Submitter : **Dr. Brian Broaddus** **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. Mark Mintz** **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-14964-Attach-1.DOC

14964

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,

Mark A. Mintz, M.D.

Submitter : Dr. Catherine 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)

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. Gregory Karnaze **Date:** 08/31/2007

Organization : Austin Radiological Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Comments regarding IDTFs and Physician Self-Referral Provisions.

CMS-1385-P-14967-Attach-1.PDF

14967

AUSTIN RADIOLOGICAL ASSOCIATION
Innovation • Excellence • Partnership

August 31, 2007

VIA ELECTRONIC SUBMISSION

Herb Kuhn
Deputy Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: CMS–1385–P

Dear Mr. Kuhn:

I am a physician member and President of Austin Radiological Association ("ARA"), a Texas professional association, comprised of seventy-two (72) radiologists that provide services in the central Texas area. On behalf of ARA, I am submitting comments with respect to the proposed Medicare Physician Fee Schedule ("MFPS") for 2008. While ARA supports some of the Centers for Medicare and Medicaid Services' ("CMS") proposed changes, the practical effect of a number of them would be detrimental to the provision of services to Medicare beneficiaries and would impose prohibitive costs upon providers. Set forth below are ARA's comments regarding some of the proposed changes we believe merit reconsideration and/or modification by CMS.

Proposed Changes to IDTF Rules

A. Sharing of Space, Equipment, and Staff

The new performance standard prohibiting IDTFs from sharing space, equipment, and staff would detrimentally affect numerous IDTF providers and radiology groups. While the prohibition on sharing space arguably may be justified, to not permit the IDTFs to share staff and portable equipment would impose an enormous financial and administrative burden on IDTFs.

Given the additional technologist credentialing requirements for IDTFs, hiring and retaining qualified technologists can be difficult. Therefore, in certain circumstances and certain areas of the country, there are not an adequate number of certain types of technologists to staff both hospitals (or other providers) and IDTFs without sharing these individuals. Implementing this prohibition would preclude many IDTFs or other providers from providing certain tests which will adversely impact Medicare beneficiaries. In addition, given the often prohibitive cost of medical equipment, in many cases, an IDTF will share certain portable equipment with a hospital or a physician group. Again, implementing this prohibition also would preclude many IDTFs from providing certain tests.

It appears that CMS could prevent the co-mingling of services by IDTFs with other providers during the time the IDTF is in operation by just prohibiting the sharing of space. Therefore, CMS should reconsider application of the new proposed change to the sharing of equipment and staff.

Additionally, radiology groups may also operate IDTFs, and these groups should be allowed to share technologists and lease portable equipment with each other since neither refer patients. This results in a more efficient use of technologists. If radiology groups and IDTFs must duplicate technologists, there often will be situations where technologists at one location have too much to do and the technologists at another location have very little to do. Not being able to efficiently share technologists drives up the cost of healthcare. ARA recommends that there be an exception created to allow IDTFs to share technologists with radiology groups or a related staffing company.

Since each IDTF site must have its own provider number, the proposed MFPS does not make it clear whether the prohibition on sharing staff extends to IDTFs owned by the same entity. This should be clarified by CMS to provide that the prohibition does not apply to IDTFs owned by the same entity as it would not make sense to prohibit an organization from utilizing its staff in the most efficient and cost-effective manner possible, which may include rotating staff among the organization's various facilities.

B. Subleasing

CMS' proposed new performance standard that provides that an IDTF may not sublease its operations to another entity should be clarified to expressly permit an IDTF to contract with a hospital to provide certain services "under arrangement" when the hospital cannot provide the services (e.g the hospital's equipment is inoperative or a specialized type of technology is unavailable, or in the case of a specialized hospital, such as a psychiatric hospital, the hospital does not have imaging or other diagnostic testing equipment to provide certain tests to its inpatients). CMS should consider establishing a limitation (such as no more than 30% of the IDTF's services could be provided under arrangement) to allow for these types of arrangements as it appears from the proposed changes that this type of arrangements would be prohibited.

C. Initial Enrollment Date

CMS is proposing a rule that states that Medicare will establish the initial enrollment date for an IDTF that would be the later of: 1) the date of filing of a Medicare enrollment application; or 2) the date an IDTF first started rendering services at its new practice location. CMS' proposed definition of "date of filing" is the date that the Medicare contractor receives a signed provider enrollment application that the contractor is able to process for approval. If the application is rejected or denied, the new date of filing would be established when the IDTF submits a new enrollment application that the contractor is then able to process for approval. Texas' Medicare fiscal intermediary, Trailblazer, is currently taking six (6) months or more to process enrollment applications. Consequently, an IDTF may be operational for several months without receiving Medicare payment and not learn for several more months that its application was accepted or denied. If denied, even for an insignificant item, all of the services previously provided cannot be billed. If passed, this change would in effect force an IDTF to limit services to Medicare and Medicaid beneficiaries until the IDTF's application is actually approved. CMS should revise its definition of "date of filing" to the date the application is received by the Medicare contractor.

D. Supervising Physician Requirements

CMS has proposed to amend the current requirement limiting the number of IDTF sites that can be supervised by one physician to three. While the actual text of the proposed rule does not specifically state to which type of physicians this limitation applies, the preamble to the proposed changes does clarify that the limitation is intended to apply to those physicians providing general supervision rather than direct

or personal supervision. We recommend that CMS clarify that this limitation only applies to the physicians providing general supervision.

However, if CMS' intent is to limit direct and personal supervision, such limitations should not apply to IDTFs in which radiology groups are owners. Most radiology groups rotate radiologists as needed to various sites and having to restrict those locations for each physician to only three sites places an unnecessary burden on the radiology group. We can understand a limitation on those physicians providing general supervision because they assume the overall direction and quality control of the tests performed as well as the training and qualification of the technologists and the proper maintenance and calibration of the equipment and supplies. However, those physicians providing direct and personal supervision do not. Please consider clarifying that this requirement relates only to general supervision.

E. Miscellaneous

In addition to the above, ARA asks that CMS reconsider its rules related to entities that do not have to enroll as an IDTF. Currently, an entity that is a radiology group or an entity that is owned by the radiology group and an entity that is **licensed** as a hospital are exempt from enrolling as an IDTF. The fact that one of the owners is a subsidiary or other related entity of a hospital or a radiology group and not owned directly by the licensed hospital entity or the radiology group itself should not be the determinative factor that requires IDTF enrollment.

ARA and a local hospital's affiliated entity own and operate three locations, which are required to enroll as IDTFs and adhere to the multitude of IDTF rules, just because the hospital entity owner does not hold the hospital license. The oversight and direct involvement by ARA radiologists is no different than if ARA exclusively owned and operated the sites. Therefore, it is recommended that CMS reconsider this directive on requiring the hospital licensed entity and the actual radiology group be the owner of entities that do not have to register as IDTFs and allow related entities of the hospital and radiology group to also own the imaging center.

Finally, CMS should be cognizant of the administrative and financial burden placed on IDTFs to comply with the IDTF reporting requirements. Currently, the three IDTFs mentioned above require a full-time clerical person and a part-time professional person to take care of all of the IDTF paperwork. We appreciate CMS' change so that much of the reporting no longer is required to be completed within 30 days of the change. However, requiring all technologist license and certification renewals to be continually updated is very time consuming. We would recommend that the IDTF be required to maintain these files for review or to produce all licenses and certificates upon request from CMS. This would greatly reduce the paperwork to the contractor and records that the contractor must maintain. The reporting requirements should be more streamlined in accordance with reporting requirements for other types of providers.

Proposed Changes to Anti-Markup Provision

A. Expanded for Professional Component and Reassigned Interpretations

We fully support CMS' position that one physician should not profit from another physician's professional services.

B. Full-time Employee Exemption

However, CMS' proposal to apply the "Anti-Markup Provision" to all technical and professional services performed by part-time employees and part-time or full-time independent contractors of a medical group is too broad. Radiology groups allow radiologists and technologists to elect to become a part-time employee after child birth, while they have small children, or when they want to reduce their work load prior to retirement. Radiologists and technologists also may want to provide services to a group practice as an independent contractor for a variety of lifestyle reasons. Surely, CMS does not want to prevent physicians or technologists from having that type of lifestyle flexibility. If this anti-markup provision were implemented to apply to all part-time employees and all independent contractors, radiology groups may no longer be able to offer these choices as the group will lose money on each diagnostic tests or interpretation provided in their groups when such tests are performed by part-time employees or independent contractors unless the related billing expenses, benefits, and other expenses related to the part-time employee or independent contractor will be permitted to be taken into consideration. Applying this rule to both the technical and professional components provided by a radiology group who utilizes part-time technologists would greatly increase health care costs and reduce the amount of services providers are able to provide Medicare patients.

While applying the provision to tests provided by part-time employees and independent contractors who are paid on a per-test basis may be administratively feasible, applying it to part-time employees or independent contractors who are paid by the hour or based on a per diem rate would not be administratively feasible. We are not even sure how CMS proposes to *not mark-up a part-time technologist* when that technologist's services are only a part of the technical component of a diagnostic test.

Further, application of the anti-markup provision to part-time employees and independent contractors should not apply to a radiology group that bills directly for the services since radiologists are exempt from Stark. The change in the rule is aimed at referring physicians, and since radiologists are not referring physicians, a radiology group practice should be exempt.

Conclusion

On behalf of ARA, I appreciate the opportunity to provide these comments on CMS' proposed changes set forth in the MFPS, and hope that they help CMS formulate the final rules.

Sincerely,

GC Karnaze M.D.

Gregory C. Karnaze, M.D.
President

Cc: Doyle Rabe (ARA)

Submitter : Dr. Yogendra Bharat **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14968-Attach-1.DOC

14968

ADVANCED PAIN MANAGEMENT

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

August 31, 2007

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

Re: CMS-1385-P

Dear Mr. Weems:

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

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

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

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

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***

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

Sincerely,

Sincerely,

Yogendra Bharat, MD
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Ms. Jeanne Thompson** **Date: 08/31/2007**

Organization : **Ms. Jeanne Thompson**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

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

RE: Physician Self-Referral Issues

Dear Mr. Weems,

I wish to comment on the July 12th proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the in-office ancillary services) exception.

I have been a physical therapist for nineteen years. During that time I have worked in for a hospital, two private physical therapy practices, a large chain physical therapy company and two separate physicians offices. I am now self-employed.

