Submitter : **Mrs. kimberly wise** **Date: 08/31/2007**

Organization : **northeastern university**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am an athletic trainer, a professional health care provider requesting the opportunity for my profession to be recognized equally within the insurance industry. Please revisit CMS1383 payment policies.
thank you,

K.Wise

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

Organization : **SWFUA**

Category : **Physician Assistant**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15027-Attach-1.DOC

15021

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,

Donald M. See, P.A.

Submitter : **Dr. Adam Thompson** **Date: 08/31/2007**

Organization : **Indiana Wesleyan University**

Category : **Other Health Care Provider**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

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

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

As a certified athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national board certification exam ensure that my patients receive quality health care. State license 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,

Adam J. Thompson, PhD, ATC, LAT

Submitter : **Dr. Anjolie Laubach** **Date: 08/31/2007**

Organization : **Duke University Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

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

Organization : Emory University

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Chris Shenberger, and have been a practicing Certified Athletic Trainer for almost 2 years. I am a graduate student working at Emory University currently. Along with my responsibilities at Emory, I am attending Georgia State University as a full-time graduate student and working towards my Masters of Science in Athletic Training from Georgia State University and plan to graduate in May 2008.

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

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

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

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

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

Sincerely,

Chris Shenberger, ATC

Submitter : Mrs. Penny Grassel **Date:** 08/31/2007

Organization : Boscobel Area Health Care

Category : Hospital

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Penny Grassel and I am a Licensed Athletic Trainer. I work at a hospital in Wisconsin seeing outpatients in the rehab department independently under my licensure guidelines. I also spend part of my day traveling to a local high school and evaluating athletic injuries and recommending appropriate treatment. Working in a rural area I feel I am able to provide a valuable service to the people in my community.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing 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,

Penny K. Grassel, LAT

Submitter : **Ms. Laura Loeb** **Date: 08/31/2007**

Organization : **ACOS and AOAO**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Comments on the proposed changes to the physician self-referral rules and the Medicare reassingment and anti-markup

CMS-1385-P-15032-Attach-1.DOC

August 31, 2007

Herb B. Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1385-P
7500 Security Boulevard
Baltimore, MD 21244–1850

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

Dear Mr. Kuhn:

The American College of Osteopathic Surgeons (ACOS) and the American Osteopathic Academy of Orthopedics (AOAO) appreciate the opportunity to provide written comments on the "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008", as published in the *Federal Register* on July 12, 2007. Specifically, we wish to comment on the proposed changes to the physician self-referral rules and the Medicare reassignment and anti-markup provisions that apply to diagnostic tests.

In general, we are very concerned that the proposed changes will add yet another layer of unnecessary complexity and confusion in an area where physicians are simply trying to provide patients with the highest quality of services in an efficient manner in one centralized location. For example, the proposed rule questions whether there should be new restrictions on "pod" labs located in physician offices. Yet, the Centers for Medicare and Medicaid Services (CMS) provides no evidence of any existing abuse in this area. There has been no evidence demonstrated of over-utilization of services or other abuses occurring because of these arrangements.

Indeed, we believe that these pod labs, conveniently located in the physician offices, have increased the quality of patient care and perhaps reduced the overall costs to the Medicare system by providing efficient and more timely care. We urge CMS to seek further data in this area to confirm whether abuses are occurring prior to making any policy changes that might in fact lead to lower quality of care and even greater costs to the system.

Also, under the proposed rule changes, the only professional or technical components of a service that a physician group could mark-up would be those performed by a full-time employee of the group. This proposed change does not reflect real-world situations. There are many cases where the physician group hires other professionals for interpretations or technical services as

independent contractors or part-time employees, particularly in rural areas. In addition to paying these professionals for these services, the physician group also incurs overhead expenses and assumes the risk in billing for these services because some services will not be paid. If the physician group is prohibited from billing more than the amount actually paid to the independent contractor or part-time employee, the physician group would actually lose money on providing the service. Thus, these services will no longer be provided in the physician office, resulting in less efficient care for the patient and perhaps even lower quality of care and increased costs.

Further, the law currently allows time-based or per-click payment arrangements, as long as the payment is set in advance at fair market value and does not change during the term of an agreement in a manner that reflects the volume of referrals. The term of the agreement must be at least for one year. However, CMS is proposing that space and equipment leases, personnel leases, billing service agreements, or management services agreements between a physician and a billing entity may not be based on per-click payments to the physician or on a percentage of collections for services referred by the physician to the billing entity. Such a change would require physicians and hospitals to restructure or terminate many arrangements, when once again there is no substantive evidence of abuse in this area.

Lastly, the proposed rule would change certain indirect compensation relationships between physicians and hospitals into direct relationships and would prohibit physician ownership of entities that provide equipment or services to hospitals. The proposed changes would require the restructuring or termination of many physician-hospital joint ventures and lease and management arrangements, including those where the compensation already is based on fair market value and the arrangements foster competition, lower costs, and better care.

In closing, we urge CMS to reconsider its proposed changes in these areas and instead gather more data to determine if these truly are arrangements where program abuse and/or over-utilization is actually occurring.

Respectfully Submitted,

Alison A. Carey, D.O. FACOS
President, ACOS

Debra K. Spatz, D.O. FAOAO
President, AOAO

Submitter : Mrs. Laurie Senn **Date:** 08/31/2007

Organization : MeritCare Health System

Category : Other Practitioner

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
_Laurie A. Senn, MSN, CRNA_____
Name & Credential
_102 Prairewood Dr. S_____
Address
_Fargo, ND 58103_____
City, State ZIP

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

Organization : Society of Gynecologic Oncologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Greetings - Please "See Attachment" for the comment letter from the Society of Gynecologic Oncologists that addresses practice expense, the work adjustor, compendia, PQRI, and 2008 payment levels.

