Submitter : **Dr. James Merrell** **Date: 08/31/2007**

Organization : **Cardiovascular Anesthesiologists, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Submitter : **Mr. Byron Miller** **Date: 08/31/2007**

Organization : **N/A**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a professional gentleman with 30 years in the education field and over 25 years as an Athletic Trainer. As an Athletic Trainer, I am certified by the NATA and hold state licensure in North Carolina. I have taught in the United States in the elementary, middle school, high school and community college levels. I have taught for several years out side the United States as well. I am currently teaching Adapted Physical Education on a k-12 system and serving as the head athletic trainer for a large high school in North Carolina. I work closely with Physical and Occupational Therapists in my teaching duties and with medical professionals in my athletic training duties. 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,

Byron Miller, ATC, LAT

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

Organization :

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Thank you for the opportunity to submit comments on the Physician Self-Referral Provisions of CMS-1385-P entitled Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008. I am a board-certified pathologist and a member of the College of American Pathologists. I practice in Rockville, MD as part of a pathology practice which services four hospitals in Maryland and has an outpatient anatomic pathology laboratory.

I applaud CMS for undertaking this important initiative to end self-referral abuses in the billing and payment for pathology services. I am aware of arrangements in my practice area that give physician groups a share of the revenues from the pathology services ordered and performed for the group s patients. My prior job was at a laboratory which is involved in such arrangements, so I have seen how the potential for abuse can negatively affect the practice of pathology and medicine as a whole. I am certain that these arrangements are an abuse of the Stark law prohibition against physician self-referrals and I support revisions to close the loopholes that allow physicians to profit from pathology services.

Specifically I support the expansion of the anti-markup rule to purchased pathology interpretations and the exclusion of anatomic pathology from the in-office ancillary services exception to the Stark law. These revisions to the Medicare reassignment rule and physician self-referral provisions are absolutely necessary to eliminate financial self-interest in clinical decision-making. I believe that physicians should not be able to profit from the provision of pathology services unless the physician is capable of personally performing or supervising the service.

Opponents to these proposed changes assert that their captive pathology arrangements enhance patient care. I agree that the Medicare program should ensure that providers furnish care in the best interests of their patients, and, restrictions on physician self-referrals are an imperative program safeguard to ensure that clinical decisions are determined solely on the basis of quality. The proposed changes do not impact the availability or delivery of pathology services and are designed only to remove the financial conflict of interest that compromises the integrity of the Medicare program.

Sincerely,
David E. Kardon, MD

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

Organization : American College of Surgeons

Category : Physician

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

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As discussed in the CY 2007 PFS final rule with comment period, CMS deferred for one year the decisions on proposed changes to the work RVUs for a number of codes from the 5 Year Review, either because they had not yet received a recommendation from the RUC or because CMS suggested that the RUC re-evaluate the original recommendation. These additional codes are still considered part of the 5 Year Review. CMS proposes to accept all of the RUC recommendations, with the exception of CPT code 93325 Doppler color flow add-on which CMS proposes to bundle. These recommendations include:

" Increased work RVUs for 10 of 11 proctosigmoidoscopy codes
" Decreased work RVUs for seven of nine anoscopy codes
We appreciate CMS willingness to consider work value adjustments for these codes as part of the most recent 5-year review of relative values. While we might have minor disagreements about the work values being proposed for a few of the protosigmoidoscopy and anoscopy codes, we generally believe that the RUC process was fair and, therefore, we appreciate CMS consideration of the RUC s recommendations.

CMS also proposes to accept a RUC recommendation to increase the work values for anesthesia services by about 32 percent. This recommendation is based on work done by the RUC s anesthesia workgroup. This workgroup used a linear regression model developed by the American Society of Anesthesiologists to value the work of the post induction period time. For other anesthesia service components, the workgroup used a building block approach, applying the results from a survey of 19 anesthesia codes.

CMS proposes to offset the increases in the work of anesthesia services by additional adjustments to the PFS budget neutrality adjustor for work. CMS estimates that the increase in the anesthesia conversion factor would result in an additional 1.0 percent increase in the budget neutrality adjuster for work. To offset the net increases in work values proposed by CMS, including those for anesthesia services, CMS is proposing a revised work adjustor of approximately 0.8816, which would correspond to a decrease of 11.84 percent for all work RVUs.