Each of these practices present there own set of ethical challenges. My comments today are to express those that I found working for or in a physician-owned physical therapy practice

Both physician-owned practices in which I worked were multi-physician practices. Most of the physicians were ethical in these practices. In the first practice there was one physician who was questionable in his referral pattern. He referred a large number of patients to therapy. I would only treat thos patients appropriate for physical therapy, but I could see that this could lead to abuse. I worked in this practice less than one year.

In the second practice in which I worked, one physician s referral pattern greatly changed once they opened their own physical therapy office. Prior to him owning a physical therapy practice, he was not known as a believer in physical therapy. When I was working at the practice he was one of the largest rerral sources. I know the phsicians did not inform patient that they were allowed to go to any provider nor did they inform them that the physical therapy practice was owned by the physicians. I did inform patients of these facts.

When I left this practice, after 1.25 years, I informed my patients of my resignation and transferred care of most of my patients to my colleagues. I did not encourage my patients to follow me, but a few of the patients I was treating at the time wanted to follow me to continue treatment. I requested the transfer from the treating physicians. Three of the physicians responded positively. Only the physician noted above did not allow his patients to leave his practice and continue treatment. I know that those patients did not continue with their treatment plan even though I did encourage them to continue with another therapist in that practice, once it was known that he would not allow them to leave.

I know in the area where I work there are many good choices for physical therapy. So it is not the availability of quality care that is necessitating the need for a physician to open or continue a physical therapy practice. I also know having worked in two physician-owned practices that communication cannot be used as the reason for having a physician-owed practice. Some physicians are open to communication and some are not even when you work in their practice. Communication by letter was still the primary way of communication with the physicians in that practice.

In conclusion, the physician-owned physical therapy practice does not provide for better care of patients and the tendency for abuse even by a small number of physicians can and should be avoided. I support the removal of physical therapy services from permitted services under the in-office ancillary exception.

Sincerely,

Jeanne L. Thompson, P.T.
Quality Physical Therapy, LLC

Submitter : Ms. Laura Saul Edwards **Date:** 08/31/2007

Organization : American Academy of Dermatology Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments letter on various issues covered by the NPRM.

CMS-1385-P-14970-Attach-1.DOC

CMS-1385-P-14970-Attach-2.PDF

American Academy of Dermatology and AAD Association

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1497C

August 31, 2007

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

DELIVERED BY MESSENGER

Attention: CMS-1385-P

RE: Medicare Program; PROPOSED Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2008

Dear Mr. Kuhn:

I am contacting you on behalf of the 15,000 members of the American Academy of Dermatology Association (AADA) to share our comments on the proposed rule for Medicare payment for physician services in 2008, as published in the *Federal Register* on July 12, 2007. Given the significant, adverse impact of this particular proposal on Medicare patients' access to virtually all medical and surgical dermatology services and upon the practice of dermatology in general, it is our sincere hope that CMS will take the Academy's concerns and recommendations to heart when issuing the final rule for implementing the CY2008 Medicare physician fee schedule.

The Sustainable Growth Rate (SGR) and the Medicare Economic Index (MEI)

Unless Congress takes action to halt yet another projected conversion factor cut resulting from the flawed SGR formula, physicians will face a 10% across-the-board reduction in payments next year. The cumulative impact of several years' worth of projected cuts coupled with short-term legislative fixes to avert them is steadily eroding the fiscal soundness and overall stability of the Medicare Part B program, and thereby puts physicians in an increasingly untenable situation. The Academy therefore strongly favors repeal of the SGR formula and replacing it with a new payment method that would accurately reflect changes in medical practice costs, such as a method based on the Medicare Economic Index (MEI).

The urgency underlying our request for a more equitable and accurate payment system cannot be overstated. If the SGR remains unchanged, then Medicare reimbursement for physician services will decline precipitously by nearly 40% over the next eight years. Yet during this same period medical practice costs as reflected by the MEI are projected to climb 20%. As millions more Americans become eligible for Medicare coverage, physicians are expected to furnish services while at the same time instituting new quality reporting and measurement requirements and meeting a growing array of compliance demands. The ability to do so is impacted in direct and indirect ways by the Medicare physician fee schedule. It should be no surprise to CMS that as physician reimbursement plummets, it is difficult for practices to comply with so many new demands, modernize practices with emerging technologies, and to see more patients, too.

For these reasons, we urge CMS to work with Congress and the physician community to repeal the SGR formula and replace it with a new formula based on the MEI. Furthermore, we urge CMS to update the MEI itself so it reflects current inputs and assumptions and not just those in place in 1973 when the index was established. Likewise, we urge CMS to reduce the proposed 1.5% MEI productivity adjustment applicable to physicians to 0.65%. This latter percentage is equivalent to the productivity adjustment proposed for all other Medicare providers next year and is also consistent with President Bush's recommendation on this matter. In addition, if CMS chose to exercise authority it already has to do so, the agency could improve the fairness of the system by retroactively removing the cost of drugs administered in physician offices from the Part B physician payment pool, thereby restoring billions of dollars that could be used to stabilize the program while promoting access to healthcare services for Medicare beneficiaries.

Impact – Budget Neutrality Adjustment

In this proposal, CMS plans to reduce all physician work relative value unit (RVU) values by -10.1% to -11.8% to achieve budget neutrality in the fee schedule. The majority of physician specialties opposes application of the budget neutrality adjuster to the work values, and has asked CMS to make this adjustment to the conversion factor. In fact, from 1998 to 2006, CMS applied the adjuster to the conversion factor. Unfortunately, CMS chose to apply the budget neutrality adjustment to work values in 2007 without providing sufficient rationale for doing so. For 2008, the Academy respectfully urges CMS to return to the well-established practice of applying any budget neutrality adjustment to the conversion factor, as supported by organized medicine.

Multiple Procedure Payment Reduction for Mohs Surgery

The proposed rule explicitly withdraws the Multiple Procedure Reduction Rule (MPRR) exemption for Mohs surgical procedures. This exemption for the Mohs Micrographic surgery codes was established in the 1992 Medicare Physician Fee Schedule and maintained by CMS within all subsequent fee schedules since 1992 (see Federal Register, Vol. 56, No. 227, Nov 25, 1991, page 59602). We believe that this CMS action will unduly impact not only those Medicare beneficiaries who have or will be diagnosed with skin cancer but also those surgical dermatologists who provide these services. We also believe that the proposal fails to articulate adequate justification for this action.

First, CMS states that "the CPT Editorial Panel removed the Mohs procedure from the -51 modifier list". This appears to be both irrelevant to the issue at hand and factually incorrect. That the removal of these codes from the exempt list is presented in a notice of proposed rulemaking (NPRM) is merely evidence that CMS recognizes that payment policy formulation responsibility lies within the agency and not CPT. Furthermore, we do not believe that the CPT Editorial Panel explicitly took this action as stated.

Second, the proposal focuses on the AMA/Specialty Society Relative Value Update Committee (RUC) by correctly noting that (1) the RUC valued each Mohs code carefully; (2) the RUC assumed each code is a separate procedure; and (3) the RUC did not consider efficiencies when the procedures are performed on the same day. However, the proposal then inexplicably relies on these very same statements to justify changing the existing and longstanding CMS policy. While these three factors are correct they do not justify the conclusion that the Mohs codes should suddenly now be subject to the Multiple Procedure Reduction Rule. For example, it is no surprise that the RUC dismissed the efficiencies issue since CMS has long recognized that there are no efficiencies inherent in these procedures when performed together. Therefore factors cited as the reason for removal from the exempt list are, in reality, the very same factors that CMS has previously considered and recognized to justify exemption. Simply stating the factors does not provide any insight into the reasoning why such a drastic change is being contemplated at this time. The proposal does not provide any explanation for this proposed change and certainly does not justify the reversal of a previously well considered and long standing CMS payment policy. CMS should therefore defer from making this change, and any proposal for change in the future should be based on a sound rationale and factual data.

CMS agreed at the time the Mohs procedures were introduced that these *"are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures....They will be*

paid separately with no multiple surgery reductions." This conclusion is still correct and applicable today.

We are also very fearful that this proposal will negatively impact Medicare beneficiaries' access to timely and quality care. Furthermore, application of the Multiple Procedure Reduction Rule is unlikely to generate significant cost savings and may paradoxically increase the cost of providing care to these patients, precisely for the reasons that CMS originally cited for granting the current exemption.

The fact that in this rule CMS appears to grant RUC policymaking authority is an interesting issue that must be addressed. First, let the Academy state here that we strongly support the RUC process and recognize the value it brings to the annual task of developing the Medicare physician fee schedule. As initially charged, the RUC has done an exceptional job over the years in expressing opinions regarding relative values for procedures. In doing this, the RUC defied the predictions of critics who claimed that reaching consensus and agreement would not be possible among the various stakeholders.

The RUC and CMS have also prevailed against the legal challenge that the RUC amounted to a Federal Advisory Committee. In defending against that particular allegation it was persuasive to the court that the RUC only provides opinions on relative values and that CMS retains the authority to make policy decisions. The RUC, it was noted, is independent and is only one source of CMS input on relative values. By contrast, all policy decisions affecting the Medicare physician fee schedule have undergone full development by CMS in the public notice and comment process. It does not appear that such an open and fair process has been followed with respect to the MPRR policy and Mohs surgery, as proposed in the NPRM by CMS. To have the RUC thus engaged in these policy formulations-- in a forum which is not open or accessible to the public, as is implied by this propsal--is unfair to the affected Medicare beneficiaries and threatens the RUC process. We disagree with using the RUC for this purpose. However, if CMS believes the RUC role should be expanded to the policy making sphere, it should be done in a direct manner by explicitly giving the RUC a public and well-articulated charge to take on this task.

In light of the concerns raised above, the Academy respectfully requests reconsideration of the proposed rule. We provide the above rationale in support of the Mohs procedure base codes, CPT 17311 and CPT 17313, as appropriately exempt from the Multiple Procedure Reduction Rule as are the other add-on Mohs codes. We therefore request continuation of the exemption from the MPRR.

TRHCA – Section 101(b) Physician Quality Reporting Initiative (PQRI)

We realize that the Tax Relief and Health Care Act of 2006 (TRHCA) places CMS in the awkward position of expanding the PQRI through the fee schedule rulemaking process although the PQRI pilot project is not yet completed, and the agency is therefore deprived of data on which to base any program expansions. This timeframe leaves no opportunity to evaluate the 2007 PQRI before moving forward with the 2008 PQRI. Because of this situation, we urge CMS to incorporate the provisions of the Voluntary Medicare Quality Reporting Act (S. 1591/H.R. 2749) into the rule for implementing the fee schedule rule next year. This legislation, which can be read by clicking on http://thomas.loc.gov, directs CMS to report the results of the PQRI 2007 to Congress before proceeding with an expansion of the program, to focus the development of measures only on identified gaps in care, and to ensure that any Medicare physicians' quality program is voluntary, among other things..