15034

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. Maher Fattouh **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15035-Attach-1.DOC

15035

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

ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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

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

ADVANCED PAIN MANAGEMENT

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

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

***

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

Sincerely,

Sincerely,

Maher Fattouh, MD
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Lee Ann Boyd **Date:** 08/31/2007

Organization : SWFUA

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15036-Attach-1.DOC

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

Dear Mr. Kuhn:

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

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

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

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

Thank you for your consideration,

Lee Ann Boyd, ARNP

Submitter : Mr. James Magee, Jr. **Date:** 08/31/2007

Organization : Kinesiotherapist

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Limiting a physician's choices for appropriate health care doesn't sound like it would be in the patient's best interest? There are so many alternative therapy choices that benefit the patient/client, from a financial standpoint as well as a functional standpoint. Please reconsider this so everyone has the opportunity to receive every therapy service possible that is deemed necessary by their physician. Thank You.

Submitter : **Dr. Brian Fisher** **Date: 08/31/2007**

Organization : **self**

Category : **Physician**

Issue Areas/Comments

Medicare Economic Index (MEI)

Medicare Economic Index (MEI)

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

RE CMS_1385-P
Anesthesia Coding

Ms Norwalk

Please support the proposal to increase Anesthesia payment under the 2008 Fee Schedule.

CMS has determined the undervaluation of anesthesia work compared to other physician services.

The $16.19 per unit payment does not cover the cost of caring for our seniors and puts an unhealthy strain on the medical system.

To help the system keep on providing good medical care please implement the anesthesia conversion factor increase as recommended by RUC.

Thank you

Brian L. Fisher, M.D.

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

Organization : **Page, Wolfgerg & Wirth LLC**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1385-P-15039-Attach-1.DOC

15039

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September 14, 2007

VIA ELECTRONIC SUBMISSION

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

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

Ladies and Gentlemen:

We are submitting comments regarding the above-referenced Proposed Rule.

Brief Overview of Our Firm

Page, Wolfberg & Wirth, LLC is a law firm with a practice limited to the representation of ambulance services and emergency medical services (EMS) agencies. We represent over 750 ambulance services across the United States in the nonprofit, for-profit and public sectors. We also represent many EMS billing companies and other organizations which serve the nation's ambulance industry. Medicare compliance and reimbursement issues constitute the predominant part of our practice. In addition, we are regular columnists and contributing authors in many of the national ambulance industry publications and the attorneys and consultants of our firm collectively give approximately 100 presentations every year on issues of concern to the industry, including Medicare

compliance and reimbursement. Our founding partners have also been active EMTs, paramedics and ambulance service administrators over the years.

Comments: Beneficiary Signature

While we appreciate the efforts of CMS to recognize and attempt to correct a problem plaguing ambulance service providers, the proposed rule is actually unnecessary based upon the current language in the regulation and the Medicare Manuals, and creates a significant burden on the part of the ambulance industry and receiving hospitals. In other words, in an attempt to improve a problem in the ambulance industry, CMS's proposed rule actually creates a larger problem. Essentially, the proposed rule is not necessary, as adequate steps are already in place which allow for "surrogate" signatures where the beneficiary is unable to sign for him or herself. It is only in the rare situations where there is an emergency transport, and where the beneficiary is incompetent to sign for him or herself (either physically or mentally unable, or both), and there is nobody available to sign on behalf of the beneficiary, that obtaining a beneficiary signature becomes a problem. These rare situations are already adequately addressed and do not necessitate additional regulatory provisions.

Ambulance providers are already well aware of the beneficiary signature requirements, as outlined in 42 CFR §424.36. Because a vast majority of ambulance transports involve beneficiaries that are competent to sign, or occur between facilities (where facility personnel or family members may be available to sign) obtaining beneficiary signatures is typically not a difficult task. It is in cases where there is an incapacitated beneficiary with nobody available to sign on his or her behalf that poses beneficiary signature problems. Currently, the language of 42 CFR §424.36(b)(5) indicates that a "representative of the provider" is permitted to sign on behalf of the beneficiary "if the beneficiary is physically or mentally incapable of signing the claim." An ambulance service is a Medicare "provider" that clearly fits within this particular exception already carved out in the regulation concerning beneficiary signature requirements. There is no need to further attempt to clarify this regulation, other than to perhaps specify that the term "provider" as used in this section is clearly intended to mean all "Medicare providers" including ambulance services.

Further, the Medicare Manuals, presumably in interpreting the beneficiary signature requirements have addressed situations where the beneficiary is unable to sign. Specifically, in cases where the "enrollee [is] physically or mentally unable to transact business and full documentation is supplied that the enrollee has no one else to sign on his behalf: The physician, supplier, or clinic may sign." (See *e.g.* CMS Manual 100-4 ("Medicare Claims Processing Manual"), Chapter 1, Section 50.1.6 "When Beneficiary Statement is Not Required for Physician/Supplier Claim," subsection A "Enrollee Signature Requirements.") Ambulance services have routinely relied upon this language, which specifically grants the ambulance service provider the authority to sign "on behalf

of the patient" as a "surrogate," provided that there is adequate documentation showing that the beneficiary was unable to sign for his or herself, and that there was nobody else available to sign on the beneficiary's behalf. Ambulance providers routinely document this information and sign on behalf of the beneficiary, in accordance with the guidance outlined in the Medicare Manual.

