suppliers, to now cover the professional component (PC) as well. By extending the antimarkup law to purchased professional interpretations, CMS is requiring group practices to restructure many legitimate clinical relationships involving both part-time employees and independent contractors.

As a threshold issue, it is not clear that CMS has the authority to expand this provision to the PC of diagnostic tests. CMS's authority for the antimarkup provision is found in Sec. 1842(n) of the Social Security Act, which clearly states: "If a physician's bill or a request for payment or services billed by a physician includes a charge for a diagnostic test...," payment for the test should be the lower of the actual acquisition cost or the supplier's reasonable charge. CMS has codified its antimarkup requirements at 42 C.F.R. § 414.50. Both law and regulation currently cover the TC which falls under a coverage category separate and distinct from that under which Medicare pays for the PC, namely physician services.

Second, there are significant practical problems in trying to extend the antimarkup provision to professional interpretations where they are performed by part-time employees or independent contractors. Group practices currently use a variety of methods to compensate independent contractors and employees under terms negotiated by the contractor or employee and the group practice. Stark and anti-kickback law considerations generally require that compensation meet a fair market value test. Independent contractors are frequently paid based on time spent providing those services, as opposed to a per interpretation price. Alternatively, payment may be made at a fixed rate per month or year. Yet another model is a per service price reflecting a blended rate of different payer pricing, not just the Medicare allowable amount. Employees, including part-time employees, are often salaried. Consequently, there is no cost or charge per professional interpretation, and it would be impossible for a group practice to determine the unit price for purposes of the antimarkup requirement. All of these relationships would need to be restructured, at great cost and administrative burden to practices.

Third, the proposal would likely lead to unintended consequences. Because a per interpretation price is not the most efficient method of compensation for purchased professional services, practices would likely develop a two-tier or multi-tiered system of compensation. If a practice continues to pay the reading physician a salary, for example, for private and other non-Medicare payers but pays for services to Medicare patients on a per-read basis, the negotiated costs associated with non-Medicare payers (based on volume, etc.) could be lower than the Medicare per-procedure rate. While a tiered structure is the logical by-product of CMS's proposal, it raises questions about whether it is appropriate to charge Medicare more on a per procedure basis than other payers.

Fourth, by defining an outside supplier as anyone other than a full-time employee of the medical group that bills for the service, the rule would discourage perfectly legitimate part-time employment practices. MGMA doubts that CMS intended to include in this regulation employees working part-time for a single medical practice, including those working part-time because they are nearing retirement age, working mothers, those caring for aging parents or members of two-physician households that each work part-time to share other family obligations. Based on its commentary accompanying last year's fee schedule proposals, CMS is concerned with contractors in pod lab arrangements. By drafting the proposal in its current form, CMS has essentially placed a hurdle in front of group practices trying to accommodate the personal and professional needs of its employees. Given the shortage of qualified health care professionals in many different specialties, CMS should be making it easier, not harder, for professionals to stay in the profession of providing care.

Finally, CMS relies on the AMA/Specialty Society Relative Value Scale Update Committee (RUC) to make recommendations on the proper reimbursement amounts within the RBRVS. Taking into consideration a number of factors, the RBRVS system establishes a proper payment amount for professional services, including interpretation of diagnostic tests. Payment recommendations incorporate the costs to a practice that extend beyond the actual acquisition cost, including legitimate administrative costs such as billing, scheduling, transcription, patient records and similar costs. By limiting reimbursement to a practice's actual acquisition cost, CMS is ignoring the value of the RBRVS system to appropriately establish a proper payment amount for services.

Proposals without accompanying regulatory language

In-office ancillary services exception

CMS asks for comment on several questions related to the "in-office ancillary" exception, and makes certain assertions in connection with that exception as originally included in the statute and interpreted by CMS in existing regulations. This approach to rulemaking, which raises the specter of possible change without providing specific proposals, can only fuel the sense of uncertainty and instability that group practices have had about the Stark law from the outset – the sense that no aspect of the law is ever sufficiently firm to permit reliance on current interpretations in structuring long term business and clinical arrangements.

For group practices, the "in-office" exception is fundamental. Taken together with the law's definition of what constitutes a bona fide group practice, it is the in-office exception that permits groups to provide comprehensive services to their patients, to compete with hospitals and other ancillary service providers and to grow and evolve with changes in technology and therapy, many of which are accompanied by a continuing – and very healthy, in MGMA's opinion – migration of services from inpatient to ambulatory care settings. Without a workable and stable in-office exception, group practice growth and development would stagnate, and physicians practicing in groups would be placed at a serious disadvantage.

Some aspects of the commentary in this section of the preamble suggest a fundamental misunderstanding of the group practice model, the advantages it brings to patient care and the reasons physicians choose to practice in groups.

First, the preamble implies that at the time of the Stark law's enactment in 1989, the typical group practice might have had only a simple in-office clinical laboratory. This seriously misrepresents the reality then as well as now. Many single specialty group practices, and virtually all larger multi-specialty groups, have historically maintained a range of diagnostic and therapeutic services provided through group facilities, of which a clinical lab is only one example. Many diagnostic and therapeutic modalities were first developed in group practices.

Second, the discussion of groups offering physical therapy and occupational therapy and of bringing specialty services "in-house," suggests that once a group has referred patients out to independently practicing physical therapists and occupational therapists or to separate specialty practices, those outside practitioners have some continuing right to a permanent stream of referrals from the group. To suggest that changes in those referral patterns could be considered a possible "abuse" strikes MGMA as a very far-fetched interpretation of what Congress originally intended. Certainly, no health care provider has a "franchise" right to continued referrals from any other health care provider, and the Stark law should not be viewed as a means of encouraging what is fundamentally anti-competitive behavior.

The preamble discussion even suggests that the "migration of sophisticated and expensive imaging or other equipment to physician offices" is in and of itself a problem, possibly demanding a regulatory response. As noted above, some of these same technologies were first developed in group practices, and we are aware of no valid policy reason to give hospitals or free-standing diagnostic and therapy companies monopoly rights with respect to the provision of ancillary services based on artificial distinctions of price or technological sophistication. The "migration" CMS notes is simply a function of clinical services moving away from high cost hospital settings, and MGMA sees no reason policy makers should wish to prevent that migration.