The Academy also believes that the proposal's requirement that measures for the 2008 PQRI program be developed through the use of a consensus-based process should be clarified to recognize the AMA Physician Consortium for Performance Improvement (PCPI) as the entity for the development of physician-level quality measures.

TRHCA – Section 101(d) Physician Assistance and Quality Initiative (PAQI)

The Academy very strongly supports using the $1.35 billion in the PAQI fund for reducing the impact of the 10% Medicare physician payment cut in 2008. The proposal to use these funds to reward quality reporting activities as part of the 2007 PQRI pilot project is inconsistent with congressional intent, as expressed in the Tax Relief and Health Care Act of 2006. We disagree that there are any legal or operational obstacles to applying the PAQI funds to offsetting the update cut. Furthermore, using these funds to offset the draconian 10% cut will provide tangible relieve for all Medicare physicians whereas only those physicians reporting to the PQRI would realized any benefit under the CMS proposal. Fairness and the looming cut demand that the entire $1.35 billion be applied towards reducing the payment cut.

Medicare Telehealth Services

The Academy appreciates CMS extending the opportunity to submit requests for added telehealth services to the Medicare program. Besides increasing access for patients, telemedicine may also reduce overall costs. The Academy believes teledermatology fits well into telehealth services category 1, for office and other outpatient visits and consultations. Dermatology patients who participate in telemedicine would otherwise likely receive treatment for their skin conditions from a non-dermatologist physician, the accuracy of the diagnoses rendered via telemedicine can be higher and diseases can

be treated effectively and at earlier stages than they would be if a patient waited until complications made a long trip to see a dermatologist imperative. Patients who are spared a long trip also benefit economically from such an arrangement because they do not bear the cost of missing work or traveling. Telemedicine moves information – not the patient.

While making treatment more effective for patients, telemedicine also helps to make optimal use of the short supply of dermatologists. While it will never replace the face to face patient visit, the Academy considers telemedicine a viable method of treatment and one important component of an overall plan to improve patient access to dermatology.

Currently, Medicare reimburses telemedicine for rural patients (defined as patients who live in non-metropolitan statistical areas) if it takes place in a live interactive ("two way") mode. The patient and physician communicate in real time but from different locations using video conferencing technology. Medicare reimbursement currently does not exist for store and forward consultations, which take place when patient pictures and information are forwarded by a referring physician to a dermatologist, who evaluates them and responds with a diagnosis and treatment plan. The AADA and the American Telemedicine Association have reviewed the effectiveness of live interactive telemedicine visits compared with store and forward and found both to be clinically equivalent to traditional face to face patient encounters. Store and forward is more convenient for both the patient and the two physicians, allowing for asynchronous communication that simplifies the amount of coordination required. Therefore, the AADA believes that dermatologic office visits conducted via live interactive or store and forward telemedicine should be covered under the Medicare program and we will actively pursue reimbursement.

Physician Self Referral Issues

Overall, the physician self-referral issue is complex enough that it warrants being extracted from this fee schedule rulemaking proposal and addressed separately. The Academy therefore urges CMS to address physician self-referral issues in a separate proposal.

Notwithstanding this request, we will address the anti-markup provision of this proposal in this comments letter. The Academy appreciates the opportunity to comment on the contemplated changes to reassignment and physician self-referral rules relating to diagnostic services (the anti-markup provisions). We believe that CMS' decision to focus on the billing of diagnostic tests of one physician or group where the diagnostic test is performed by someone other than a full-time employee is appropriate. In addition, CMS' approach of paying the lesser of the Medicare fee schedule amount, actual charges, or the charges of the physician performing the diagnostic interpretative test is reasonable. We believe that the proposal to expand the anti-markup provisions from the

current technical component to include and cover the professional interpretative component not only simplifies the billing of such services but also strengthens the anti-markup prohibition. We agree that the physician performing the interpretation should be the only entity billing for this professional service. We recognize that some of these proposed measures may be needed in response to perceived Medicare abuses and to discourage business arrangements that carry significant risks of fraud and waste through kickbacks, fee-splitting and mark-ups, reassignments, generation of unnecessary pathology lab tests, inappropriate referrals, and other dubious practices.

We are, however, concerned that the proposed changes contemplated by CMS regarding anti-markup provisions related to anatomic pathology laboratory services may prevent dermatologists from practicing their specialty and risk harming patient care. It appears that much of CMS' rationale regarding diagnostic services has been focused disproportionately on issues related to size and location of laboratories, and the unfair presumption that physicians (such as dermatologists and dermatopathologists who are trained and able to biopsy, diagnose, and treat their patients) should not be allowed to order diagnostic tests they also perform as part of their full scope of service. **The Academy wishes to emphasize a key point: dermatologists who order a diagnostic test, should be able to perform and bill for such a test.** CMS should consider the adverse impact such constraints can have on our specialty by denying dermatologists and their patients access to accurate and timely interpretation of skin biopsies, and the attendant risk of compromising patient safety and quality of care.

The Academy strongly encourages CMS to consider the negative implications such revisions would have by preventing patients from access to care and restricting dermatologists—the physician specialists treating the majority of melanoma patients—from exercising their choice of dermatopathologists. All dermatologists have training and experience in dermatopathology. Indeed, dermatopathology is an integral part of a dermatologist's professional training. Dermatologists receive intensive training in dermatology, which includes
dermatopathology and dermatologic surgery. With this background and knowledge, dermatologists are singularly qualified to diagnose and treat the wide variety of dermatologic conditions as well as benign and malignant skin tumors. Dermatologists perform many specialized diagnostic procedures and often purchase the technical component (slide preparation) in order to be able to perform their own in-house diagnostic interpretation and pathology report.

The Academy is concerned that the proposed rule may be misinterpreted and misapplied so as to prevent a dermatologist from being able to read their own slides. As many dermatologists choose to interpret their own dermatopathology, the Academy supports the right of dermatologists to be able to continue to perform their own dermatopathology diagnostic interpretation, including having the ability to purchase the technical component, in accordance with current Medicare regulations, from an outside

lab vendor in order to provide their own in-house professional diagnosis and render cost-effective quality patient care. We wish to remind CMS that the expertise of dermatopathologists is relatively cost-effective because as the foremost experts in reading and interpreting skin biopsy specimens, dermatopathologists are able to detect and properly diagnose skin biopsies the first time around. Moreover, the consultative communication that goes on between dermatologists and their trusted dermatopathologists is essential; without communication or trained eyes, the skin's subtle signs may confuse and mislead. Misdiagnosis leads not only to deficient care by forcing patients to undergo unnecessary procedures, but also increases the cost of care and the risk of a liability lawsuit. Conversely, an early and correct diagnosis allows a problem to be treated before it becomes more severe—and thus more costly to treat.

We consider dermatopathologic interpretation of biopsies an integral part of a dermatologist's ability to serve their patients. Many dermatologists prefer to refer skin biopsy specimens to specialized dermatopathology labs directed and staffed by dermatologists and/or pathologists with expertise in dermatopathology and immunopathology. Pathologists employed with national reference labs often lack this high level of training and expertise to accurately interpret skin biopsies. Accurate interpretation of skin biopsies requires an ability to recognize and record the details of the specimen, and to synthesize these findings with the clinical data available. Failure to interpret skin biopsies can mislead the clinician and interfere with appropriate medical or surgical therapy, potentially harming the patient.

The Academy wishes to remind CMS that changes contemplated in the anti-markup provision final rule, designed to address of pathology lab services, need to be simple, straightforward, and uncomplicated so as to lighten the regulatory burden, minimize the margin of error, and contain costs. To that end, we wish to emphasize the following points:

- Dermatologists should have the opportunity and the right to interpret their own specimens and be reimbursed appropriately for the professional component as part of their professional scope of services.

- According to current CMS purchased diagnostic test regulations, if the tissue is prepared by an outside lab, either the lab should bill Medicare directly for the technical component, or the dermatologist can submit the bill to Medicare for the ***lesser of either*** the net lab charge, actual physician billing charge, or the Medicare fee schedule amount. We believe that such a scenario offers straightforward guidance to allow a physician to follow the basic premise ***when performing a medical service, the physician should be reimbursed for that service—nothing more, nothing less.***

- We recommend a back-to-basics approach wherein one could not mark up a "purchased diagnostic test". Whether it is the technical component or the professional component, if there is ***no mark up allowed***, there would be no problem. Indeed, such a clear and uncomplicated guideline would allow dermatologists to read their own slides and be reimbursed appropriately for this service and dermatopathologists, who have full-service labs, to be reimbursed fairly and appropriately for their services and not be in jeopardy of participating in fee-splitting and mark-up arrangements.

We believe that the best patient care is given when dermatopathologists are focused on managing their lab and being responsible for various regulations in their lab, rather than running around and dividing their attention among different "pod" lab practices for purposes of marking up assigned pathology services. We believe that by removing the financial incentives for markups and eliminating the opportunity of profit for increased self-referrals, CMS can effectively addresses its concerns raised in the anti-markup proposed rules. Medicare patients can be assured improved quality of care if their physicians have access to expert opinions from specialists trained in the evaluation of skin biopsy specimens. By working together, we believe we can help ensure patient safety and quality of care.

Proposed Elimination of Exemption for Computer-Generated Facsimiles

As office-based physicians, dermatologists recognize electronic prescribing (e-prescribing) is as much a patient safety issue as it is a workflow issue. Indeed, the most apparent benefits for dermatologists using e-prescribing include: speedy point-to-point ordering, transmission and tracking from prescribing physician to dispensing pharmacies; reduced medication errors or duplication; increased accuracy and transparency of the transaction; improved legibility; efficiency gains in practice workflow and reduced administrative steps; as well as enhanced ability to share and coordinate patient care information. The Academy is concerned with the proposed elimination of the exemption for computer-generated faxes from the e-prescribing standards by January 2009. By doing so, CMS may be overlooking the need for greater implementation flexibility and operational scalability for the prescribing office-based specialists, including dermatologists.