The preamble to the proposed rule outlines several conditions that must first be established before a "surrogate" would be able to sign in lieu of the beneficiary. First, the beneficiary must be physically or mentally incapable of signing at the time of service when determining whether a substitute signature is required. This is an accurate portrayal of the current requirements of the regulation, as adopted in the Medicare Manuals, and as currently practiced by the ambulance industry. Ambulance services currently take steps to obtain a "surrogate signature" in situations where it is documented that the beneficiary is unable to sign for his or herself due to physical or mental constraints. In accordance with the Medicare Manual an appropriate surrogate signature can include a representative of the ambulance service. Second, none of the parties listed in 42 CFR§424.36(b)(1)-(5) must be available to sign. As outlined above, the ambulance service is a Medicare "provider" which is permitted to sign on behalf of the beneficiary. As a result, there is no reason to create a new portion of the rule to specifically address situations where the beneficiary is unable to sign with specific reference to ambulance transports. Third, the ambulance provider must maintain documentation in its files for four (4) years. We have no problem with any requirement that requires the ambulance service to maintain records for this period of time, as this time frame is consistent with the documentation retention requirements imposed by CMS.

The proposed regulation, however, imposes three specific additional "documentation" requirements: 1) a contemporaneous statement made by an ambulance employee present during the trip; 2) the date and time the beneficiary was transported and the name of the location at which the beneficiary was received; 3) a signed contemporaneous statement from a representative of the facility that received the beneficiary. Collectively, these "documentation" requirements create an unnecessary and onerous burden on both the ambulance service and the receiving facility (presumably a hospital), and, in light of the above, are actually unnecessary.

There is no reason to require a contemporaneous statement by the ambulance service.

There is no rational reason that a "contemporaneous statement" by the ambulance service be required. Because a representative of the "provider" is already permitted to sign the "Assignment of Benefits" Form (used by the ambulance service to capture the beneficiary's signature) on behalf of the beneficiary, there is no reason to require some "contemporaneous statement." The Assignment of Benefits Form includes a date, and most ambulance services (when signing on behalf of a beneficiary) will reference the reason that the beneficiary was unable to sign for him or herself. Further, information

included on the "narrative" portion of the "patient care report" or "pre-hospital care report" ("PCR") (which is completed by the ambulance personnel) will document the condition of the beneficiary that indicates why he or she was unable to sign for him or herself. If a beneficiary signature was not obtained, and the beneficiary was unable to sign, and nobody else was available, and such facts are documented, a "representative" of the ambulance service typically signs the Assignment of Benefits Form on behalf of the beneficiary. To require a "contemporaneous statement" from the ambulance service, as signed by the ambulance service personnel actually on the scene indicates that an employee signing the "Assignment of Benefits" Form (as permitted by the Medicare Manual in interpreting the present regulation) would be inadequate. To require some "contemporaneous statement" would in fact be redundant. There is no reason why this should be the case.

Similarly, there is no reason that the date and time the beneficiary was transported, and the location of the receiving facility must be part of any contemporaneous statement. This information is clearly part of either the "Assignment of Benefits" Form, or included on the PCR already. The PCR records the date of the transport, the time of the dispatch, the time of arrival on scene with the beneficiary, and the time of arrival at the receiving facility, as well as the name of the receiving facility. To have to repeat all of this information on a "contemporaneous statement" would be time consuming, and would merely be a repetition of information already captured at other locations on the ambulance documentation.

<u>There is no reason to require a contemporaneous statement by the receiving facility.</u>

There is absolutely no reason at all to require a signed contemporaneous statement from a representative of the receiving facility. First, this places a significant burden on the receiving hospital. The hospital personnel are already dealing with registering the patient, adhering to federal laws such as EMTALA, trying to treat and triage the patient, receiving clinical documentation from the ambulance staff, and should not have to, nor be required to complete a "contemporaneous statement" to outline that a particular beneficiary was in fact incapable of signing for him or herself. The hospital has no regulatory incentive to complete this statement. Hospital personnel may refuse to sign a statement under the erroneous belief that personal or facility financial responsibility will result. Similarly, asking the hospital to sign a statement that the patient was incapable of signing creates a slippery slope. Consider, for example, a situation where the beneficiary was incapable of signing at the time the ambulance service arrived, but was more capable at the time he or she arrived at the hospital. How is a receiving hospital supposed to document the patient's abilities or limitations during a time at which it did not personally observe the patient?

The need for a hospital employee to sign a statement confirming that the patient was in fact received and that the beneficiary was incapable of signing also implies that

the ambulance services cannot be trusted to follow the rules. Ambulance service personnel are trained to administer pre-hospital emergency care. Consequentially, as part of their training, and through patient evaluation, ambulance personnel are able to determine whether or not a patient is capable of signing. For a hospital employee to have to "verify" this finding, and to confirm that the beneficiary was actually received at the hospital greatly calls into the question the knowledge, skill, and integrity of the ambulance service personnel, a person who has dedicated his or her life to providing emergency services to the community and serving the Medicare beneficiaries that CMS strives to protect. Further, it asks the hospital personnel to make a decision about a patient at a time that person did not observe the patient.