Turning to the specific questions on which CMS has solicited comment, we offer these responses:

Limiting the "in-office" exception to certain low tech-services provided at the time of an office visit. MGMA strongly opposes any attempt to arbitrarily divide DHS into those that groups can provide and those they are prohibited from providing. The law's restriction on group provision of DME, and CMS's response to the unintended consequences of it in early rulemakings, amply illustrates the pitfalls of this approach. Instead of letting physicians and patients make choices based on clinical efficacy and patient convenience, the government would be making choices based on arbitrary distinctions of cost or technology, or worse, based on considerations of which diagnostic and therapy lobbies have the most legislative or regulatory "clout."

Similarly, MGMA strongly opposes any attempt to define the in-office exception around a single office visit. Congress appropriately legislated an "in-office" exception, not an "in-visit" or an "incident to" exception. (Even the "incident to" coverage category is not limited to services provided at the time of an initial physician visit.) Any attempt to define such limitations would inevitably produce arbitrary distinctions, micromanagement of clinical decision-making and inconvenience to patients forced to visit other providers for services related to the course of treatment their group practice physician is otherwise willing and able to provide.

Changes to the exception's "site of service" test. MGMA recognizes that some long distance attempts to qualify small amounts of office space as a group's "same building" or "centralized building" may stretch the original purpose of the "in-office" exception. The solution to that problem, however, should not be some arbitrary limitation on the size, number or location of group practice facilities. As groups grow and evolve, their facilities are constantly evolving to meet both clinical needs and patient convenience. MGMA would be pleased to comment on any specific proposal CMS promulgates that would address abusive arrangements without throwing the baby out with the bathwater.

Ancillary equipment owned by "nonspecialists." MGMA strongly opposes any change to the "in-office" exception that would restrict its applicability based on specialty distinctions. Except for the rare situations where CMS limits Medicare coverage of a particular service by specialty through a duly-promulgated national coverage determination, physician provision of both professional and ancillary services should be subject to licensure, and in some cases certificate of need laws at the state level and professional liability

considerations. Using the Stark law to exclude certain physician specialties from providing certain ancillary services, or granting exclusive franchises to certain specialties for certain services, would be inherently anti-competitive.

Other restrictions on ownership or investment. MGMA believes that the statute as originally enacted contains ample restrictions on physician ownership of ancillary service joint ventures. Absent legislation, MGMA sees no need for further rulemaking in this area.

Obstetrical malpractice insurance subsidies

MGMA applauds CMS in its efforts to make more accessible the Stark exception that allows hospitals and other entities to provide subsidies for obstetrical malpractice insurance in rural or underserved areas.

"Stands in the shoes"

MGMA is confused by this section of the preamble, which states that " (w)e propose to amend Sec. 411.354 (c) to provide...." yet no proposed change to the regulatory language was included in the NPRM. Looking strictly at the example given in the preamble (physician contracting with a medical foundation controlled by a hospital), we fail to see why it is not adequate to analyze physician referrals to the foundation clinic for DHS under the personal services exception, and physician referrals to the hospital for DHS under the definition of "indirect" compensation arrangements, and if applicable, under the corresponding exception for indirect compensation.

Based on CMS' stated reasons for considering a new "stand in the shoes" policy, and without any more illuminating specifics, it appears that CMS is concerned with complicated structures designed to circumvent the law's prohibition on self-referral. If so, the statute includes a separate enforcement provision for circumvention "schemes." If, for some reason, CMS considers this authority inadequate, it should ask Congress to revisit the specifics of that provision.

Recalls and replacement devices

As the use of technology increases, so will the need to recall and/or replace medical devices implanted in Medicare beneficiaries. This will automatically necessitate additional physician visits, whether it is to replace the medical device or to monitor it. MGMA urges CMS to factor the cost for these additional visits into the SGR. Additionally, MGMA recommends that CMS work with the medical community to identify visits associated with these devices.

MGMA is also concerned regarding the liability questions that arise from these recalls and device replacements. Providers should not be held responsible for notifying patients or failing to notify patients of these recalls. These questions of liability hold the potential to increase professional liability insurance if providers are held responsible for alerting patients to these recalls. Instead, it should be the responsibility of the device manufacturers. If the responsibility for recall notification is placed on providers, future increases in professional liability insurance will need to be factored into the Medicare payment calculation. MGMA asks that CMS consider these costs into its analysis of the situation.

Proposed elimination of exemption for computer generated facsimiles

MGMA is strongly supportive of electronic prescribing and other health information technology (HIT). We believe utilization of electronic prescribing will improve clinical care and reduce administrative costs. The challenge for medical groups, however, continues to be how best to adopt this technology in the most cost-effective manner.

In this proposed rule, CMS is proposing to eliminate the exemption for computer-generated facsimiles to adhere to the NCPDP SCRIPT standard. While we are supportive of the elimination of the exemption for computer-generated facsimiles, we urge caution in moving too quickly to mandate use of the SCRIPT standard. Recent history has shown that the health industry in general, and providers specifically, have struggled to meet HIT-related compliance dates.

The HHS mandate that all covered entities (including medical groups) comply with numerous regulations as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Medicare Prescription Drug, Improvement and Modernization Act of 2003, including electronic prescribing standards, has resulted in significant cost and considerable disruption to the health care system. In order to comply with most HIT and administrative simplification regulations, medical groups are forced to rely on non-covered entities for compliance – software vendors. Many medical groups have experienced difficulties in upgrading their practice management and clinical systems to comply with federal HIPAA regulations. Upgrades in many cases have been expensive, and in some cases, vendors refuse to upgrade older versions of their products, thus forcing practices to purchase new, and very expensive, software.

In the electronic prescribing realm, a large number of smaller practices in particular rely on computer-generated facsimiles to send prescriptions to pharmacies, although some do not currently use the SCRIPT standard. While we agree that full implementation of the SCRIPT standard will result in an increased level of administrative simplification, the benefits of sending a computer-generated facsimile, even for those that do not utilize the SCRIPT standard, are well documented. Medical errors caused by illegible handwritten prescriptions are eliminated; faster processing of prescriptions occurs at the pharmacy; and record keeping at both the medical group and pharmacy locations is improved. Many of these benefits are reduced or lost when paper prescriptions are utilized. We are concerned that if medical groups are unable to get their software upgraded to the SCRIPT standard by the proposed January 2009 deadline, they may revert to paper prescriptions.