The Academy believes that e-prescribing can be a means to improving patient safety and increasing efficiency in the delivery of quality care. While the Academy encourages dermatologists who are keen on adopting new health information management technologies to do so, we are concerned that another unfunded e-prescribing mandate—particularly in the face of CMS' 2008 proposal to cut Medicare physician payments—will be counterproductive. We are concerned that many dermatology practices may lack the software that permits them to transmit computer-generated faxes

using the e-prescribing SCRIPT standard. Moreover, complying with this rule could require the purchase of costly new products and staff retraining. The Academy urges CMS to assess regularly the readiness level of both physician practices and pharmacies and extend the compliance date if too few organizations adopt this standard prior to the proposed implementation date of Jan. 1, 2009. While we support efforts to move the healthcare industry steadily toward full adoption of the e-prescribing standard, we request that such efforts take into account the realities of small and medium office-based practices. Therefore, we encourage CMS to increase the level of educational activities targeted to office-based physicians. To achieve this, CMS should augment its current level of educational outreach on health information technology, and particularly e-prescribing. Such outreach should target small and medium sized office-based practices, with special focus on steps required to implement and achieve return on investment from use of the SCRIPT standard, and coordinate with industry to ensure communication of a unified and consistent message.

Furthermore, the Academy calls on CMS to increase the level of health information technology vendor educational activities. As the industry found with the recent National Provider Identifier experience, physicians and their practices must often rely on entities, not covered by Medicare provisions, to come into compliance with those provisions. CMS should work more closely with health IT vendors to ensure that they understand the regulation and what the government expects of their covered-entity customers. CMS should offer vendors technical assistance to facilitate the development of appropriate products for all covered entities. The Academy suggests that CMS conduct regular assessments of industry progress. CMS should survey the industry on a regular basis after the final Medicare rule takes effect. These regular polls should include all provider types, pharmacies and health IT vendors. Ascertaining the number of health IT 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.

Finally, we urge CMS to 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 small and medium office-based practices have sufficient time to update their electronic prescribing systems and train clinical and administrative staff.

While we understand CMS' objective to foster greater practice automation through the migration toward the e-prescribing SCRIPT standard, based on the proposal to eliminate the exemption for computer-generated facsimiles, we strongly urge CMS to augment its educational activities, regularly assess the readiness level of the industry and extend the SCRIPT standard compliance date should the industry not be ready to adopt it a year after the effective date of the 2008 physician-fee-schedule final rule. The

Academy believes that it would be better to extend the compliance date than penalize practitioners. Forcing physicians to revert to paper prescriptions might jeopardize patient safety. While the Academy is confident that e-prescribing can help advance safe, quality-based, efficient and affordable patient care, further consideration must be given to overcoming the above structural, operational and fiscal barriers that prevent e-prescribing from becoming a widespread standard practice.

Conclusion

Let me conclude by reiterating the Academy's appreciation for this opportunity to comment on the various Medicare fee schedule changes proposed by CMS. We are eager to work with the agency to address these serious concerns in a manner that promotes access to dermatology services for Medicare patients while promoting fairness for the physicians delivering those services. I encourage you to contact Laura Saul Edwards (at ledwards@aad.org or 202.712.2602) and Norma Border (at nborder@aad.org of 847.240.1814) on our staff to discuss our concerns and the ways we can resolve them in he final rule for implementing the 2008 fee schedule. Thank you.

Sincerely,

Brett M. Coldiron, MD, FAAD
Chair, Health Care Finance Committee

BMC/jeb/nb/wb/lse

Attachment

cc: Diane R. Baker, MD, FAAD, President
Mary E. Maloney, MD, FAAD, Secretary-Treasurer
C. William Hanke, MD, FAAD, President-Elect
Margaret E. Parsons, MD, FAAD, Chair, Council on Government Affairs, Health Policy, and Practice
Allan M. Wirtzer, MD, FAAD, Chair, Coding & Reimbursement Task Force
Darryl M. Bronson, MD, FAAD, Chair, Dermatopathology Task Force
Daniel M. Siegel, MD, FAAD, AAD Representative to the AMA RUC
Bruce A. Deitchman, MD, FAAD, AAD Alternate Representative to the AMA RUC
Dirk M. Elston, MD, FAAD, AAD Advisor to the AMA CPT Advisory Committee

James A. Zalla, MD, FAAD, AAD Representative to the AMA Correct Coding Initiative Committee
Ronald A. Henrichs, CAE, Executive Director & CEO
Karen Collishaw, Deputy Executive Director, AADA
Judit Magel, PhD, Senior Director, Practice Management, Science & Research
Laura Saul Edwards, Director, Federal Affairs
Norma Border, Senior Manager, Coding & Reimbursement
Jayna Bonfini, Assistant Director, Federal Affairs
William Brady, Manager, Practice Management

of the global fee for the second highest valued procedure, and at 25 percent of the global fee for each succeeding procedure. Each procedure after the fifth procedure will be paid by special report. Our medical consultants advise us that cases with more than five procedures should be extremely rare. We believe that the added documentation requirement along with physician comparative performance reports and our intra-operative computer edits will prevent abuse of the multiple surgery policy through excessive "unbundling".

For certain dermatology services, there are separate CPT codes for multiple surgical procedures (for example, CPT codes 11201, 17001, and 17002). For these procedures, the multiple procedure rules will not apply. Rather, we are presenting RVUs for these codes. For other dermatologic procedures, we believe a 50 percent reduction in the value is appropriate for the second procedure since pre- and post-work and practice expenses will be diminished. However, beyond the second procedure, since there may not be the same reductions in work effort that is associated with multiple surgery through the same incision, a physician may submit a "by report" bill when three or more lesions are removed.

[Mohs Micrographic Surgery]

Comment: Some commenters stated that Mohs micrographic surgery, CPT codes 17303 through 17310, should be exempt from the multiple surgery reductions. These are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures.

Response: We agree that these surgical procedures are contemplated to be separate staged procedures; they will be paid separately with no multiple surgery reductions.

[Multiple Surgery Policy for Multiple Trauma]

Comment: Some commenters expressed concern that the multiple surgery policy would result in inadequate payment when a number of different surgeons are operating on different body parts at the same time, such as in the case of a multiple trauma patient.

Response: These cases will not be subject to the multiple surgery policy. The multiple surgery policy will apply to multiple surgery done by the same surgeon on the same day. Each physician will be paid separately for his or her services.

c. *Bilateral surgery (CPT modifier 50).* The bilateral modifier is used to indicate cases in which a procedure was performed on both sides of the body. The CPT identifies surgical procedures that are typically bilateral in nature. For these codes, the bilateral modifier would not result in increased payment.

In the absence of any evidence with respect to the actual difference in work for bilateral procedures, we proposed to continue the historic practice of paying 150 percent of the global fee.

[Bilateral Surgery Code Applying to Ophthalmic Procedures]

Comment: The CPT code for bilateral surgery (CPT modifier 50) should not apply to ophthalmic procedures or to the extremities (hands, feet, knees) as it requires the same amount of work for each eye, foot, etc. This policy would merely encourage physicians to bring the patient in on two separate occasions and do each eye, foot, etc., separately.

Response: Harvard did not have data on the resources involved in miscellaneous bilateral surgery and surveyed very few procedures that were bilateral. Like the multiple surgery policy, the use of a bilateral modifier and payment by carriers at 150 percent of the global fee in bilateral cases is a long accepted practice. Until resource data are available, we plan to continue the 150 percent policy. While the actual intra-operative services may be the same for each eye or extremity, we believe the pre-operative and post-operative services are reduced.

d. *Providers furnishing less than the global fee package (CPT modifiers 54, 55, and 56).* Under the current reasonable charge policy, the sum of all allowances for all practitioners who furnished parts of the services included in a global fee (and who billed using one or more of these modifiers) must not exceed the total amount of the allowance that would have been paid to a single practitioner under the global fee for the procedure. We proposed to continue to pay the same amount for surgical services when they are furnished by several physicians as we would pay if only one physician furnished all of the services in the global package. However, we proposed to pay each physician directly for the services furnished to the beneficiary based on the RVUs of the component furnished.

[Physicians Other Than Surgeons Should be Paid Without Regard to Global Fee]

Comment: Commenters objected to the policy that the sum of payments to multiple physicians furnishing services within a global package (CPT modifiers 54, 55, and 56) may not exceed the value of the global fee for the procedure. They stated that since only the pre- and post-operative services of the surgeon were studied by Harvard in setting the global RVUs (not the services of other physicians such as cardiologists, internists, anesthesiologists, intensivists, or other physicians who may furnish this care), a physician other than the surgeon who furnish follow-up care should be paid without regard to the total global fee.

Response: We disagree. The concept of a global fee for a surgery for which the surgeon charges a single global fee and furnishes all usual and necessary services associated with a surgery and follow-up recovery is a long established concept. To ensure equitable payment under the fee schedule, it is necessary to establish a uniform national global package for each surgery. Since the surgeon usually can be expected to furnish the complete package of services, it is entirely appropriate that the value of the package be established on the basis of the value of the surgeon's services. When someone other than the surgeon furnishes services that the surgeon would normally furnish, he or she is merely substituting for the surgeon. The value of the package does not change.

However, there appears to be some misunderstanding concerning the services of other physicians—for example, a nephrologist, an infectious disease specialist for severe infection—furnishing services in addition to those normally furnished by the surgeon when a patient develops renal insufficiency. As discussed in the section of the proposed rule on global surgery, if the services of these other physicians are required in addition to the normal pre- and post-operative services of the surgeon, they will be paid outside of the global fee.

[Apportioning Payment for Post-Operative Care Furnished by Different Physicians]

Comment: A commenter suggested that, if normal post-operative care is furnished by more than one physician, the payment should not be apportioned according to the number of days in the portion of the 90-day period furnished by each physician since the number of visits and intensity of care required during different times in the period varies. The commenter stated that as an example, under the proposal in the proposed rule, a physician furnishing the first 30 days of post-operative care would receive 33 percent of the value of the care, while the physician furnishing the last 60 days of care would receive 66 percent. The commenter noted that, in

Submitter : Mr. Steven Wojcik **Date:** 08/31/2007

Organization : National Business Group on Health

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

14971

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. Carlos Rodriguez** **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 : **Randy Schmitz** **Date: 08/31/2007**

Organization : **University of North Carolina at Greensboro**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

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

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,

Randy Schmitz, PhD ATC

Submitter : **Miss. Danelle Dykstra** **Date: 08/31/2007**

Organization : **South Mountain Community College**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am an athletic trainer that has been working in the health care field for 3 years. I just recently graduated from a post professional athletic training program to enhance my education in athletic training. I currentyl work at South Mountain Community College, as an athletic trainer, bachelors and masters in athletic training, and BOC certified ATC.

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,

Danelle Dykstra, ATC

Submitter : **Dr. Omar Benitez** **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-14975-Attach-1.DOC

14975

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,

Omar Benitez, M.D.