Further, consider some additional "side effects" that could result in the event that this proposed rule is finalized. First, in the event that hospital personnel refuse to sign a contemporaneous statement does this act amount to a "refusal" for which the beneficiary may be billed? Certainly a beneficiary who was unable to sign for himself or herself, and where the hospital has refused to sign should not be held responsible for payment. Likewise, does the inability of the ambulance service to obtain the contemporaneous statement from the receiving facility preclude the ambulance service from being able to bill to or collect from the Medicare program? If so, such a penalty improperly punishes the ambulance service for the refusal or failure on the part of the hospital to sign the contemporaneous statement. Likewise, if the hospital refuses to sign the form, could efforts then be made by the ambulance service to try to get the beneficiary to sign, after the fact? If so, the ambulance is in no better a position than it is presently. It is either left trying to obtain a beneficiary signature after the fact, or would presumably be able to submit a claim for payment without the hospital's contemporaneous statement (as it presently does).

Second, shouldn't patient care by both the ambulance personnel and the hospital's emergency department be of paramount concern? At times, a hospital emergency room is grossly overcrowded. To require the hospital to sign a statement attesting that a patient was incapable of signing the ambulance Assignment of Benefits form takes precious time away from hospital staff whose focus should be on providing care to the beneficiary. If the ambulance personnel must wait until a hospital employee is available to prepare the contemporaneous statement, the ambulance is left "out of service" and unavailable to respond to other emergency calls, thereby potentially endangering other beneficiaries awaiting emergency ambulance response.

Third, why must the hospital sign the contemporaneous statement at the time the patient is presented at the ER? No other signature requirement rules require such immediacy. In fact, ambulance services typically must follow-up with beneficiaries or physicians (as in the case of the "physician certification statement" for non-emergency transports) to obtain signatures. If a "contemporaneous statement" must be made by the hospital, the ambulance should be able to at least follow-up with the hospital after the

fact, in the event that it is impossible to get the statement signed at the time the beneficiary is first brought to the ER.
There is no need to require ambulance services to obtain a patient assignment of benefits signature since ambulance services fall under "mandatory assignment.

Please also allow us to take this opportunity to offer our position as to the basic purpose of the beneficiary signature requirement. For the reasons offered below, we believe that this is an unnecessary requirement that should be abandoned. One purpose of obtaining a beneficiary signature is for the beneficiary to authorize an "assignment of benefits." However, in accordance with 42 CFR §414.605(b) all ambulance claims are automatically submitted on an "assignment related basis" under the concept known as "mandatory assignment." This regulatory requirement renders obtaining the beneficiary's signature to "assign benefits" to the ambulance obsolete. Also, though, the beneficiary signature is used as an authorization for the release of records to CMS. However, in accordance with HIPAA at 45 CFR §164.506(c)(3), a health care provider is authorized to release health care records for "payment" purposes. A provider, such as an ambulance service, is clearly permitted, and in fact authorized, to release beneficiary information, without the beneficiary's permission, for payment purposes. Since CMS serves as the payer of the ambulance claims, release of any beneficiary records is clearly permitted, if not required, for payment purposes, and should not require a beneficiary signature. In short, therefore, requiring the beneficiary's signature for ambulance transports serves no true purpose.

Alternatively, since CMS is contemplating making a change to the signature rule with respect to ambulance services, please consider modifying the signature rule for emergency transports only. In other words, the signature requirements should be relaxed in emergency situations, where the beneficiary is under duress, and may be unable to sign for him or herself. The reasons for this are multiple. First, please note that the HIPAA regulations recognize that in emergency situations, the health care provider (such as ambulance services) is not required to obtain a signed acknowledgement from the beneficiary that the Notice of Privacy Practices was received. A similar exception could be made with respect with the need to obtain a beneficiary signature to assign benefits. Second, seeking a beneficiary signature, or trying to obtain the signature of a surrogate in emergency situations places a large burden on the beneficiary or the surrogate. In emergency situations where patient care should be of paramount concern, spending time and effort in trying to capture a beneficiary signature is unnecessary. This would relieve the beneficiary of the responsibility to sign during emergency situations, and allow the crew to attend to the needs of the patient instead of focusing on trying to capture a signature. Third, the ambulance service does not have an extensive patient registry process, the way a hospital or nursing home does. The ambulance crew is with the patient for a limited amount of time, and in emergency situations, that time is spent on lifesaving measures. The ambulance services do not have the staff or the time to spend extensive time to follow-up with each and every emergency patient that it transported to try to

obtain a patient signature, and does not have the luxury (unlike the hospital) of being able to visit the beneficiary's hospital bed to obtain additional information.

Conclusion.

In conclusion, adequate safeguards already exist to ensure that a patient signature, or a proper "surrogate" signature is obtained. We are of the opinion that the proposed change in the regulation is unnecessary. Ambulance services presently obtain patient signatures or appropriate surrogate signatures in accordance with the language of the current regulation and Medicare Manuals. In an effort to attempt to be "sympathetic to the concerns of ambulance providers and suppliers" CMS has proposed a requirement that is burdensome to both ambulance services and hospitals alike by adding more steps to a procedure already practiced by the ambulance industry- that of obtaining patient signatures, or in certain situations, appropriate surrogate signatures.

Additionally, since the patient signature rule is being considered, please consider removing completely the patient signature requirement, or in the alternative, at least relaxing the patient signature requirement in emergency situations. This would resolve the apparent problem facing the ambulance services that prompted CMS to propose the signature rule in the first place.

We appreciate the opportunity to offer our comments on the proposed rule.