The following recommendations may offer an approach that meets the government's desire to move the industry toward full adoption of the SCRIPT standard, yet takes into account the realities of medical groups and others relying on non-covered entities to comply with the standard.

- **Increase the level of CMS provider educational activities.** CMS should augment its current level of educational outreach on HIT, and electronic prescribing specifically. This outreach should focus on the steps to take to implement and achieve a return on investment from utilization of the SCRIPT standard. This outreach should: 1) target small and medium sized physician practices; 2) target rural providers, community health centers, and other "at-risk" organizations; 3) expand the current very successful face-to-face and conference call activities; and 4) coordinate closer with industry to ensure that a unified message is communicated.

- **Increase the level of CMS vendor educational activities.** As the industry found with the 4010 transactions and the national provider identifier, providers and others must rely on non-covered entities to come into compliance. CMS should work more closely with the vendor community to ensure that they understand the regulation and what the government expects of their covered-entity customers. CMS should partner with industry organizations such as MGMA, other provider organizations, the Workgroup for Electronic Data Interchange, and other industry groups to conduct face-to-face vendor forums across the country. CMS should offer vendors technical assistance to facilitate the development of appropriate products for all covered entities.

- **Conduct regular assessments of industry progress.** CMS, perhaps with the assistance of the National Committee on Vital and Health Statistics, the Agency for Healthcare Research and Quality, MGMA or other government agency or industry organization, should survey the industry on a regular basis after the final rule is effective. These regular surveys should not only include all provider types and pharmacies, but also the vendors themselves. Ascertaining the number of vendors that have updated their products and the number of medical groups and pharmacies that have adopted the standard will be critical to ensure that physicians do not revert to paper prescribing.

- **Extend the compliance date based on industry readiness.** CMS should extend the compliance date should industry surveys not show an appropriate level of migration to the SCRIPT standard. It is critical that medical groups and other have sufficient time to update their electronic prescribing systems and train clinical and administrative staff.

Overall, we are supportive of the proposal to eliminate the exemption for computer-generated facsimiles, but we strongly urge CMS to augment its educational activities, regularly assess the readiness level of the industry and extend the compliance date should the industry not be ready to adopt the SCRIPT standard by the proposed date of one year after the effective date of the CY 2008 PFS final rule. We believe that it would be more advantageous to extend the compliance date than to penalize practitioners and potential adversely impact patient safety by forcing physicians to revert paper prescriptions.

MGMA appreciates your consideration of these comments and looks forward to collaborating to educate medical group practices on the numerous Medicare program changes. If you have any questions, please contact Lisa P. Goldstein in the Government Affairs Department at (202) 293-3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and Chief Executive Officer

Submitter : **Dr. Dan Ellis** **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. carl borromeo** **Date: 08/31/2007**

Organization : **Dr. carl borromeo**

Category : **Physician**

Issue Areas/Comments

Medicare Economic Index (MEI)

Medicare Economic Index (MEI)

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Sincerely,

Carl J. Borromeo MD

Submitter : **Dr. Jasper Rizzo** **Date: 08/31/2007**

Organization : **SWFUA**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Physician Self-Referral Provisions

CMS-1385-P-14954-Attach-1.DOC

#14954

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,

Jasper J. Rizzo, D.O.

Submitter : **Dr. Aaron Brown** **Date: 08/31/2007**

Organization : **Dr. Aaron Brown**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: File Code CMS-1385-P
Medicare Program; Proposed Revisions to Payment Policies Under the Physician
Fee Schedule and Other Part B Payment Policies for CY2008
Dear Mr. Kuhn:
I appreciate the opportunity to comment on one of the issues included in the Proposed Rule referenced above.
Anesthesia Coding (Part of 5-Year Review):
I commend the Centers for Medicare and
Medicaid Services (CMS) for recognizing the undervaluation of anesthesia work. I urge CMS to increase the value of the work component of anesthesia services by 32% as proposed in the July 12, 2007 Federal Register (Vol 72, No 133, pp 38148-38149).
Since the implementation of the Resouree Based Relative Value System (RBRVS) in 1992, The American Society of Anesthesiologists (ASA) has consistently argued that the conversion factor used by CMS has undervalued anesthesia care. A 2005 ASA survey of 267 anesthesia groups showed that the median conversion factor used by private payers was $50 per unit. In contrast, the 2005 Medicare conversion factor was $17.76 35.5% of private. This gap has grown in the last two years. A 2007 ASA survey of 284 anesthesia groups showed that the median private payer conversion factor is $55 per unit, while the 2007 Medicare conversion factor fell to $16.19 a mere 29.4% of private. Meanwhile, Medicare's rates for medical/surgical procedures paid under the RBRVS methodology are typically equal to about 80% of private payer rates.
ASA has brought the problem of anesthesia work undervaluation to all three Five Year Reviews conducted since the RBRVS system was adopted. At the conclusion of the third Five-Year Review, the RUC unanimously agreed that anesthesia work is undervalued and recommended that CMS increase Medicare's anesthesia conversion factor to rectify this situation. We are both relieved and pleased that the Agency has recognized this undervaluation and intends to address this inequity in the 2008 Physician Fee Schedule effective January 1, 2008. Physicians still face many challenges to reasonable and adequate payment, some relevant to all of medicine and others specific to anesthesiologists; however, this update will help defray some of the costs associated with providing the expert anesthesiology medical care our nation's seniors deserve.
In preparing for the 2005 Five Year Review, the ASA considered the 2000 Five Year Review. The RUC's Anesthesia Workgroup divided an anesthesia service into five subparts:
' Pre-service work
' Equipment/Drug/Supply preparation
' Induction period procedures
' Post-induction period procedures
' Post-procedure work.

ASA determined that the RUC's 2000 Workgroup did a rather accurate job in valuing the anesthesia work involved in all the above subparts except for the post-induction procedure period. To address this subpart, the ASA developed a linear regression model which posited that the higher the base unit value, the greater the work of the pre- and post-procedures periods and the greater the intensity of the work during reportable anesthesia time. The ASA and the RUC agreed that the intensity of the post-induction period should range from that assigned to the values the RUC recommended for second provider moderate sedation up to that assigned to a critical care service. Ultimately the RUC Workgroup used the ASA model to value the post-induction period and created a building block approach to determine the values for the other subparts. This approach demonstrated that the work element of an anesthesia service is undervalued by 32%.
Again, I urge CMS to increase the value of the work component of anesthesia services by 32% as proposed in the July 12, 2007 Federal Register (Vol 72, No 133, pp 38148-38149).