Submitter : **Dr. Barbara Leighton** **Date: 08/31/2007**

Organization : **Washington University in Saint Louis**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-year Review)

Dear Ms. Norwalk:

I strongly support the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. Thank you for recognizing and addressing the fact that anesthesia services are severely undervalued.

Anesthesia work has been undervalued relative to the work of other physicians ever since the RBRVS was created. Now, the payment per unit ($16.19) does not cover the cost of caring for senior citizens. Anesthesia departments caring for large numbers of senior citizens have difficulty providing that care in the current financial climate.

The RUC recommends that CMS correct the 32% undervaluation of anesthesia services. This would result in an increase of the anesthesia conversion factor by almost $4.00 per unit. I strongly support the implementation of this recommendation.

Thank you for considering this important matter.

Sincerely,
Barbara L. Leighton MD
Professor of Anesthesiology
Washington University in Saint Louis

Submitter : **Mr. Jeff Jahnel** **Date: 08/31/2007**

Organization : **University of Tennessee at Chattanooga**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Jeff Jahnel I am a certified and licensed athletic trainer currently employed at the University of Tennessee at Chattanooga.

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

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

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

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

Sincerely,

Jeff Jahnel MS, ATC

Submitter : Mr. Andrew Lundgren **Date:** 08/31/2007

Organization : North Park University

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Andrew Lundgren and I am the Program Director of Athletic Training and Associate Professor at North Park University in Chicago. For the past 12 years I have taught at the institution preparing students to enter the profession of athletic training. Liek numerous other allied health professions, athletic training has undergone a significant educational reform to keep up with the changing landscape of 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 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,

Andrew Lundgren, ATC
Associate Professor
Athletic Training Program Director

Submitter : Mrs. Jill Schubert **Date:** 08/31/2007

Organization : Baldwin-Wallace College

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer formerly employed as a physician extender as well as a clinical athletic trainer contracted to two high schools. Currently I serve as both a faculty member and assistant athletic trainer at Baldwin-Wallace College within the accredited Athletic Training Education Program. One of my responsibilities in addition to teaching athletic training students in both the clinical and didactic setting is to also instruct a non-major athletic training class. I take that opportunity to educate students about what is required to become an athletic trainer as well as what skills an athletic trainer possesses among other things. Those students are always amazed to discover the educational content standards required of an accredited athletic training education program which include:

" Acute care of injury and illness
" Assessment of injury and illness
" Exercise physiology
" General medical conditions and disabilities
" Health care administration
" Human anatomy
" Human physiology
" Kinesiology/biomechanics
" Medical ethics and legal issues
" Nutritional aspects of injury and illness
" Pathology of injury and illness
" Pharmacology
" Professional development and responsibilities
" Psychosocial intervention and referral
" Risk management and injury/illness prevention
" Statistics and research design
" Strength training and reconditioning
" Therapeutic exercise and rehabilitative techniques
" Therapeutic modalities
" Weight management and body composition

In addition I typically hear a gasp of surprise when I announce that our students upon graduation are competent in over 500 psychomotor skills. As an educator preparing prospective athletic trainers for employment in the field of athletic training, knowing all the content that we cover, and being confident that the athletic training students can competently perform skills of an allied health professional, I am obviously distraught about CMS-1385-P. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Jill Schubert MS, ATC, LAT
Assistant Professor HPE

Submitter : Mr. Timothy Lengle **Date:** 08/31/2007

Organization : Rider University

Category : Other Health Care Provider

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please see attached letter

Submitter : Dr. Marco Araujo **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14981-Attach-1.DOC

14981

ADVANCED PAIN MANAGEMENT

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

August 31, 2007

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

Re: CMS-1385-P

Dear Mr. Weems:

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

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

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

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

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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

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

ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ADVANCED PAIN MANAGEMENT

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

***

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

Sincerely,

Sincerely,

Marco Araujo, MD
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

14983

NASW
National Association of Social Workers

August 30, 2007

Herb Kuhn
Acting Director
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

Subject: CMS-1385-P Medicare Program: Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008

Dear Mr. Kuhn:

I am writing to you on behalf of the National Association of Social Workers (NASW) and its 150,000 members. The oldest and largest professional social work organization in the United States, NASW promotes, develops, and protects the practice of social work and social workers.

NASW appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008," published in the Federal Register dated July 12, 2007. Our comments are listed below.

TRHCA-SECTION 101 (b): PQRI

Proposed 2008 PQRI Quality Measures
NASW supports the following three proposed non-physician quality measures that were developed by Quality Insights of Pennsylvania:
(1) Screening for Clinical Depression
(2) Screening for Cognitive Impairment
(3) Patient Co-development of Treatment Plan

We recommend that clinical social workers have access to two AMA/PCPI measures listed in Table 17, 72 Fed. Reg., 38201, as part of the bonus incentive program. They are:
(1) Patients who have Major Depression Disorder who meet DSM-IV Criteria
(2) Patients who have Major Depression Disorder who are assessed for suicide risks

These two measures also fall within the scope of clinical social work practice.

MEDICARE TELEHEALTH SERVICES §410.78(b)

NASW supports the expansion of telehealth services, which are critical to rural Medicare beneficiaries. Because clinical social workers are unable to seek reimbursement for the neurobehavioral status exam, we recommend that CMS also expand the telehealth services to include the new CPT Code 96125, "Cognitive Performance Testing." The CPT Editorial Panel approved this code in 2007 for non-physician practitioners who did not have access to the neurobehavioral status exam but who performed similar services.

RESOURCE BASED PE RVUs

This is the second year that clinical social workers will receive cuts due to the practice expense formula's change in methodology. NASW continues to oppose the new methodology, which negatively affects clinical social workers as mental health practitioners.

Social workers incur limited practice expenses due to the nature of their services. We continue to advocate for the adoption of an alternative practice expense methodology that would provide a practice expense balance for those in health care and mental health care or an exemption for mental health providers from the new practice expense methodology for calculating costs.

CORF ISSUES

CORF Social and Psychological Services

NASW supports the use of Health and Behavior Assessment Codes in Comprehensive Outpatient Rehabilitation Facilities (CORFs). The family is a very important part of treatment. Situations may arise that require a meeting with a family member without the beneficiary present.

For example, sensitive rehabilitative barriers to treatment may exist, which require an interview with the family only, especially when the family may have problems adjusting to the rehabilitation plan. Therefore, we recommend the addition of 96155 - whose descriptor reads, "family (without the patient present)" - to the proposed list of CPT codes 96150-96154.

§410.100

Social workers perform social work services, not "social services" or "social" services. We recommend that CMS change:

(1) All references to "social services" to "social work services"
(2) All references to "social" services" to "social work" services.

The phrase "social work services" adequately describes the depth and breadth of social workers' skills and expertise.

§410.100(h)

NASW finds the proposed definition for social and psychological services restrictive. Therefore, we recommend that the definition include social work, biopsychosocial functioning, and discharge plans.

The recommended definition should read:

> Social work and psychological services include the assessment and treatment of an individual's biopsychosocial, mental and emotional functioning and the response to and rate of progress as it relates to the individual's rehabilitation plan of treatment and discharge plans.

§485.70

Additional information is required in order for NASW to make an informed recommendation regarding the qualifications of social workers who work in CORFs. The social work profession recognizes several levels of social work education and licensure for social workers.

If the proposed definition increases the required skills of social workers in CORFs, it may be appropriate to advance the qualifications to the level of "Master of Social Work." However, if the proposed definition does not expand the skills of social workers in CORFs, it seems appropriate for the qualifications to remain at the educational level of the "Bachelor of Social Work."

Thank you for the opportunity to offer comments on the proposed rules. We look forward to the final rule in November 2007. Meanwhile, please contact me at 202-336-8200 if you have any questions about any of NASW's comments.

Sincerely,

Elizabeth J. Clark

Elizabeth J. Clark, PhD, ACSW, MPH
Executive Director

Submitter : Dr. Pradnya haldankar **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 :

Category : **Physician**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

See attachment

CMS-1385-P-14985-Attach-1.DOC

14985

August 31, 2007

Via Electronic Mail

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

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

Re: July 2, 2007 Medicare Physician Fee Schedule Proposed Regulations

Ladies and Gentlemen:

We are a group of 11 urologists who practice in the Atlanta, Georgia area. Back in the spring of 2002, we formed a joint venture limited liability company that provides lithotripsy services for the treatment of kidney stone disease. Prior to our 2002 joint venture, we had partnered with another organization to provide lithotripsy services for the treatment of kidney stone disease. Over the years we have provided services to a total of seven hospitals and one surgery center and have treated over 16,000 patients who suffered from kidney stones. We believe that had it not been for the formation of our LLC we would not have been able to have had access to advances in technology for treating kidney stone disease, leaving only an invasive surgical procedure as the solution for such a common aliment.

Today, our patients are treated with extracorporeal shockwave technology on an outpatient basis that reduces the expenses to cure the aliment and provides improved patient care. Based upon the proposed CMS regulations, we are concerned and need clarification about five areas: 1) Under Arrangement agreements; 2) Per Procedure Fees; 3) Percentage Fees; 4) In Office Ancillary Services; and 5) Stand in the Shoes provisions.

Under Arrangement Contracting.

Our LLC has entered into service agreements to provide lithotripsy services "under arrangement" to local hospitals and one surgery center. We believe that in doing so we have been better able to provide medical care to our patients because we are more in tune with advancements in technology. Frankly speaking, our LLC is much more likely to invest in new technology than a hospital that has to balance the needs of other departments. Additionally, since the new lithotripters are mobile and no longer have to be bolted down to the floor, our LLC has been able to create a mobile route whereby we can provide greater access to patients in rural under-served areas that cannot afford this type of technology. By having the physicians agree to be mobile, we have lowered hospital costs by sharing expensive equipment among many hospitals.

As we understand it, CMS interpreted "entity" under the Stark provisions to only mean the entity billing for the service in an under arrangement contract, which in our case would be the hospital or ASC. As we understand proposed CMS regulations, it appears that CMS is trying to change the Stark definition of entity to mean not only the hospital/ASC that bills for the services, but also the entity that the designated health service ("DHS") or "causes a claim to be presented" for the DHS. We need CMS to clarify its position on this matter in light of the *American Lithotripsy Society vs. Thomas* case in which lithotripsy received a exception from being included as a DHS. If lithotripsy is not a DHS, then it would seem that our LLC cannot be deemed to be performing a DHS or causing a claim to be submitted for a DHS, but we seek CMS's confirmation.

Also, we seek CMS's clarification on whether services that are not DHS when performed outside of a hospital (e.g., lithotripsy or treatment for an enlarged prostate (BPH)) cannot be DHS services if they are deemed directly performed by our LLC.