Very truly yours,

/s/ Stephen R. Wirth
Stephen R. Wirth

/s/ Douglas M. Wolfberg
Douglas M. Wolfberg

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

Organization :

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15040-Attach-1.DOC

1560

NARA
NATIONAL ASSOCIATION OF REHABILITATION PROVIDERS AND AGENCIES

12100 Sunset Hills Road
Suite 130
Reston, Virginia 20190
(703) 437-4377
FAX (703) 435-4390
www.naranet.org

August 31, 2007

Mr. Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1398-P
P.O. Box 8018
Baltimore, MD 21244-8018

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

PHYSICIAN SELF-REFERRAL ISSUES

Dear Administrator-Designate Weems:

These comments are submitted on behalf of the National Association of Rehabilitation Providers and Agencies ("NARA"). NARA's members are Medicare-certified rehabilitation agencies and comprehensive outpatient rehabilitation facilities which provide physical therapy, occupational therapy, and speech-language pathology services to tens of thousands of Medicare beneficiaries annually. Physician referral issues have long been of great concern to NARA's members and they are very appreciative of the opportunity to comment on those matters set forth in the Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 which were published in the Federal Register on July 12, 2007.

NARA is of the view that the "In-Office Ancillary Services Exception" to the prohibition on physician self-referral has created opportunities and incentives for physicians to devise arrangements through which physicians refer their patients to physical therapy providers in which they have a financial interest. For this reason, NARA recommends that the Centers for Medicare and Medicaid Services ("CMS") promulgate a rule or other enforceable standard that eliminates physical therapy as a designated health

service which is permissible under the in-office ancillary services exception. NARA advances this recommendation for several reasons:

First, Medicare's requirement that a patient receive a referral from a physician before seeking physical therapy care grants physicians the exceptional power to direct referrals to specific physical therapy providers and away from others. Furthermore, the financial pressures experienced by many doctors as a result of payment reductions by public and private payors (as well as a myriad of other factors) creates a powerful incentive for them to exercise their referral authority to direct their referrals to entities in which they have a financial interest. In this way, the referrals become an additional source of revenue for the physician.

Second, Medicare's referral requirement diminishes competition for physical therapy services in the health care market to the detriment of patients, payors, and physical therapists. NARA's members are cognizant of efforts by some physicians and doctors groups to present physical therapists with the option to either join the physician practice as an employee or contractor or be denied any further referrals from the physician or group. Under such circumstances, it is extremely difficult, and often impossible, for physical therapists who have their own practices to compete for patients and remain in business. As a result, patients have fewer physical therapists from which to choose their caregiver.

Third, physician-owned physical therapy services frequently result in higher utilization of therapy services and increased costs. For example, a study of such services published in the Journal of the American Medical Association in 1992 reported that both gross and net revenue per patient were 30 to 40 percent higher in facilities owned by referring physicians and that visits per patient were 39 to 45 percent higher in such facilities. (Mitchell JM, Scott E. Physician Ownership of Physical Therapy Services: Effects on Charges, Utilization, Profits, and Service Characteristics. JAMA. 1992; 268: 19-23). The New England Journal of Medicine also published a report which demonstrated that physical therapy costs incurred by the California Workers' Compensation Program where higher when the care was rendered by physician-owned physical therapy providers. (Swedlow A, Johnson G, Smithline N, Milstein A. Increased Costs and Rates of Use in the California Workers Compensation System as a Result of Self-Referral by Physicians. N Engl J Med. 1992; 327: 1502-1506).

Fourth, the HHS Office of Inspector General ("OIG") has consistently identified material problems with the provision of physical therapy services in physicians' offices. In 1994, the OIG found that nearly 78 percent of physical therapy provided in doctors' offices did not meet the Medicare definition of "physical therapy" services. (U.S. Department of Health and Human Services, Office of Inspector General, Physical Therapy in Physician's Offices March 1994)). More recently, in May 2006, the OIG reported that 91 percent of physical therapy billed by physicians during the first 6 months of 2002 did not meet Medicare's requirements, resulting in improper payments of $136 million. A medical review of the claims concluded that 34 percent of the care that had been provided was undocumented, 26 percent was not medically necessary, and 57

percent was furnished without a plan of care or without a documented plan of care. (US Department of Health and Human Services, Office of Inspector General, Physical Therapy Billed by Physicians (May 1, 2006)).

It is NARA's belief that the in-office ancillary services exception to the federal self-referral prohibition has encouraged some physicians to craft referral arrangements that are purposely designed to take advantage of the exception and that these arrangements may be harmful to patients, Medicare, and physical therapists who must compete in the marketplace in the face of such arrangements. The true solution to this problem is to remove physical therapy as a service which may be excepted from the Stark self-referral proscription. There is precedent for this course of action: the in-office ancillary services exception is not applicable to durable medical equipment or parenteral and enteral nutrients. See Section 1877(b)(2) of the Social Security Act. Accordingly, NARA recommends that CMS modify its rules to ensure that physical therapy is no longer a designated health service which may be excepted from the referral ban under the in-office ancillary services exception.

Sincerely,

Gregg Altobella
President

Submitter : **Dr. Nalini Sehgal** **Date: 08/31/2007**

Organization : **Uni Wisconsin Hospital and Clinics**

Category : **Physician**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

comment letters regarding "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008."

Submitter : Mr. Gregg Nibbelink **Date:** 08/31/2007

Organization : McDaniel College

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam,
My name is Gregg Nibbelink and I am the head athletic trainer at McDaniel College. My responsibilities are to evaluate, care, rehabilitate athletic injuries and return athletes to activity. I am in charge of a small sports medicine staff that is comprised of a total of 5 athletic trainers that have followed accredited college programs and subsequently passed a national ceritification exam. I received my undergraduate degree from Towson State University (86) and my Masters from Ohio University (89).