The magnitude of the proposed increase for anesthesia services and its impact on the work value adjuster causes us again to question the wisdom of achieving budget neutrality through an adjuster for work instead of through adjustments to the conversion factor. We continue to believe very strongly that it is confusing and even misleading to publish work values in Addendum B of the proposed rule and elsewhere that are not real or true for Medicare because they are adjusted downward by a budget neutrality factor prior to payment being made. We also believe that the magnitude of the net work value increases approved during the latest 5-year review, together with the use of a budget neutrality adjuster for work, has seriously and inappropriately disadvantaged services that were not reviewed during this 5-year review particularly those services with a relatively large proportion of their RVUs in the physician work component. We believe that a number of services that may have appeared to be properly valued at the beginning of the 5-year review process (when compared to work values in place at that time for the full range of physicians services) and therefore not recommended for re-examination, are no longer fairly valued in comparison to services that received significant work value increases. In other words, we believe that the relativity of the system has been seriously distorted and that this has been made worse by use of a budget neutrality adjuster for work. We, once again, urge CMS to reconsider the use of this adjuster.

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

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Under the multiple procedure payment reduction policy, reimbursement for subsequent surgical procedures performed during the same operative session by the same physician is reduced by 50 percent. The Mohs micrographic surgery codes have been exempt from the multiple procedure payment reduction rules since the inception of the PFS. The current RVUs developed for each Mohs micrographic surgery base code are based on an assumption that each code is performed separately. CMS does not believe these codes should continue to be exempt from the multiple procedure payment reduction because the RVUs for these services do not take into account the efficiencies that occur when multiple procedures are performed in one session. Therefore, CMS proposes to apply the multiple procedure payment reduction rules to these codes.

We support this change and believe it is fair and consistent with CMS multiple procedure payment policies already affecting a wide range of procedures with codes in the Surgery/Integumentary System section of CPT.

Coding--Reduction In TC For Imaging Services

Coding--Reduction In TC For Imaging Services

As required by Section 5102(b)(1) of the Deficit Reduction Act of 2005 (DRA), CMS caps the technical component (TC) of the PFS payment amount for imaging services (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). The DRA defines imaging services as imaging and computer assisted imaging services, including X ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.

Certain ophthalmologic procedures were not included in the original list of services believed to meet the DRA definition of imaging procedures, but CMS is now proposing to add the following six procedures to the list of those subject to the OPPS cap, effective January 1, 2008:

Code Description
92135 Scanning computerized ophthalmic diagnostic imaging (e.g., scanning laser) with interpretation and report
92235 Fluorscein angioscopy (includes multiframe imaging) with interpretation and report
92240 Indocyanine-green angiography (includes multiframe imaging) with interpretation and report
92250 Fundus photography with interpretation and report
92285 External ocular photography with interpretation and report for documentation of medical progress (e.g., close-up photography, slit lamp photography, goniophotography, stereo-photography)
92286 Special anterior segment photography with interpretation and report; with specular endothelial microscopy and cell count

The College strongly opposes the addition of the six ophthalmic procedures to the list of imaging services subject to the DRA payment cap. We believe that CMS' initial decision with respect to these codes was the correct one. We do not believe that procedures involving photographic equipment or an angioscope (a type of microscope) can be considered 'imaging' for purposes of the DRA provision any more than other procedures involving the use of microscopes or other forms of magnification should be so considered. None of the six ophthalmic procedures in question could reasonably be classified as X ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy. Therefore, we urge CMS to reconsider this proposed change.

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

In the proposed rule, CMS has identified and is soliciting comments on three possible payment locality reconfigurations, each of which strikes a different balance between intra-locality variations and the redistributive impacts. CMS is considering adopting one of these approaches for California in the final rule and would evaluate the impacts in California before considering a broader application of the policy in the future.

First, we unhesitatingly endorse CMS plan to proceed cautiously before deciding whether to apply any new payment locality methodology outside of California, and only after a very thorough assessment of the impact the new methodology would have on all stakeholders in California. We worry, for example, that changes to payment localities, either in multiple or single locality states, could negatively impact rural areas, by reducing Medicare payments and thereby increasing the risk of physician flight from those areas. A June 2007 report by the Government Accountability Office (GAO) acknowledges this potential problem. A new payment locality methodology, applied broadly, could also impose a significant administrative burden on CMS, Medicare contractors, and physicians and their office staff. And any new methodology will, by definition, produce redistributive effects, which are especially worrisome given continuing uncertainties regarding future updates to the conversion factor under the Medicare PFS. For example, we note that the redistributive effects of Option 3 in California would range from +7.6 percent for one county to -7.3 percent for 14 counties. In our view, any redistributive effects that are more than de-minimus should be phased in over several years. Finally, we believe that any broad application of a new payment locality methodology should be accompanied by a firm commitment to re-examine the reasonableness of the new locality configuration at least every 5 to 10 years.