While we certainly can appreciate that CMS is concerned that physician under arrangement contracting results in over utilization and higher costs to the Medicare program, lithotripsy and BPH services are therapeutic and not diagnostic. The underlying medical condition and be objectively determined (i.e., kidney stone or enlarged prostate), so there is no risk of over utilization. You either have kidney stones or you don't – there is no guesswork. Lithotripsy and BPH laser are not like diagnostic testing with its higher risk of overutilization based upon the subjective judgment of the physician ordering the tests. We believe that any new rule should only apply to potentially abusive diagnostic tests and not beneficial therapeutic ventures with no risk of over-utilization.

We believe that Congress through the Stark I and Stark II legislation clearly intended under arrangement contracting to only require a compensation exception and not an ownership exception. We would ask CMS to clarify its intent.

Per Procedure Fee Prohibition.

As we mentioned, our LLC is comprised of 11 physicians and we have over 200 combined years of experience practicing in the specialty of urology. All of us have had to work with hospital administration and if it is one thing we know it is that hospitals are adverse to risk. Hospitals don't often appreciate the benefits of new technology because it is too risky. Purchasing the best new equipment, or entering into a fixed monthly lease over a term of one year or more, are capital risks hospitals often don't want to accept, particularly when they can't predict procedure volume.

But we, as physicians, understand the benefits of new technologies in improving patient care, and are willing to accept the capital risks inherent in a per procedure lease to a hospital. Rural hospital procedure volume may be too low to allow for a fixed monthly rental of technology, which could reduce access to the latest innovative technologies in poorer markets. Congress clearly wished to preserve per procedure fees in the Stark legislative history, and we do not believe that CMS can contradict congressional intent through a prohibition of such fee arrangements. What we need CMS to confirm is that the per procedure payment prohibition

would not apply to the Stark indirect compensation arrangement exemption relied upon by our LLC.

Percentage Fee Prohibition.

The percentage fee prohibition contained in the definition of "set in advance" that is a requirement of many Stark exceptions, but it is not in the indirect compensation arrangement exception relied upon by our LLC. Please confirm that the percentage fee prohibition would not apply to indirect compensation arrangements. Lithotripsy reimbursement rates may increase or decrease and payor mixes may change. Percentage fee arrangements allow hospitals and equipment vendors (like our LLC) to share in these market risks, and are often preferred by hospitals. These arrangements ensure that a hospital will never make an equipment rental payment in an amount greater than what it collects for the service from even the lowest cost insurer.

Stand in the Shoes.

As we understand it, the proposed CMS regulations concerning "Stand in the Shoes" could potentially restrict our LLC's ability to contract with ambulatory surgery centers (ASCs) owned or controlled by hospitals. The Medicare ASC Approved Procedure List does not allow for reimbursement of Stark DHS procedures, so Stark should not be implicated by a physician LLC contracting with an ASC. ASCs are lower cost providers of services. Physician-owned ventures should be encouraged to contract with ASCs, regardless of their ownership and control, if it results in savings to the Medicare program. If our understanding of the proposed CMS regulation is correct, then this prohibition would deter physicians from joint venturing with hospitals to form ASCs. Instead, physicians would develop only wholly-owned ASCs.

In-Office Ancillary Services Exception.

As physicians, we are constantly looking for ways to improve patient care, which in large part means finding new technology to improve the delivery of patient care. In urology, recent advancements have been made by using CT imaging so that we are better able to visualize the location of a patient's kidney stone(s). The old way to visualize a stone was to take an X-ray, but this proved to be not as effective as taking a CT image because a CT image permits us to see other soft tissue and have a much greater degree of enhancement of the treatment area.

As a practical matter, we have invested in CT imaging and provide it in our office for easy patient access and convenience. The use urology ancillary services such as CT imaging has become a truly integral to a urology professional practice and directly benefits our patients. If we hadn't done so, then we would have to send our patients back to the hospital to wait around to get the scan and waste even more time with having to have the hospital route the information back to our offices so that then we could review the scan and then have to call the patient. This proved incredibly inefficient and ineffective. We are able to take the scan in our office and convey the results in the same day, which ultimately provides better patient care.

We believe that Congress clearly indicated what DHS services were excluded from the exception and what DHS were to be included within the exception. We believe that CMS cannot

now issue regulations in contradiction with Congressional intent. Revisions to the Stark Statute are not necessary to address perceived overutilization abuses that may occur within the exception. Overutilization abuse concerns should be directly addressed through more diligent enforcement of the Federal Anti-Kickback Statute.

In conclusion, we ask CMS to separate those beneficial therapeutic joint ventures which are not of themselves DHS 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 models.

We appreciate your time and consideration.

Sincerely,

Greater Atlanta Lithotripsy, LLC
Management Committee

By: /s/
Thomas Schoborg, M.D.

By: /s/
Alex Garcias, M.D.

By: /s/
Bruce Branitz, M.D.

By: /s/
Paul Rubin, M.D.

By: /s/
James Libby, M.D.

By: Prime Lithotripsy Services, Inc., its manager

By: /s/
Gary Kozen, Vice President

Submitter : **Dr. Nabil Ali** **Date: 08/31/2007**

Organization : **University of Alabama School of Medicine**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

1-1987

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

Center For Medicare And Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Sir or Madam:

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

I. Technical Comments to the Proposed Revisions

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

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

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

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

II. General Comments in Support of Centralized Pathology Laboratories

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

A. Unsupported Rationale for the Elimination of Centralized Pathology Laboratories

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

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

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

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

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

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

B. Benefits of Path Lab Arrangements

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

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

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

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

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

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

C. Controlling the Risk of Over-utilization

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

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,

Stanton P. Champion, MD
President
Urology Tyler, PA

Submitter : Mr. Garrettt Law **Date:** 08/31/2007

Organization : First Presbyterian Day School

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am an Athletic Trainer in the Middle Georgia area. Currently I work in a secondary school setting, although I have, in the past, worked in a clinical setting.

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

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

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

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

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

Sincerely,

CMS-1385-P-14989

Submitter : Ms. Laura Saul Edwards **Date:** 08/31/2007

Organization : The Mohs Coalition

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment, a letter submitted by the Mohs Coalition.

CMS-1385-P-14989-Attach-1.DOC

CMS-1385-P-14989-Attach-2.PDF

August 23, 2007

The Honorable Herbert Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20201
Phone: 202-690-6726

Re: CMS 1385-P: 2008 Medicare Fee Schedule, Section II.E.2
Coding – Multiple Procedure Payment Reduction for Mohs Surgery

Dear Acting Administrator Kuhn:

On behalf of the members of the American Academy of Dermatology Association (AADA), the American College of Mohs Surgery (ACMS), the American Society for Dermatologic Surgery (ASDS) and the American Society for Mohs Surgery (ASMS), we are jointly submitting comment to you on the 2008 Medicare Fee Schedule: Proposed Rule regarding the explicit withdrawal of the Multiple Procedure Reduction Rule (MPRR) exemption for Mohs surgical procedures. We appreciate this opportunity to offer comment on Section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule.

This proposed CMS action takes away the specific exemption accorded to the Mohs Micrographic surgery codes in the 1992 Medicare Physician Fee Schedule and maintained by CMS within all subsequent fee schedules since 1992 (see Federal Register, Vol. 56, No. 227, Nov 25, 1991, pg. 59602). We believe that this CMS action will unduly impact not only those Medicare beneficiaries who have or will be diagnosed with skin cancer but also those surgical dermatologists who provide these services. We also believe that the NPRM fails to articulate adequate justification for this action.

First, CMS states that "the CPT Editorial Panel removed the Mohs procedure from the -51 modifier list." This appears to be both irrelevant and factually incorrect. That the removal of these codes from the exempt list is presented in an NPRM is evidence that CMS recognizes the payment policy formulation responsibility lies with the agency and not CPT. We also do not believe that the CPT Editorial Panel explicitly took this action as stated.

Second, the NPRM correctly states that 1) the AMA/Specialty Society Relative Value Update Committee (RUC) valued each code carefully; 2) the RUC assumed each code is a separate procedure, and 3) the RUC did not consider efficiencies when the procedures are performed on the same day. The NPRM then relies on these statements to justify changing the existing longstanding CMS policy. While these three factors are correct, they do not justify the NPRM's stated conclusion that these codes should not be exempt from the multiple procedure reduction rule. It is no surprise that the RUC did not consider efficiencies since CMS has long recognized that there are no efficiencies inherent in these procedures when performed together. Therefore, factors cited as the reason for removal from the exempt list are, in reality, the very same factors that CMS has previously considered and recognized to justify exemption. Simply stating the

factors does not provide any insight into the reasoning why a change is contemplated. The NPRM does not provide any explanation for this proposed change and certainly does not justify the reversal of a previously well-considered and long- standing CMS payment policy. CMS should defer from making this change and any proposal for change in the future should be based on sound rationale and factual data.

CMS agreed in the 1992 Medicare Fee Schedule: Final Rule that these *"are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures....They will be paid separately with no multiple surgery reductions."* This conclusion is still correct and applicable today.

We believe this proposal will negatively impact Medicare beneficiaries' access to timely and quality care and application of the Multiple Procedure Reduction Rule will not likely generate significant cost savings and may paradoxically increase the cost of providing care to these patients.

The American Academy of Dermatology (AAD), the American College of Mohs Surgery (ACMS), the American Society for Dermatologic Surgery (ASDS) and the American Society for Mohs Surgery (ASMS) support the RUC process and recognize the value it brings to the annual Medicare physician fee schedule development. As initially charged, the RUC has done an exceptional job over the years in expressing opinions regarding relative values for procedures. In doing this, the RUC defied the predictions of critics who claimed that agreement would not be possible among the various stakeholders.

The RUC and CMS have also prevailed against the legal challenge that the RUC amounted to a Federal Advisory Committee. In defending against that allegation it was persuasive to the court that the RUC only provides opinions on relative values and that CMS retains the authority to make policy decisions. The RUC, it was noted, is independent and is only one source of CMS input on relative values. All policy decisions have undergone full development by CMS in the public notice and comment process.

The policies adopted by CMS such as multiple procedure reductions, bundled services, and prohibition against operating surgeons from separately billing for anesthesia and assistant at surgery restrictions are all examples of policy decisions by CMS. They do not strictly represent issues of relative value but rather they represent policy formulations that guide payment and medical practice. To have the RUC engaged in these policy formulations in a forum which is not open or accessible to the public is unfair to the Medicare beneficiaries affected and threatens the RUC process. We disagree with using the RUC for this purpose, but if CMS believes the RUC role should be expanded it should only be done by giving the RUC a public and well-articulated charge to take on this task.