Sincerely,
Aaron C. Brown, M.D.

Submitter : **Mrs. Betsy Hasko** **Date: 08/31/2007**

Organization : **Williamsport Area Ambulance Service Cooperative**

Category : **Other Health Care Provider**

Issue Areas/Comments

Beneficiary Signature

Beneficiary Signature

August 29, 2007

Department of Health and Human Services
Centers for Medicare & Medicaid Services

REF: File code CMS -1385-P

After careful review of the proposed revisions to the payment policies of ambulance services under the ambulance fee schedule for CY 2008 the administrative staff of Susquehanna Regional EMS has issues relating to the documentation requirements that are being proposed.

During an emergency situation the ambulance crew s primary concern is for the immediate evaluation and treatment of the patient. You state you are sympathetic to the difficulty of receiving patient signatures during these situations. But to require additional documentation to be produced by the ambulance crew and the receiving facility after the fact is extremely difficult or impossible.

For the ambulance crew and/or the billing personnel to try and retrieve this same specific documentation from the receiving agency will be virtually impossible. The additional time required to get this documentation would be immense. We strongly support the continuation of the current processes for getting signature and the use of the existing form.

Thank you.

Betsy D. Hasko
Coordinator, WAASC

Submitter : Mr. Robert Gray **Date:** 08/31/2007

Organization : Cleveland Clinic Sports Health

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Hello, My name is Robert S. Gray, MS, ATC/L. Presently, I am the Coordinator of Athletic Training Community Affairs and Clinical Rehabilitation Manager on Main Campus for Cleveland Clinic Sports Health. I have been employed at the Cleveland Clinic for the past 16 years in the Sports Medicine / Sports Health section. I hold a Master's Degree in Education with a Specialization in Athletic Trainng from Indiana State University in Terre Haute, Indiana. Along with my Master's Degree, I have been a certified athletic trainer through the NATABOC (National Athletic Trainers Association Board of Certification) and a licened athletic trainer through the Ohio Physical Therapy, Occupational Therapy, and Athletic Trainers Board since 1991. Currently, Cleveland Clinic Sports Health employs approximately 40 certified and licensed athletic trainers who provide quality care to all of our patients, either in the out-patient setting or in the high school or collegiate setting.

Submitter : **Dr. Tammy Norwood** **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. Dermot More-O'Ferrall **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14959-Attach-1.DOC

#14959

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

Kerry Weems
Centers for Medicare & Medicaid Services
Department of HHS
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.**

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

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

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

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

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,

Dermot More-O'Ferrall, MD
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Ms. Denise Garris** **Date: 08/31/2007**

Organization : **American College of Cardiology**

Category : **Physician**

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

See Attachment

CMS-1385-P-14960-Attach-1.PDF

CMS-1385-P-14960-Attach-2.PDF

14960

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W. Douglas Weaver, M.D., F.A.C.C.
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Michael J. Wolk, M.D., M.A.C.C.
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William A. Zoghbi, M.D., F.A.C.C.

**ex officio*

Chief Executive Officer
John C. Lewin, M.D.

August 2, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C5-01-14
Room 313 HHH
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Deputy Administrator Kuhn:

The American College of Cardiology (ACC) is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC has reviewed the notice of proposed rulemaking 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)** web posted on July 2, 2007. Our goal in reviewing proposed Medicare policy changes is determine whether those that affect cardiovascular specialists and their patients are rational and consistent with methods that have been established over the past 15 years. The College believes that rational and fair physician payment policies are essential if CMS is to retain credibility with providers and the public.

This letter will focus on CMS's proposal to bundle CPT 93325 into other echocardiography procedures. We will address other provisions of the NPRM in a separate letter.

CODING--ADDITIONAL CODES FROM 5-YEAR REVIEW

CMS proposes to bundle CPT 93325 into all other CPT codes for echocardiography services codes76825, 76826,76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, 93350, asserting that color flow Doppler is "intrinsic" to all echocardiography procedures. The ACC strongly disagrees with the approach CMS has proposed and we urge that the proposal be retracted. In evaluating CMS's proposal we considered three primary issues:

- Is color flow Doppler intrinsic to all echocardiography services?
- Do the RVUs for the existing echocardiography codes (other than CPT 93325) account for the distinct physician work and practice expense associated with 93325?
- Can the already-scheduled changes to CPT codes for echocardiography address CMS's concerns?

Is color flow Doppler intrinsic to all echocardiography services?

The ACC does not agree with CMS' assertion that color flow Doppler is "intrinsic" to all echocardiography services. Historically, 1-dimensional echo (M-mode) was developed in the 1970's, 2-dimensional echo became common in the early 1980's, spectral Doppler (93320) grew in the late 1980's, and color flow Doppler (93325) became common in the early 1990's. Each new technology required new transducers and new equipment. Over time it has become common to perform routine 2-dimensional echocardiography (93307) with spectral Doppler (93320) and color flow Doppler (93325), but the Doppler services have not become an intrinsic part of any echo service. Every echo case does not require Doppler. In every echo case where Doppler is used, there is a conscious decision to adjust the imaging mode and acquire a different type of information with very different clinical implications. Examples of its use include the assessment of heart murmurs and the assessment of timing and magnitude of systolic and diastolic left ventricular contraction. Color Doppler is critical for differentiating mild degrees of valve regurgitation that do not require surgical intervention from more significant degrees of valve regurgitation that are treated by valve repair or replacement.

If, as CMS asserts, color flow Doppler is intrinsic to all echocardiography services, it would be reasonable to expect that it would be utilized uniformly across all echocardiography base procedures. The attached table, which shows 2005 Medicare claims data from the Medicare 5% sample file, demonstrates that there is significant variation in the use of color flow Doppler across the family of echocardiography codes. The data indicate that 95% of the Medicare claims for 93307 also include a claim for 93325 performed on the same day. In 2005, the 93307/93325 combination accounted for approximately 93% of all Medicare claims for 93325. Color flow Doppler is performed in conjunction with the remaining base echocardiography procedures 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93350 less frequently, ranging from 23% for 93317 to 68% of claims for 93312.