In terms of the specific options under consideration, we wonder whether any county-based analysis will be sufficiently robust to support fair and reasonable adjustments to the existing payment locality configurations. CMS itself, in commenting on the June 2007 GAO report mentioned above, notes that the data that would be used in calculating county-level GAFs for more than 90 percent of counties is actually based on information gathered for larger geographic areas since, for example, Census data are available only for a limited number of counties. Yet such county-level GAF calculations would necessarily be a part of any of the options CMS is considering. In this regard, we wonder especially what the significance of current data limitations might be under Option 3 where the resulting localities would be allowed to include non-contiguous counties from across a given state.

In sum, at this time, we are unable to offer unqualified support for any of the options CMS is considering, or to suggest an alternative methodology. However, we look forward to working with CMS on the payment locality issue and to learning more about the impact of any potential change to the locality configuration in California.

Malpractice

Malpractice

CMS is seeking input on how to address the apparent anomaly in the PLI values assigned to technical component (TC) and professional component (PC) services, in which TC codes may be assigned higher PLI RVUs than the PC codes. Two proposed methods--swapping PC and TC PLI RVUs or adjusting the PLI components of TC and PC services until their RVUs are equal--have been rejected by CMS on methodological grounds.

The College has been following the work of the AMA/Specialty Society RVS Update Committee (RUC) PLI Workgroup and agrees that it does not seem possible to separately identify professional liability costs for technical professionals. Indeed, we believe that these costs are covered by the general practice setting liability insurance and so should already be included in payments made in both the facility and physician office settings. Consequently, we concur with the PLI Workgroup recommendation that CMS should reduce the PLI technical component to zero. The PLI RVUs should then be recalculated to ensure that they are redistributed across all physician services. This would be accomplished by modifying the budget neutrality adjustment applied as the last step in the methodology of assigning PLI RVUs. The total pool of available PLI RVUs would not change as a result of this proposal.

Physician Self-Referral Provisions

Physician Self-Referral Provisions

While CMS is not proposing to change the in-office ancillary exception (IOAE), we share concerns expressed by others about some of the language used to characterize the use of this exception. For example, CMS refers to hundreds of letters from physical therapists and occupational therapists that the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices without elaborating on the propriety or harm of this activity. In fact, when PTs and OTs work in a medical practice, patients have more provider options, potentially greater convenience, and often greater comfort knowing that their PT and OT works elosely with their physician.

We request that CMS elaborate on its concerns in this area, engage in discussions with stakeholders on this issue, and analyze whatever data may exist to determine the relative cost-effectiveness of PTs and OTs in medical practiees and in other settings.

Resource-Based PE RVUs

Resource-Based PE RVUs

As part of the calculation of the practice expense (PE) equipment costs, the Centers for Medicare & Medicaid Services (CMS) assumes equipment is in use 50 percent of the time a physician's office is open. In the proposed rule, CMS acknowledges that it does not have sufficient empirical evidence to justify an alternative assumption and proposes no change at this time.

Like others, we suspect strongly that a uniform 50 percent utilization rate may be too low. However, we agree with CMS that insufficient information currently exists to adopt an alternative utilization assumption with respect to equipment. We further urge CMS not to assume that data relating to the utilization of one type of equipment could be fairly applied to other types of equipment. In sum, we recommend that CMS continue to proceed in a careful and thorough manner in its evaluation of equipment utilization.

TRHCA--Section 101(d): PAQ1

TRHCA--Section 101(d): PAQ1

TRHCA requires the Secretary to establish a Physician Assistance and Quality Improvement Fund (PAQI) to be available for physician payment and quality improvement. The statute appropriates $1.35 billion for this purpose in 2008. CMS notes that these funds may be used to buy down the scheduled 10 percent negative update to the physician fee schedule or to support a quality improvement program. The proposed rule indicates that CMS intends to use these funds to extend the PQRI for another year on the same basis as in place for the last 6 months of 2007. Funds from the PAQI Fund would be used to pay bonuses to physicians who satisfy the reporting performance standards. The rule estimates that the bonus payments would be between 1.5 percent and 2 percent of allowed charges for 2008 with payments actually made early in 2009. CMS states that reducing the scheduled negative adjustment to the fee schedule conversion factor is not feasible because of the fixed pool of funds available ($1.35 billion), although it estimates that if the entire amount were applied to reduce the negative update it would fall by 2 percentage points.

The College does not support CMS decision to use the Physician Assistance and Quality Improvement Fund (PAQI) for PQRI bonuses in 2008 (paid in 2009). We strongly believe that addressing the projected 9.9% cut in the physician fee schedule is a more appropriate use of the funds available and provides a greater incentive for continued participation in the Medicare program. It has been shown that improved quality can lead to greater efficiency and cost savings in health care delivery, therefore it is appropriate to continue to fund the PQRI bonus program from the Medicare Trust Fund and direct PAQI funds to minimizing the anticipated reduction in the physician fee schedule.