In light of the concerns raised above, the American Academy of Dermatology (AAD), the American College of Mohs Surgery (ACMS), the American Society for Dermatologic Surgery (ASDS) and the American Society for Mohs Surgery (ASMS), respectfully request reconsideration of the proposed rule. We provide the above rationale in support of the Mohs procedure base codes, 17311 and 17313, as appropriately exempt from the multiple procedure

reduction rule, as are the other add-on Mohs codes. We therefore request maintenance of the existing exemption from the MPRR.

We would appreciate the opportunity to meet with CMS to discuss this issue as soon as possible. Please feel free to contact Laura Saul Edwards at ledwards@aad.org or (202) 842-3555.

Respectfully,

Diane Baker, MD,
President, American Academy of Dermatology

David G. Brodland, M.D.
President, American College of Mohs Surgery

Alastair Carruthers, FRCPC,
President, American Society for Dermatologic Surgery

Sharon Tiefenbrunn, MD,
President, American Society for Mohs Surgery

cc: Terrence Kay, Director, Hospital and Ambulatory Policy Group
Amy Bassano, Director, Practitioner Services Division

Enclosure: Federal Register, Vol. 56, No. 227, Nov 25, 1991, page 59602

of the global fee for the second highest valued procedure, and at 25 percent of the global fee for each succeeding procedure. Each procedure after the fifth procedure will be paid by special report. Our medical consultants advise us that cases with more than five procedures should be extremely rare. We believe that the added documentation requirement along with physician comparative performance reports and our intra-operative computer edits will prevent abuse of the multiple surgery policy through excessive "unbundling".

For certain dermatology services, there are separate CPT codes for multiple surgical procedures (for example, CPT codes 11201, 17001, and 17002). For these procedures, the multiple procedure rules will not apply. Rather, we are presenting RVUs for these codes. For other dermatologic procedures, we believe a 50 percent reduction in the value is appropriate for the second procedure since pre- and post-work and practice expenses will be diminished. However, beyond the second procedure, since there may not be the same reductions in work effort that is associated with multiple surgery through the same incision, a physician may submit a "by report" bill when three or more lesions are removed.

[Mohs Micrographic Surgery]

Comment: Some commenters stated that Mohs micrographic surgery, CPT codes 17303 through 17310, should be exempt from the multiple surgery reductions. These are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures.

Response: We agree that these surgical procedures are contemplated to be separate staged procedures; they will be paid separately with no multiple surgery reductions.

[Multiple Surgery Policy for Multiple Trauma]

Comment: Some commenters expressed concern that the multiple surgery policy would result in inadequate payment when a number of different surgeons are operating on different body parts at the same time, such as in the case of a multiple trauma patient.

Response: These cases will not be subject to the multiple surgery policy. The multiple surgery policy will apply to multiple surgery done by the same surgeon on the same day. Each physician will be paid separately for his or her services.

c. *Bilateral surgery (CPT modifier 50).* The bilateral modifier is used to indicate cases in which a procedure was performed on both sides of the body. The CPT identifies surgical procedures that are typically bilateral in nature. For these codes, the bilateral modifier would not result in increased payment.

In the absence of any evidence with respect to the actual difference in work for bilateral procedures, we proposed to continue the historic practice of paying 150 percent of the global fee.

[Bilateral Surgery Code Applying to Ophthalmic Procedures]

Comment: The CPT code for bilateral surgery (CPT modifier 50) should not apply to ophthalmic procedures or to the extremities (hands, feet, knees) as it requires the same amount of work for each eye, foot, etc. This policy would merely encourage physicians to bring the patient in on two separate occasions and do each eye, foot, etc., separately.

Response: Harvard did not have data on the resources involved in miscellaneous bilateral surgery and surveyed very few procedures that were bilateral. Like the multiple surgery policy, the use of a bilateral modifier and payment by carriers at 150 percent of the global fee in bilateral cases is a long accepted practice. Until resource data are available, we plan to continue the 150 percent policy. While the actual intra-operative services may be the same for each eye or extremity, we believe the pre-operative and post-operative services are reduced.

d. *Providers furnishing less than the global fee package (CPT modifiers 54, 55, and 56).* Under the current reasonable charge policy, the sum of all allowances for all practitioners who furnished parts of the services included in a global fee (and who billed using one or more of these modifiers) must not exceed the total amount of the allowance that would have been paid to a single practitioner under the global fee for the procedure. We proposed to continue to pay the same amount for surgical services when they are furnished by several physicians as we would pay if only one physician furnished all of the services in the global package. However, we proposed to pay each physician directly for the services furnished to the beneficiary based on the RVUs of the component furnished.

[Physicians Other Than Surgeons Should be Paid Without Regard to Global Fee]

Comment: Commenters objected to the policy that the sum of payments to multiple physicians furnishing services within a global package (CPT modifiers 54, 55, and 56) may not exceed the value of the global fee for the procedure. They stated that since only the pre- and post-operative services of the surgeon were studied by Harvard in setting the global RVUs (not the services of other physicians such as cardiologists, internists, anesthesiologists, intensivists, or other physicians who may furnish this care), a physician other than the surgeon who furnish follow-up care should be paid without regard to the total global fee.

Response: We disagree. The concept of a global fee for a surgery for which the surgeon charges a single global fee and furnishes all usual and necessary services associated with a surgery and follow-up recovery is a long established concept. To ensure equitable payment under the fee schedule, it is necessary to establish a uniform national global package for each surgery. Since the surgeon usually can be expected to furnish the complete package of services, it is entirely appropriate that the value of the package be established on the basis of the value of the surgeon's services. When someone other than the surgeon furnishes services that the surgeon would normally furnish, he or she is merely substituting for the surgeon. The value of the package does not change.

However, there appears to be some misunderstanding concerning the services of other physicians—for example, a nephrologist, an infectious disease specialist for severe infection—furnishing services in addition to those normally furnished by the surgeon when a patient develops renal insufficiency. As discussed in the section of the proposed rule on global surgery, if the services of these other physicians are required in addition to the normal pre- and post-operative services of the surgeon, they will be paid outside of the global fee.

[Apportioning Payment for Post-Operative Care Furnished by Different Physicians]

Comment: A commenter suggested that, if normal post-operative care is furnished by more than one physician, the payment should not be apportioned according to the number of days in the portion of the 90-day period furnished by each physician since the number of visits and intensity of care required during different times in the period varies. The commenter stated that as an example, under the proposal in the proposed rule, a physician furnishing the first 30 days of post-operative care would receive 33 percent of the value of the care, while the physician furnishing the last 60 days of care would receive 66 percent. The commenter noted that, in

Submitter : Dr. Luciana Berceanu **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14990-Attach-1.DOC

ADVANCED PAIN MANAGEMENT

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

August 31, 2007

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

Re: CMS-1385-P

Dear Mr. Weems:

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

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

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

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

RESOURCE-BASED PE RVUs

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***

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

Sincerely,

Sincerely,

Luciana Berceanu, MD
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : **Mrs. Sydnie Freeman** **Date: 08/31/2007**

Organization : **The Orthopedic Specialty Hospital**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer working in a physical therapy clinic exclusively with orthpedic injuries. I am a graduate of Brigham Young University, where I graduated with a defree in Exercise Science: Athletic Training. I passed my national exam in order to receive certification as an Athletic Trainer in this country. I have also been licensed as an Athletic Trainer in the state of Utah because of my education and qualifications. I mostly work with physical therapy patients doing therapeutic exercise, but I also work with the local high schools in my area covering sporting events.

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,

Sydnie Freeman, BS, ATC, LAT

Submitter : Dr. Justin Lee **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. Thomas Summanen** **Date: 08/31/2007**

Organization : **Ohio State University Sport Medicine Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam:

I am an Athletic Trainer at the Ohio State University Medical Center s Sports Medicine Center. I am privileged to work with a wide variety of patient populations. I am most proud to work with disadvantage youth in the inter city of Columbus, Ohio. I am afraid that if the CMS continues with it s proposed rule changes it will further increase healthcare disparities of this population. The proposed rule changes will also decrease the number of quality healthcare professional providing care to our expanding active older adult 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.
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,

Thomas H. Summanen, MS, ATC, CSCS
OSU Sports Medicine Center
2050 Kenny Road
Columbus, Ohio 43221
614-293-2385
Thomas.summanen@osumc.edu

Submitter : **Dr. C. Nolan Stephens** **Date: 08/31/2007**

Organization : **Dr. C. Nolan Stephens**

Category : **Chiropractor**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

MEI

My patients would be severely impacted by the proposed change of the X-ray requirements. If I have to refer my patients to another practitioner to identify there need for care (which I have already accessed) this would not only delay there treatment, but would increase their expenditure. Many of these patients are on fixed incomes which barely afford them food. This requirement not to allow medical/osteopaths to take X-rays for chiropractors would place the patient and the doctors at risk of delaying the treatment of what might be a life threatening illness. Please reconsider your position in this matter.

Sincerely,

C. Nolan Stephens

Submitter : Mr. Richard Sage **Date:** 08/31/2007

Organization : eRx Network, LLC

Category : Health Care Industry

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

See Attachment

CMS-1385-P-14997-Attach-1.DOC

14997

eRx Network

301 Commerce Street • Suite 3150 • Fort Worth, TX 76102-4102 • 817-887-0300 • 817-820-1506 (fax)

eRx Network Comments on the Proposed Rule Concerning E-Prescribing and Computer-Generated Fax Exemption

August 31, 2007

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

Dear Sir or Madam:
eRx Network, LLC is a leading provider of claims management and analysis services, Medicare and Medicaid billing services and e-Script physician communication services to the retail pharmacy industry. We appreciate the opportunity to comment on the proposal to revise § 423.160(a)(3)(i) to eliminate the computer-generated fax exemption for all prescriber/dispenser transactions.

eRx Network represents retail pharmacy and physician aggregators in the adoption of electronic prescriptions. Electronic prescribing has significant benefits for both prescribers and pharmacies, including reduced medication errors, quicker processing and better patient compliance. We believe that electronic prescribing will be the primary method of communication between the prescriber and the pharmacy. eRx has worked hard to encourage participation in this very important service to deliver prescriptions to pharmacy and allow pharmacies to automate their request for additional prescription refill authorizations. We must realize that this implementation must include a transitional process to deal with technology enhancements and the fact that true electronic prescribing is only operational once both the originator and destination are able to support the technology. We must also recognize that the transition to electronic prescribing is evolutionary and will take time to gain critical mass. We have several concerns and suggestions regarding CMS' proposed rule that we have outlined below.