The claims data from the 5% sample file also show varying frequency of use of color flow Doppler with the codes for fetal echocardiography CPT codes 76825, 76826, 76827 and 76828 and echocardiography for congenital anomalies. It is critical to note, though, that Medicare claims data for these procedures are scant and do not form an adequate basis upon which conclude that color flow Doppler is an intrinsic part of any of these procedures.

Based on analysis of the data shown in the table the ACC believes that Medicare claims data do not support CMS's contention that color flow Doppler is intrinsic to all echocardiography services. *We therefore strongly urge CMS to maintain 93325 as a separately payable service for all other echocardiography codes in 2008.*

Do the RVUs for the existing echocardiography codes (other than CPT 93325) account for the distinct physician work and practice expense associated with 93325?

CMS's proposal to bundle 93325 into all other echocardiography procedures does not address the issue of compensation for the additional physician work and practice expense associated with performing color flow Doppler. When color flow Doppler is performed in conjunction with another echocardiography service, the sonographer must spend additional time to acquire the color flow images and the physician must spend additional time and work to interpret and report on those images. The RVUs for CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315,

93317, 93350 do not include this physician work and practice expense. We have recommended that CMS not bundle 93325 into any other echo codes. However, if CMS decides to proceed with any part of its bundling proposal for 93325, we believe that RVUs for those codes should be adjusted to reflect the additional physician work and practice expense required to perform 93325.

Can the already-scheduled changes to CPT codes for echocardiography address CMS's concerns?

The ACC and the American Society of Echocardiography have been in communication with CMS and the RUC concerning appropriate action to take with respect to 93325 since the code was first addressed during the five year review in 2005. As a result of this ongoing dialogue and the ACC/ASE response to concerns expressed by both CMS and the RUC, separate reporting of 93325 will decline sharply beginning in 2009 even if CMS withdraws its bundling proposal. During its June 2007 meeting the AMA CPT Editorial Panel approved a proposal from the ACC and the American Society of Echocardiography for a new CPT code combining 93307, 93320, and 93325. The new code will be implemented in January 2009. As noted above, Medicare claims data show that 93325 is used most often in conjunction with 93307 and this combination accounts for more than 90% of all claims for 93325. Similarly, claims for CPT 93320 can also be expected to decline precipitously in 2009 because 94% of the claims for 93320 are submitted in conjunction with a claim for 93307.

The ACC and ASE will present physician work and practice expense recommendations for the new combined echocardiography code at the September 2007 meeting of the RUC. We believe that implementation of the new combined echocardiography code -- with RVUs reflecting the RUC's evaluation of the physician work and practice expense associated with the code-- will largely address CMS's concerns about separate reporting of 93325.

We urge CMS to defer any decisions about bundling of 93325 until the RUC has made its recommendations for the new echocardiography code.

The ACC is eager to work collaboratively with CMS to determine a rational and fair solution to concerns about utilization of 93325. We believe a face-to-face meeting between representatives of cardiology and key CMS staff would be helpful. ACC's Regulatory Affairs staff will contact CMS to try to arrange a meeting in the very near future.

As always, the ACC commends CMS for its willingness to work in partnership with the physician community to strengthen the Medicare program. Please feel free to contact Denise Garris, Associate Director, Coding and Reimbursement at 202-375-6496 or dgarris@acc.org with any questions.

Sincerely,

James T. Dove, M.D., F.A.C.C.
President

cc: Thomas Ryan, M.D., President, American Society of Echocardiography
James Blankenship, M.D., Chair, CV-RUC
Jack Lewin, M.D., Chief Executive Officer, American College of Cardiology
Robin Wiegerink, Executive Director, American Society of Echocardiography

Medicare 5% Sample LDS SAF Physician/Supplier File 2005.
All Claims Lines with the Indicated CPT Codes -- Crosstab Showing Add-on Codes Appearing With Base Codes

		Count of Claims With Add-on Codes					Percent of Base Code Claims Having Add-On Code				
Base Codes	All Claims	93320	93321	93325	92978	92979	93320	93321	93325	92978	92979
Total all claims	422,018	379,204	4,280	376,567	1,587	178					
No base code on claim	10,454	4,678	252	6,936	1,576	176					
76825	40	-	-	18	-	-	0%	0%	45%	0%	0%
76826	5	-	-	3	-	-	0%	0%	60%	0%	0%
76827	31	-	-	6	-	-	0%	0%	19%	0%	0%
76828	22	-	-	6	-	-	0%	0%	27%	0%	0%
93303	293	249		253	-	-	85%	0%	86%	0%	0%
93304	44		16	28	-	-	0%	36%	64%	0%	0%
93307	369,139	357,750	669	349,376	11		97%	0%	95%	0%	0%
93308	5,327	654	2,262	2,115	-	-	12%	42%	40%	0%	0%
93312	10,997	6,469	292	7,423	-	-	59%	3%	68%	0%	0%
93314	1,008	431	65	531	-	-	43%	6%	53%	0%	0%
93315	102	58		61	-	-	57%	0%	60%	0%	0%
93317	64	48	-	15	-	-	75%	0%	23%	0%	0%
93350	24,492	8,861	716	9,796	-	-	36%	3%	40%	0%	0%

Note: Totals reflect 5% sample data. Multiply by 20 to get estimated US totals. Data blanked if fewer than ten claims.

ReedSmith

Daniel A. Cody
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Email: dcody@reedsmith.com

Paul W. Pitts
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August 31, 2007

VIA ELECTRONIC MAIL AND OVERNIGHT COURIER

Ms. Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments to the Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Ms. Norwalk:

Reed Smith LLP is a global law firm representing virtually every type of entity operating in or related to the health care industry. This representation includes, among others: academic medical centers; device manufacturers; durable medical equipment suppliers; home health agencies; hospices; hospitals; pharmaceutical companies; physician groups; rehabilitation facilities; and skilled nursing facilities. On behalf of our clients, this letter provides comments and recommendations to the proposed changes to the Medicare Physician Fee Schedule for calendar year 2008 published in the Federal Register (72 Fed. Reg. 38,122) by the Centers for Medicare & Medicaid Services ("CMS") on July 12, 2007. We appreciate the opportunity to provide these comments and recommendations.