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

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

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry; therefore, it is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially in rural areas, to further restrict their ability to receive those services. The standards currently employed by hospitals to staff positions allows for patients to receive excellent, cost-effective treatment.

Since the CMS seems to have come to these changes witout clinical or financial justification, I would strongly encourage the CMS to consider recommendations of thse professioanls 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.

I would be unconscionable to prohibit qualified health care professionals from delivering care to those in need. It is equally disturbing that services would be restricted to those who truly need it, because of politics.

Sincerely,
Gregg Nibbelink, MS, ATC
Head Athletic Trainer
McDaniel College

Submitter : Mrs. Kristin Swartz **Date:** 08/31/2007

Organization : Mrs. Kristin Swartz

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer working in a primary care physician office for the past 6 years. I have been a victim of Medicare regulations in the past, losing my job of eight years at a hospital affiliated outpatient rehabilitation clinic.

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

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

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

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

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

Sincerely,

Kristin M. Swartz, ATC

Submitter : Dr. Maxim Gorelik **Date:** 08/31/2007

Organization : Advanced Pain Management

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1385-P-15044-Attach-1.DOC

1SC-141

ADVANCED PAIN MANAGEMENT

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

August 31, 2007

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

Re: CMS-1385-P

Dear Mr. Weems:

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

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

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

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

RESOURCE-BASED PE RVUs

ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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

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

ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***

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

Sincerely,

Sincerely,

Maxim Gorelik, MD
Advanced Pain Management
4131 W Loomis Road
Greenfield, WI 53221

Submitter : Ms. Patricia Sellner **Date:** 08/31/2007

Organization : National Athletic Trainers Association

Category : Other Practitioner

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am a certified athletic trainer who works very hard works in a high schools setting> I am the only health care professional in this district. I rely on the expertise of many certified athletic trainers who work in rehab clinics and physicians offices. The care given by these professions in the clinical settings is essential to the student athletes I treat. The level of care and professionalism shown by these professionals is important in the recovery of all the patients they care for there. Please preserve their ability to practice in the clinical setting. They have insight into many areas of rehabilitation that our aging population needs as we continue to be active as we ages. Please maintain this area of practice for the certified athletic trainer.

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

Organization : Society of Gynecologic Oncologists

Category : Physician

Issue Areas/Comments

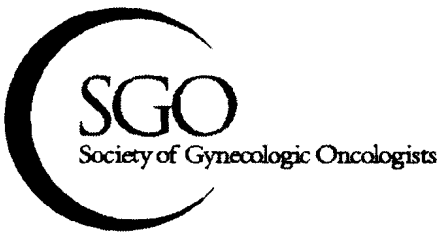
GENERAL

GENERAL

Greetings - Please "See Attachment" for the comment letter from the Society of Gynecologic Oncologists addressing practice expense, work adjustor, compendia, PQRI, and 2008 Payment Rates.

CMS-1385-P-15046-Attach-1.DOC

15046



August 31, 2007

Mr. Herb Kuhn
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8010
Baltimore, MD 21244-8010

Delivered via http://www.cms.hhs.gov/eRulemaking/01_Overview.asp

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

Dear Mr. Kuhn:

On behalf of the Society of Gynecologic Oncologists (SGO), we are pleased to submit comments in response to Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2008 and other Changes to Payment under Part B. The SGO is a national surgical specialty society of physicians who are trained in the comprehensive management of women with malignancies of the reproductive tract. Its purpose is to improve the care of women with gynecologic cancer by encouraging research, disseminating knowledge which will raise the standards of practice in the prevention and treatment of gynecologic malignancies, and cooperating with other organizations interested in women's health care, oncology and related fields. SGO is the leading organization of gynecologic oncologists in the United States.

Our comments will address CMS' proposals regarding practice expense, budget neutrality, compendium, PQRI, and Medicare 2008 Payment Rates.

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

A. Equipment Use Rate

SGO agrees with CMS that the 50 percent utilization rate for medical equipment is appropriate for equipment used as part of office-based surgical procedures. For surgical specialties, procedure-specific equipment such as a LEEP machine used for the removal of abnormal cervical cells may be in use approximately one or two days a week, depending on the service mix of a specific office. In general for surgical specialties, surgeons spend two days at the hospital performing inpatient and outpatient surgical procedures. Surgeons then usually spend another two days performing office-visits to

follow-up on patients that have already received surgery and to conduct visits to prepare a patient for surgery. Most surgeons perform office-based or minimally invasive surgical procedures that use procedure-specific equipment one day a week or approximately 20% of their practice time.

The American College of Obstetricians and Gynecologists (ACOG) has conducted a survey of a group of its members regarding their use of ultrasound equipment, a fairly common piece of equipment in an ob/gyn's office SGO urges CMS to not assume that higher utilization found by MedPAC for some types of imaging equipment is automatically similar for all types of imaging equipment – i.e. ultrasound - or for other types of equipment. Instead, CMS needs to use specialty and code specific data, such as ACOG's survey, to answer these types of questions in the future.

B. Changes to PE Inputs in Ob/Gyn Codes

SGO commends CMS for making changes to the content and price of the pelvic exam pack by adding in a sterile drape and its cost. Also, SGO commends CMS for standardizing the equipment used in post-operative follow-up visits to include both a power-table and a fiber-optic lamp. It is important that gynecologic oncologists be able to account for the additional cost incurred to their practice by using a power table with stirrups and a fiber-optic lamp to assess healing of the reproductive tract.