A total elimination of the fax exemption will have more adverse impacts than benefits. We are still educating prescribers and pharmacies on the benefits of e-prescribing and many, if forced to choose between a mix of e-prescribing, manual printing and faxing vs. an entire manual process of hand writing the prescription, will select the latter. The current workflow for many physicians and pharmacies is to select the destination from an electronic listing and transmit the final accepted order through their application. The routing of the transaction is transparent to the prescriber/pharmacist. If the destination can accept the transaction electronically, then it is delivered in that manner. If the destination cannot accept the prescription or refill request electronically, then the application translates the transaction to a computer-generated fax for delivery. This can be due to regulatory restrictions (i.e. control substance prescriptions), lack of a partnership agreement, or necessary technology to support the NCPDP SCRIPT transactions. Moving away from computer-generated faxing impacts both the prescriber and pharmacy; the prescriber will receive phone calls for refill requests from pharmacies that are currently sending computer-generated faxes, and pharmacies will be forced to print, then manually fax, or call-in all refill requests that cannot accept SCRIPT e-prescribing. We believe that the impact to work flow for both prescribers and pharmacies will be significant.

As mentioned above, DEA regulations prohibit the e-prescribing of a prescription for a controlled substance. This prohibition acts as a tremendous barrier to prescriber adoption of e-prescribing. As currently written, CMS' proposed rule would exacerbate the problems caused by this prohibition. If

prescribers could use neither electronic prescribing (because of DEA regulations or contractual issues) nor computer-generated faxes (because of the CMS proposed rule) for controlled substance prescriptions, then many prescribers would have to revert to using traditional fax machines or paper and oral prescriptions for controlled substances. For these reasons, until such time that DEA amends its regulations to allow for the electronic prescribing of controlled substances, we believe that prescribers and dispensers need to retain the ability to use computer-generated faxes to send and receive prescriptions for controlled substances. In fact, this policy should apply in any circumstance in which a prescriber or dispenser is prohibited from complying with the NCPDP SCRIPT standard for reasons beyond their control.

We do agree that in situations where the prescriber's software can generate SCRIPT transactions, but the ability is "turned off" because electronic communication with the pharmacy has not yet been established, that we should support the effort to encourage these prescribers to establish a connection through their Point Of Care (POC) vendor, train and implement true e-prescribing. We do, however, question the statement made that only 15 percent of prescribers now using software that is capable of generating SCRIPT transactions are doing so. Our experience in working with POC vendors shows a much greater support for the transition to e-prescribing, but the development, certification and implementation process can be time intensive or cost prohibitive. We believe that the rule should continue to allow for computer-generated faxing with some guidelines, including allowing prescribers and pharmacies to use computer-generated faxes when the destination does not yet support e-prescribing, or as a backup when the electronic communication is unavailable.

Another major concern is that there is no way for the destination to understand if the source sent the fax electronically or manually. If the destination owns the same level of responsibility as the sender of a fax, then the industry would need to stop faxing altogether to ensure compliance with this rule. We recommend that the responsibility and accountability to be in compliance with the rule is exclusive to the originator of the fax; the destination must expect that the fax received is rule compliant.

In cases where the prescriber uses software (such as a word processing program) that creates and faxes the prescription document, but does not have true e-prescribing capabilities need to be allowed to continue to send computer-generated faxes. Many physicians are using Electronic Health Record (EMR) systems that do not have the capability to support e-Prescribing using the SCRIPT standard. Many of these applications were originally written for hospital settings and medical claim processing using HL-7 standard rather than NCPDP's SCRIPT standard. These prescribers are not capable of supporting e-prescribing using the standards being adopted by this rule. Requiring these entities to comply with the NCPDP SCRIPT Standard would force the vast majority of them to revert to paper faxes. This, as stated in the original ruling, "would impose a significant burden on those entities presently using computer-generated faxing". Although many argue that the industry is not moving quickly enough, we have seen significant improvement toward the support of electronic prescribing since this rule was published. We encourage collaboration between physician's offices and health information technology vendors to enable electronic connectivity with pharmacies. We should be finding ways to encourage this group to move to SCRIPT e-prescribing rather than force a decision that is often outside of the control of the physician or pharmacy in the case of software capabilities. Again, as the original rule stated, "the statutory direction is that the Secretary has to issue uniform standards with the specific objective of improving efficiencies, including cost savings, in the delivery of care, and designed so that the standards, to the extent practicable, do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists." We interpret these statutory objectives as enabling us to ensure that existing functionalities and workflow are not disrupted for a large number of prescribers and pharmacies. This change would have a significant impact on both prescribers and pharmacy systems. As indicated earlier, many prescribers and pharmacies would revert to handwritten paper prescriptions or computer-generated prescriptions that are printed in hard copy and manually faxed to the dispenser. This

practice would stand as a significant obstacle to the broader statutory goals of the electronic prescription drug program provisions, as well as limit the ability of Medicare beneficiaries and the Medicare program to benefit from the patient safety and cost savings anticipated from e-prescribing drugs under Part D of Title XVIII of the Act. We recommend that the rule allows for an exemption for prescribers/pharmacies that have software that does not yet support SCRIPT transactions.

A concern documented with the original rule published in November, 2005 stated that "absent an exemption, entities transmitting computer-generated faxes would be required to comply with the adopted foundation standards. This would cause computer-generated faxers to revert to paper prescribing". We believe this to be the case as well. While we readily support the SCRIPT standard and the move to support this standard by all physicians and pharmacies, it is not realistic to expect this adoption to happen quickly. We should find ways to encourage the quick adoption of this standard, not mandate a policy moving the industry away from this important process. Some suggestions include tax breaks for SCRIPT electronic prescription implementation, increased reimbursement rates to pharmacies and physicians that support SCRIPT electronic prescriptions, and to encourage insurance companies to offer discounts on malpractice insurance for using electronic prescribing.

We are also concerned about the impact and implications that the elimination of the exemption would have on independent pharmacies. Rather than an automatic expectation that this mandate would increase the number of SCRIPT transactions fairly significantly in a relatively short time period, it is our view that independent pharmacies are not waiting for economic incentives to participate in e-prescribing. Most are very supportive and are currently working with their software vendors to implement this service.

There are also situations when there is not an agreement between the prescribing and pharmacy vendor to allow sending transactions electronically even though both are capable of communicating using the SCRIPT standard. Because of the infancy of this service, there are limited connectivity vendors to support the transactions to and from the prescriber and dispenser. This rule should not force either party to send or receive transactions without a business agreement, nor should it force either party to sign an agreement that is not in the best interest of the prescriber or pharmacy in order to be compliant with this rule. We recommend that the rule continue to allow for computer-generated faxes in these situations as well.

Another concern with the proposed change relates to back up systems. Both parties need to have the ability to support an effective back up process when communication or software errors occur. Currently many vendors support a 'failover to fax' feature in cases of SCRIPT outages. This rule change would eliminate this capability and force hard halts in this communication process. We would recommend that any change in guidance would include the ability to use computer-generated faxes for back-up systems.

We believe that patients should have free choice to use the prescriber and the pharmacy of their preference. Accordingly, if a patient chooses to use a prescriber that has the capability to electronic prescribe using the NCPDP SCRIPT Standard but chooses a pharmacy that does not have such capability, or vice versa, that prescriber/dispenser should have the right and ability to send the prescription message by the means that is most efficient and best for the circumstances, including by a computer-generated fax.

There is no way for a pharmacy to know if the prescriber with whom they are communicating is able to receive an electronic transmission in a SCRIPT-compliant manner or if the prescriber is converting a pharmacy-initiated transmission into a fax. Nationwide, pharmacies currently transmit hundreds of thousands communications every day to prescribers, mostly refill requests. This number continues to grow as prescription volumes increase. To require pharmacies to know if a prescriber can receive a

communication in a SCRIPT-compliant manner before sending the communication would reverse all gains made in the adoption of electronic connectivity. Logistically, this would be impossible, and would cause pharmacies to revert to traditional faxing for most communications with prescribers.

For these reasons, the NCPDP SCRIPT enabled sending entity should be able to send a computer-generated fax if the receiving entity is not capable of receiving an NCPDP SCRIPT message and the sender believes that a computer-generated fax is the best and most efficient way to send the prescription message. Of course, if both the sender and the receiver are both capable of communicating with the NCPDP SCRIPT standard, then they should do so (unless another exemption applies).

The effective date of this proposed rule is problematic, due to the fact that the industry is working on an implementation timetable built around the requirements of e-prescribing standards adoption spelled out in the Medicare Modernization Act of 2003 (MMA) and associated rules. The MMA requires that providers who write prescriptions electronically use the final standards that are in effect when they conduct e-prescribing transactions as of April 1, 2009. We are concerned that prescribers will be confused if the effective date of this proposed rule is January 1, 2009. We recommend that all changes to the e-prescribing rule be effective on April 1, 2009.

We encourage CMS to revise the fax exemption so as not to eliminate the exemption in its entirety, but rather narrow the exemptions for this rule to the following conditions:

1. The prescriber or dispenser's software does not have the capabilities to support the NCPDP SCRIPT transaction
2. The prescriber or dispenser sending a transaction has the capability of supporting the NCPDP SCRIPT transaction but the receiving party does not have this capability
3. Applicable law, regulation, or lack of necessary business agreement would prohibit the ability to send an NCPDP SCRIPT transaction to the receiving party
4. Primary systems are not able to send NCPDP SCRIPT transactions, such as system, network or power outages

I would be happy to answer any questions that you have regarding our comments related to this very important issue.

Sincerely,

Richard B. Sage
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Submitter : Dr. Gwendolyn Boyd **Date:** 08/31/2007

Organization : University of Alabama at Birmingham

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please fix the inequitable payments to anesthesiologists which are currently one third below what they need to be to continue to assure quality care for our elderly and disabled citizens. As the daughter of an 88 year old mom, I am particularly concerned for her health and medical care. As a professor of anesthesiology I am concerned for the future of my chosen specialty if those to whom we pass the torch are grossly underpaid for their services. The teaching rule for sure needs to be rectified for anesthesiologists no other specialty is penalized for educating their future colleagues as we are.
Thank you for your kind consideration for the care of our elderly and disabled. Anesthesia has become so much safer through the dedicated efforts of our academic anesthesiologists discovering new techniques, medications and monitors. these should continue!!!!!!!
Please help.

Submitter : Dr. Michael Strickland **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-14999-Attach-1.DOC

14999

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,

Michael G. Strickland, D.O.