Our comments are focused on the "Physician Self-Referral Provisions" and limited to the proposal to change the definition of "entity" in the Stark law (42 C.F.R. § 411.351). Specifically, CMS proposes to make a significant change in the definition of "entity" which would severely proscribe so-called "under arrangements" that include referring physicians as owners. We are very concerned that the proposed rule will adversely impact the quality of certain services that are currently managed by entities having physician ownership. Similarly, the proposed rule will limit the ability of physicians to actively participate in the management and leadership of certain medical services offered by health care providers to their patients. The broadly worded definition of "entity" in the proposed rule will have unintended and far-reaching consequences, impacting entities and arrangements not previously subject to the Stark law.

Given these concerns, we urge CMS to: (1) withdraw the proposed change in the definition of "entity"; (2) reject the recommendation of the Medicare Payment Advisory Commission ("MedPAC") that the definition of physician ownership be expanded to include interests in "an entity that derives a substantial proportion of its revenue from a provider of designated health services"; and (3) study the prevalence and value of services furnished "under arrangements" with physician-owned entities. Alternatively, CMS should tailor its changes so as not to impose unnecessarily stringent requirements

Submitter : Ms. Jessica Van Handel **Date:** 08/31/2007

Organization : Institute for Athletic Medicine

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Jessica Van Handel and I am a certified athletic trainer practicing in the state of Minnesota. I currently work for both Fairview Clinic/Institute for Athletic Medicine and the Orthopaedic Sports Institute as an athletic trainer primarily for the high school population. I am also a teacher. I cover double coverage events all over the Twin Cities Metro area. Before this, I was a student at Minnesota State University, Mankato, where I received my Bachelor's Degree in Athletic training in 2003, and continued on to receive my teaching licensure in 2005. I am currently working to finish up my Master of Arts in Teaching. I was certified by the NATABOC in spring of 2003, and began working as the head athletic trainer at a small high school in southern Minnesota through the Orthopaedic and Fracture Clinic in Mankato. And although I am only practicing athletic training part time, it is still one of my top passions in life.

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,

Jessica Van Handel, ATC
IAM, Fairview & OSI, Therapy Partners, Inc.

CMS-1385-P-14962 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **Daniel Cody** **Date & Time:** **08/31/2007**

Organization : **Reed Smith LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14962-Attach-1.DOC

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August 31, 2007

VIA ELECTRONIC MAIL AND OVERNIGHT COURIER

Ms. Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments to the Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Ms. Norwalk:

Reed Smith LLP is a global law firm representing virtually every type of entity operating in or related to the health care industry. This representation includes, among others: academic medical centers; device manufacturers; durable medical equipment suppliers; home health agencies; hospices; hospitals; pharmaceutical companies; physician groups; rehabilitation facilities; and skilled nursing facilities. On behalf of our clients, this letter provides comments and recommendations to the proposed changes to the Medicare Physician Fee Schedule for calendar year 2008 published in the Federal Register (72 Fed. Reg. 38,122) by the Centers for Medicare & Medicaid Services ("CMS") on July 12, 2007. We appreciate the opportunity to provide these comments and recommendations.

Our comments are focused on the "Physician Self-Referral Provisions" and limited to the proposal to change the definition of "entity" in the Stark law (42 C.F.R. § 411.351). Specifically, CMS proposes to make a significant change in the definition of "entity" which would severely proscribe so-called "under arrangements" that include referring physicians as owners. We are very concerned that the proposed rule will adversely impact the quality of certain services that are currently managed by entities having physician ownership. Similarly, the proposed rule will limit the ability of physicians to actively participate in the management and leadership of certain medical services offered by health care providers to their patients. The broadly worded definition of "entity" in the proposed rule will have unintended and far-reaching consequences, impacting entities and arrangements not previously subject to the Stark law.

Given these concerns, we urge CMS to: (1) withdraw the proposed change in the definition of "entity"; (2) reject the recommendation of the Medicare Payment Advisory Commission ("MedPAC") that the definition of physician ownership be expanded to include interests in "an entity that derives a substantial proportion of its revenue from a provider of designated health services"; and (3) study the prevalence and value of services furnished "under arrangements" with physician-owned entities. Alternatively, CMS should tailor its changes so as not to impose unnecessarily stringent requirements

upon existing relationships nor implicate entities and arrangements properly excluded from the Stark law. Ultimately, the current structure of the Stark law adequately addresses "under arrangements" and before CMS undertakes such a dramatic change in policy, the agency must fully understand the nature of these relationships, the value of physician participation in certain ancillary services offered by health care providers, and more thoroughly study the likely consequences of the proposed rule.

I. PHYSICIAN SELF-REFERRAL PROVISIONS

A. The "Under Arrangements" Proposal

1. Current Law

The Social Security Act and its Medicare provisions permit health care providers – such as hospitals, rural primary care hospitals, skilled nursing facilities, home health agencies, and hospices – to furnish services to beneficiaries "under arrangements" with third party vendors. The vendor has a contractual relationship with the provider for delivery of the services, and the provider (but not the vendor) bills for the services. According to CMS, the purpose of services provided "under arrangements" is to provide a means for hospitals and other providers "to obtain specialized healthcare services that it does not itself offer, and that are needed to supplement the range of services that the provider does offer its patients." 67 Fed. Reg. 50,091 (Aug. 1, 2002).

Taking the example of a hospital, while the vendor furnishes the services "under arrangements" with the hospital, the hospital remains fully responsible for patient care. Indeed, the Medicare Conditions of Participation require the hospital's governing body to be responsible for services furnished to its patients "under arrangements," including that (1) the governing body ensure that the services performed under a contract are provided in a safe and effective manner, and (2) the hospital maintain a list of all contracted services, including the scope and nature of the services provided. See 42 C.F.R. § 482.12(e)(1)-(2). Even when a physician-owned vendor provides services "under arrangements" to a hospital, the hospital must offer the minimum of administrative responsibility and control regardless of whether the services are provided "under arrangements."