II. "Coding – Additional Codes From Five-Year Review"

A. Use of a Work Adjustor for Budget Neutrality

SGO is concerned about the continued negative impact of the last five-year review on the pool/distribution of work RVUs per specialty, and then per code. The impact of the proposed 32% increase in work RVUs for anesthesia codes would again, by law, require CMS implement a proposed budget-neutrality adjustor of approximately 11.8 percent. SGO urges CMS to re-consider this proposal and instead apply the budget neutrality adjustor to the physician fee schedule conversion factor.

Applying the budget-neutrality adjuster to the work RVUs is contrary to long-held CMS policy. In the past, when CMS applied a budget neutrality adjustor to the work RVUs, it caused considerable confusion among many non-Medicare payers, as well as physician practices, that adopt the resource-based relative value scale (RBRVS). CMS later acknowledged the confusion and ineffectiveness of applying the budget neutrality adjustor to the work RVUs. However, going back to this practice means that many non-Medicare payers have now figured out how to apply the budget neutrality adjustment to the work RVUs proposed in Addendum B and thus they too are taking these reductions, even though they are not subjected to any budget neutrality laws.

Furthermore, constant fluctuations in the work RVUs due to budget neutrality adjustments impede the process of establishing work RVUs for new and revised services. In recognition of these difficulties, CMS has been applying budget neutrality adjustments, due to changes in the work RVUs, to the physician fee schedule conversion factor since 1998 and needs to revert back to this practice for 2008.

III. "Drug Compendia"

The discussion in this rule regarding the process for deciding and listing future compendia appears to be appropriate; however, it is even more important that CMS immediately add at least one new compendium.

The SGO joins with the AMA, ASCO, and the American Cancer Society in urging CMS to officially add the NCCN Drugs and Biologics Compendium, published by the National Comprehensive Cancer Network (NCCN), to the list of recognized compendia to determine the medical acceptability of an off-label use of a drug or biological in an anti-cancer chemotherapeutic regimen as soon as possible.

As CMS is aware, the American Medical Association Drug Evaluations (AMA-DE) is no longer in publication. The United States Pharmacopeia – Drug Information (USP-DI) will cease publication under that name in 2007, and any successor publication is unknown at this time. Thus, only the American Hospital Formulary Service – Drug Information (AHFS-DI) will remain as a recognized and previously evaluated compendium for coverage of off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen.

No single compendium is sufficiently comprehensive or timely to list all relevant off-label indications, and it is counter to Medicare cancer patients' best interests to rely on a single compendium. Thus, the current situation is unsatisfactory and needs to be rectified by both the addition of new compendia by the Secretary and greater reliance on peer-reviewed medical literature, such as the journals affiliated with various specialty societies that treat cancer patients, an example being the journal of the SGO, Gynecologic Oncology, to determine the medical acceptability of an off-label use of a drug or biological in an anti-cancer chemotherapeutic regimen.

As discussed in the CMS' proposed rule, MedCAC extensively evaluated current and potential compendia for coverage of off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen at its meeting of March 30, 2006. While none of the compendia fully satisfied all of the desirable characteristics identified by MedCAC, the NCCN Drugs and Biologics Compendium scored highest on all of the criteria used by the Committee to define a robust and evidence-based compendium.

Given the need for additional compendia under Section 1861(t) (2) (B) of the Act, the widespread support for recognition of the NCCN Drugs and Biologics Compendium, and the very positive evaluation of this compendium by the MedCAC, the SGO urges the agency to immediately add the NCCN Drugs and Biologics Compendium to the list of recognized compendia to determine the medical acceptability of an off-label use of a drug or biological in an anti-cancer chemotherapeutic regimen.

IV. TRHCA – Section 101(b) – PQRI

A. Clarification between process for measure development and for measure approval

SGO appreciates CMS using this proposed rule in an attempt to provide greater clarity regarding the role of a consensus organization in both the measure development process and the measure approval process. SGO believes it is very important to the future of the PQRI program and the quality movement to have better, more complete definitions regarding

what constitutes an appropriate venue and organizations and processes for these roles. SGO also believes that it is imperative that PQRI measures be generated for the purposes of development and then submitted and endorsed for the approval process by physician specialty societies and organizations.

Because this is a dynamic process defining characteristics of a consensus organization, and having CMS continually updating a list of organizations that meet these characteristics will enhance transparency and will enable more physician societies to participate in the process through the various organizations. We urge CMS to meet with the quality improvement leaders of the physician societies and organizations to define the characteristics of "approved" consensus measure development groups and consensus measure approval groups.

B. The Need for Greater Transparency Regarding the Process

We want to bring to CMS' attention the need for greater transparency and for, structured governance of some of the consensus organizations, such as the AQA. Without a concrete governance system, there is a lack of rigorous and scientific evaluation and arbitrary decisions regarding some measures that may be in the 2007 program and now may not be in the 2008 program. Having physicians gear up to report measures for six months and then no longer will produce no robust data and leads to frustration, , and a lack of interest in participation in future quality improvement projects. . Thus CMS should ensure that once a measure is on the list, it will stay on the list of approved measures for at least a specific number of years, versus just six or 12 months.

C. Structural Measures Currently Under Development

The SGO encourages CMS to consider participation in a physician society developed patient outcomes registry as a structural measure, even to the point that it would be considered, "a super measure". With such a "super measure" participation in the registry, assuming the data could be accessed by CMS would be considered successful participation in PQRI. The type and level of data sets that are included in these patient registries can provide CMS with data regarding patterns of quality care for specific indications that will never be realized with the type of reporting currently contained within the PQRI program.