Currently, the Stark regulations treat any transaction where a health care provider purchases services from a vendor "under arrangements" as a compensation arrangement, rather than an ownership interest. See id. § 411.354(a)(3)(iv), (c); 66 Fed. Reg. 856, 942 (Jan. 4, 2001). Moreover, the definition of "entity" only includes the person or entity billing for the designated health services ("DHS") service. See id. § 411.351. This approach permits a provider to enter into a service agreement where the provider purchases a discrete service from a vendor owned in whole or in part by physicians. Importantly, however, these arrangements must comply with a Stark compensation arrangement exception, such as the personal services exception, equipment rental exception, fair market value ("FMV") exception, or exception for indirect compensation arrangements. Each of these narrowly-tailored exceptions includes specific protections against abuse, such as overutilization.

2. The Proposed Rule

As noted above, since the effective date of the Phase I regulations on January 4, 2002, CMS has defined "entity" as including only the person or entity that bills Medicare for DHS, but not the person or entity that performs the DHS (if that person or entity is not also billing Medicare). See 42 C.F.R. § 411.351. CMS now proposes to extend the definition of "entity" to include the person or entity: (1) performing the DHS; and (2) presenting a claim or causing a claim to be presented to Medicare. In the proposed rule, CMS expresses its concern that hospital outpatient services furnished "under arrangements" with a vendor owned by referring physicians creates a risk of overutilization. See 72 Fed. Reg. at 38,186. Further, CMS cites "leasing, staffing, and similar entities having physician

ownership" as raising concern. See id. at 38,187. CMS also states that there may be no legitimate reason for such an arrangement other than allowing a physician to make money on referrals, particularly where the services furnished by the joint venture were previously directly furnished by the hospital. See id. at 38,186. Finally, CMS expresses concern that the "under arrangements" services might be furnished in a less medically-intensive setting, but billed at higher outpatient hospital prospective payment system rates. See id.

While CMS believes that its proposal to change how "entity" is defined sufficiently addresses the agency's concern, CMS also request comments on a related recommendation by MedPAC to expand the definition of physician ownership. In its March 2005 Report to Congress, MedPAC recommended changes to prohibit referrals by a physician who has an ownership in an entity "that derives a substantial proportion of its revenues from a [DHS] provider." As such, CMS now requests comments regarding whether to "implement the MedPAC approach, either in some combination with our proposed approach or instead of our proposed approach" and "what should constitute a 'substantial' proportion of revenue derived from providing DHS." Id. at 38,187.

B. Comments to "Under Arrangements" Proposal

1. Current Law Provides Protection Against Abuse

The Stark regulations currently treat "under arrangements" as compensation and not ownership relationships. Nonetheless, "under arrangements" must comply with stringent Stark exceptions for compensation arrangements. These exceptions are designed to prevent abuse and overutilization, and to ensure that medical decision-making is not corrupted. Indeed, in its proposed rule, CMS provides no explanation why the rigorous requirements of the compensation exceptions to the referral prohibition (discussed below) do not provide adequate protection against abuse.

For example, the personal services exception requires that: (1) the arrangement be set out in writing and specify the services covered; (2) the arrangement cover all of the services furnished by the physician to the entity; (3) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purpose of the arrangement; (4) the term of each arrangement must be for at least one year; (5) the compensation must be set in advance, not exceeding FMV, and may not take into account the volume or value of referrals or any other business generated between the parties; and (6) the services do not involve the counseling or promotion of a business arrangement. See 42 C.F.R. § 411.357(d)(1)(i)-(vi).

As another example, the indirect compensation exception requires that: (1) the compensation received by the physician (or immediate family member) must be FMV for items and services actually provided, not taking into account the volume or value of referrals or other business generated by the referring physician for the DHS entity; (2) there is a signed, written agreement specifying the services covered; and (3) the arrangement must not violate the anti-kickback statute, or laws or regulations governing billing or claims submission. See id. § 411.357(p)(1)-(3).

2. The "Under Arrangements" Proposal Could Adversely Impact Properly Structured and Beneficial Management Arrangements

As noted above, the proposed rule would expand the definition of "entity" to include the person or entity (1) performing the DHS and (2) presenting or causing the submission of a Medicare claim. The revised, broadened definition of "entity," however, arguably could make properly structured and beneficial management arrangements "under arrangements" for purposes of the Stark law. Moreover, such management arrangements would be subject to unnecessarily stringent requirements for satisfaction of a Stark law exception.

For example, one type of service a hospital may obtain from an outside entity is management or consulting services. Companies specializing in management and consulting services, which are sometimes owned by physicians, contract with hospitals to manage the day-to-day operations of certain services offered by the hospital. Although the ultimate control and responsibility for the service (including billing for the service) is retained by the hospital, a physician-owned management company provides, among other things: (1) critical expertise in the discrete service area, (2) administrative efficiencies, and (3) involvement of physicians in the management and supervision of services.

Indeed, physician-owned management companies provide valuable services to hospitals beyond those provided by a hospital's medical staff. For example, physician-investors in management companies assist in controlling hospital costs by participating in supply utilization committee meetings. From a quality perspective, physician-investors assist in modifying and improving the hospital's clinical protocols by reviewing aberrant cases and communicating best practices to the medical staff. Similarly, physicians provide both new and existing staff members training in the latest treatments and clinical practices. Lastly, physician-investors are involved in decisions regarding the effectiveness and necessity of obtaining new technology. Under a management arrangement, physician-owned entities provide hospitals with unique knowledge and access to experienced clinicians.

As these management services do not include the actual performance of DHS, they are most appropriately viewed as not being "under arrangements." Even if they were deemed "under arrangements," under current law, the rigorous Stark compensation exceptions (e.g., indirect compensation exception) are still available to protect the arrangement. With the proposed rule, however, it is possible that the management company in such an arrangement could be viewed as an "entity" by either comprising part of the hospital's DHS or as having "caused a claim to be presented for Medicare benefits for the DHS." As such, the arrangement would need to comply with a more limited Stark ownership (rather than compensation) exception for protection.

It is unclear whether CMS intended the proposed rule to apply the unnecessary stringent Stark ownership exceptions to such arrangements when the compensation exceptions provide sufficient protection against abuse. Such an outcome could ultimately prohibit hospitals from obtaining beneficial management and consulting services from entities even partly-owned by physicians. The proposed rule could put these expert management services in jeopardy. As such, we urge CMS to: (1) withdraw the proposed change in the definition of entity; (2) specifically exclude entities not performing DHS from the definition of "entity;" or (3) otherwise tailor any changes to the Stark law so as not to impose unnecessarily stringent requirements upon these types of relationships.

3. The "Under Arrangements" Proposal Could Improperly Impact Entities and Arrangements Not Previously Subject to the Stark Law

Moreover, the expanded definition of "entity" in the proposed rule arguably could inappropriately impact entities and arrangements that never have been subject to the Stark law. Specifically, the expanded definition is so broad that entities not previously covered arguably could be subject to the Stark law merely because their goods or services comprise part of the DHS billed by the provider.

For example, orthopedic surgeons may have an ownership interest in a manufacturer of spinal implants. The manufacturer then sells its implants to the hospital where the surgeon performs his or her surgeries. Under the proposed rule, the manufacturer arguably could be considered an "entity" subject to the Stark law. Specifically, the proposed definition of "entity" would extend to an entity that "performs the DHS." As inpatient and outpatient hospital services are DHS, spinal implants could be viewed as being part of the DHS furnished to Medicare patients and billed by the hospital.

It is unclear whether CMS intended its proposed change to apply this broadly. Such an outcome could extend the Stark regulations to a large number of entities and arrangements not previously subject to law's prohibitions. As such, we urge CMS to: (1) withdraw the proposed change in the definition of "entity;" (2) specifically exclude entities not performing DHS from the definition of "entity;" or (3) otherwise tailor any changes to the Stark law so as not to implicate these relationships properly excluded from the Stark law.

4. MedPAC's "Substantial Proportion of Revenue" Test is Flawed

In addition to the recommendations above regarding the proposed rule, we note that MedPAC's "substantial proportion of revenue" test is similarly flawed. The MedPAC test is overbroad and would have unintended and far-reaching consequences. Specifically, the MedPAC proposal is not limited to entities performing, furnishing, or billing DHS. Instead, the MedPAC test would effectively prohibit physician ownership of entities providing any service to a provider of DHS, as long as the service resulted in revenue significant enough to trigger the test's application. Stated differently, any entity wholly or partially owned by physicians would be required to satisfy one of the stringent and limited Stark ownership exceptions for protection.

Such an expansive limitation fails to recognize the unique expertise physicians bring to a provider's clinical operations. Health care providers are complex organizations facing increasing competition in the numerous services they offer. Providers lacking innovative leadership in certain services must necessarily rely upon outside vendors, especially those having physician-owners. Accordingly, these vendors play an important role in bringing expertise, increasing quality of care, and improving cost-effectiveness. Indeed, physicians are uniquely able to merge clinical expertise with operational knowledge. As such, we urge CMS to reject MedPAC's "substantial portion of revenue" test.

5. CMS Has Provided No Data or Evidence to Substantiate its Concerns Regarding "Under Arrangements"

The proposed rule does not provide any substantiated reasons for treating "under arrangements" as ownership relationships. In the January 4, 2001 Phase I rule, the Health Care Financing Administration (now CMS) cited three specific reasons for treating "under arrangements" as compensation and not ownership relationships.

> First, given the sheer number of these arrangements, we think prohibiting these arrangements, would seriously disrupt patient care. Second, almost all these arrangements could be restructured to fit into a combination of the personal service arrangements and equipment lease exceptions (or fair market value exception), although this restructuring will in some cases be administratively burdensome. Third, we believe there is precedent in the statute for treating this situation solely as a compensation arrangement.

66 Fed. Reg. at 942.

We are aware of nothing occurring in the intervening years mitigating the stated reasons for treating "under arrangements" as compensation relationships. The number of these types of arrangements has not decreased and likely has increased. These arrangements have been and can be structured to satisfy applicable Stark compensation exceptions, thereby providing sufficient protection against abuse. Further, patient care would be disrupted by treating "under arrangements" relationships as ownership interests and requiring the reorganization of these relationships.

In the proposed rule, CMS offers no evidence to support its new concerns or even an indication of how the agency substantiated its concerns. Instead, CMS simply repeats general "concerns" and "beliefs:"

- "We continue to have concerns with services provided under arrangements."
- "We believe that the risk of overutilization...."
- "We have received anecdotal reports of hospital and physician joint ventures that provide hospital imaging services formerly provided by the hospital directly."
- "There appears to be no legitimate reason for these arranged for services."
- "We are also concerned that the services furnished under arrangements to a hospital are furnished in a less medically-intensive setting."
- "It appears that the use of these arrangements may be little more than a method to share hospital revenues."
- "We believe that more and more procedures are being performed as arranged for hospital services."

Ultimately, CMS is proposing a significant change in the manner in which hospitals obtain certain vital services to their patients without substantiating its concerns, beliefs, or anecdotal reports. A substantial change in policy, such as the proposed rule, should be supported with reasoned analysis of available evidence. If additional research or data has been collected to substantiate its concerns, CMS has not made that evidence available for public comment. The agency's concerns, beliefs, and anecdotal reports are insufficient to overcome the reasons first articulated for treating "under arrangements" as solely compensation relationships.

II. CONCLUSION

We urge CMS to: (1) withdraw the proposed change in the definition of entity; (2) specifically exclude entities not performing DHS from the definition of "entity;" or (3) otherwise narrowly tailor any changes to the Stark law so as not to impose unnecessarily stringent requirements or implicate relationships properly excluded from the Stark law. The proposed rule is a dramatic change in policy and will result in a major change in how certain services are delivered to patients. Ultimately, physician involvement in the management and operations of health care providers is a long-standing tradition in our health care system, and the proposed rule as currently structured would severely and adversely impact that tradition.

We also urge CMS to reject the recommendation of MedPAC that the definition of physician ownership be expanded to include interests in "an entity that derives a substantial proportion of its revenue from a provider of designated health services." MedPAC's recommendation is even more expansive than the proposed rule. Finally, we urge CMS to not adopt the proposed rule without further study of the prevalence and value of services furnished "under arrangements" with physician-owned entities.

We appreciate the opportunity to submit these comments and recommendations. We are available and would be pleased to discuss these issues further with CMS.

Sincerely,

Reed Smith LLP

DAC:PWP