D. Using a Medical Registry to Submit Data

Given that in the future there may be instances where SGO members who participate in a registry may be reporting data through that registry to satisfy a PQRI quality measure, we wanted to bring the following concerns to CMS' attention: 1) the data would have to be free of any information that could be used to identify the patient; 2) CMS would need to work with the existing registries regarding forms and processes used for patient consent regarding how the data could be used; 3) A method to export the data by individual record would have to be developed that

allows either physicians or patients to decide not to have their data shared with CMS; and 4) Physicians must be in control of their data at all times. That being said, the SGO is extremely interested in working with CMS to develop such a patient data registry reporting system.

V. Medicare Physician Payment Rate for 2008

In 2008, physicians and other health care practitioners whose payment rates are tied to the physician fee schedule face a 10% payment rate cut. The SGO urges CMS to work with Congress to avert this cut and ensure that physician payment updates for 2008 and subsequent years accurately reflect increases in medical practice costs.

Payments to physicians in 2007 are essentially the same as they were six years ago in 2001. Due to the SGR, physicians now face drastic Medicare payment cuts totaling almost 40% over the next eight years. Yet, during this same time period, the Medicare Economic Index (MEI), which measures increases in medical practice costs, is expected to increase by about 20%. Physicians cannot absorb these draconian cuts.

Only physicians and other health professionals face steep cuts under this flawed payment formula. Other providers, such as nursing homes and hospitals have payment updates that reflect the cost of inflation. Further, the 10% cut in payment rates facing physicians is in stark contrast to Medicare Advantage (MA) plans, which are paid on average 112% above the cost of traditional Medicare, with a significant number of MA plans paid from 120% to more than 150% of traditional Medicare. These overpayments are shortening the life of the Medicare trust fund.

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If the SGO can provide CMS with additional information regarding this matter, please do not hesitate to contact Jill Rathbun, SGO Director of Government Relations at 703-486-4200.

Sincerely,

Carol L. Brown, MD
Carol L. Brown, MD
Chair, Government Relations Ctme.

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

Organization : WEST ASHLEY HIGH SCHOOL

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 for a high school in Charleston, SC. I attended a private university in Cleveland, TN then obtained my Masters Degree at East TN State University. I have been in this profession for 10 years and greatly enjoy the career path that I have chosen.

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,

Solmaz Z Chadwell, ATC/MA

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

Organization : **Miss. Amanda Phillps**

Category : **Other Health Care Provider**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
I am a recent graduate and a newly certified athletic trainer. I have completely a very practically based program, including internships that encompassed on field and clinical care, to become more than proficient at injury recognition, treatment, management, and rehabilitation. I am currently working through a clinical outreach program as a high school athletic trainer. I am responsible for the care of more than 150 high school football players and take pride in my ability to care for these athletes' well-being.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Amanda Phillips, ATC

Submitter : **Ms. Erin Dunn** **Date: 08/31/2007**

Organization : **California Institute of Technology**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am an Assistant Athletic Trainer at the California Institute of Technology in Department of Athletics and Recreation. I provide athletic training services to all intercollegiate athletes, as well as the general student population, faculty and staff. I obtained my Bachelor of Science in Athletic Training, and my Master of Science in Biokinesiology. I am a certified and licensed athletic trainer, as well as a certified strength and conditioning specialist. Prior to my position at the California Institute of Technology, I was a staff athletic trainer at the USC University Hospital in Los Angeles, CA.

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

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

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

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

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

Sincerely,

Erin J. Dunn, MS, ATC, LAT, CSCS

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

Organization : **Apex Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

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

Subject: Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule
Dear Mr. Weems:
I am an independent physical therapist in the Spokane area of Washington State, and I wish to comment of the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the in-office ancillary services exception. These comments are intended to highlight the abusive nature of physician-owned physical therapy services and support PT services removal from permitted services under the in-office ancillary exception.
I have been a physical therapist in a private, outpatient physical therapy clinic since 2003. During this time, our clinic has had a good working relationship with the local physicians and referral source; however, in the past 2 years, these local physicians have begun their own physical therapy clinics and have forced their patients to utilize only those services.
Examples of abusive arrangements our clinic has noted include patients who are encouraged strongly by their physician or health care provider to attend physical therapy only at the physician s physical therapy clinic. A frustrated Medicare patient told me that he was encouraged strongly to attend physical therapy at the physician s owned clinic which was approximately a 30 minute drive from his home. Unfortunately, there are eleven independent physical therapy clinics within five to fifteen minutes from this patient s home. The patient refused to drive 30 minutes and the physician s staff reluctantly gave this patient our clinic s name. Another patient seen by the same physician group was instructed that further testing, to include x-rays, was being delayed because our clinic documentation was not readily available. She was also told that had she attended physical therapy at the physician s physical therapy clinic the delay would not have occurred. This statement was misleading, because all clinical documentation was available to the physician and was located in the patient s chart which was located in the exam room.
Many patients do not know that they have a choice as to the physical therapy clinic that they attend. Patients who already have a history or a relationship established with a certain clinic have been told that the physician would prefer that they discontinue that relationship and attend therapy at the physician s physical therapy clinic. The inability to attend physical therapy at a clinic of the patient s choosing is poor care and is abusive.
I do feel the in-office ancillary services is defined so broadly in the regulations that it facilitates the creation of abusive referral arrangements. Because of Medicare s referral requirements, these local physicians have a captive referral base of physical therapy patients in their offices.
I would like to thank you for your consideration into this matter. I hope that these issues can be resolved in the Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule.
Sincerely,

Lindsey Masiarek, MPT
Apex Physical Therapy, PLLC
1111 E. Westview Ct. Ste A
Spokane, WA 99218