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

The College also strongly supports CMS plans to evaluate and test mechanisms for collecting quality measures from patient data registries as an alternative to submitting data through the claims processing system. Of the options proposed for testing, we believe option 3 where the data registry calculates and reports the quality information--presents the least opportunity for compromising beneficiary medical information and is most closely aligned with the intent of registry reporting. Clinical data and outcomes data captured in registries presents the best available alternative for moving beyond process measures and claims-based reporting to begin to measure true outcomes of care, and we encourage CMS to pursue these possibilities much more aggressively. Surgical care is particularly well-suited to outcomes measurement through data registries. The College currently has multiple operational data registries and a collaborative data registry development project underway through the Surgical Quality Alliance. We welcome the opportunity to collaborate with CMS in the testing of registries for reporting to the PQRI program.

We would also like to see CMS consider implementing a structural measure that recognizes a physician s participation in a national clinical data registry as a measure of quality.

Finally, with respect to these clinical data registries, we would note that many medical and surgical specialty organizations have put their plans to collect national health care quality and safety data on hold pending release of the regulations that would allow them to become patient safety organizations under the terms of the Patient Safety and Quality Improvement Act, which President Bush signed into law over two years ago. There can be no question that further delay in the implementation of this law, which the physician community overwhelmingly supported, is hampering our ability to collect and disseminate information that will improve the quality of healthcare for all patients.

CMS-1385-P-13619-Attach-1.PDF

#13619

American College of Surgeons

Washington Office: 1640 Wisconsin Avenue, NW • Washington, DC 20007 • 202/337-2701 • FAX 202/337-4271
e-mail: postmaster@facs.org ACS Web site: http://www.facs.org

August 31, 2007

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

Dear Mr. Kuhn:

On behalf of the 72,000 Fellows of the American College of Surgeons, we are pleased to submit comments on a variety of issues addressed in the proposed rule published July 12, 2007, which proposed changes to the Medicare physician fee schedule (PFS) and other Medicare Part B payment policies.

Resource-Based PE RVUs

As part of the calculation of the practice expense (PE) equipment costs, the Centers for Medicare & Medicaid Services (CMS) assumes equipment is in use 50 percent of the time a physician's office is open. In the proposed rule, CMS acknowledges that it does not have sufficient empirical evidence to justify an alternative assumption and proposes no change at this time.

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Geographic Practice Cost Indices

In the proposed rule, CMS has identified and is soliciting comments on three possible payment locality reconfigurations, each of which strikes a different balance between intra-locality variations and the redistributive impacts. CMS is considering adopting one of these approaches for California in the final rule and would evaluate the impacts in California before considering a broader application of the policy in the future. The options are:

> ***Option 1***: Using this option, a county with a Geographic Adjustment Factor (GAF) that is more than 5 percent greater than the GAF for the locality in which the county resides would be removed from the current locality. A separate locality would be established for each county that is removed. Application of this approach in California would remove three counties (Santa Cruz, Monterey, and Sonoma) from the Rest of California payment locality and Marin County from the Marin/Napa/Solano payment locality and create separate payment localities for each of these counties.
>
> ***Option 2***: This approach is similar to option 1, but the new localities would be structured differently. CMS would use the same 5 percent threshold methodology but instead of creating four new localities—one for each county--the three counties that are removed from the Rest of California locality would be combined into one new locality. Marin County would still be removed from the Marin/Napa/Solano locality to become its own locality.
>
> ***Option 3***: CMS would sort the counties by descending GAFs and compare the highest county to the second highest. If the difference was less than 5 percent, the counties would be included in the same locality. The third highest would then be compared to the highest county GAF. This iterative process would continue until a county has a GAF difference that is more than 5 percent. This numerical organization of payment localities based on costs would reduce the number of payment localities in California from 9 to 6 and create a structure where areas with similar costs would be grouped together even if they are not contiguous.

First, we unhesitatingly endorse CMS' plan to proceed cautiously before deciding whether to apply any new payment locality methodology outside of California, and only after a very thorough assessment of the impact the new methodology would have on all stakeholders in California. We worry, for example, that changes to payment localities, either in multiple or single locality states, could negatively impact rural areas, by reducing Medicare payments and thereby increasing the risk of physician flight from those areas. A June 2007 report by the Government Accountability Office (GAO)

acknowledges this potential problem. A new payment locality methodology, applied broadly, could also impose a significant administrative burden on CMS, Medicare contractors, and physicians and their office staff. And any new methodology will, by definition, produce redistributive effects, which are especially worrisome given continuing uncertainties regarding future updates to the conversion factor under the Medicare PFS. For example, we note that the redistributive effects of Option 3 in California would range from +7.6 percent for one county to -7.3 percent for 14 counties. In our view, any redistributive effects that are more than *de-minimus* should be phased in over several years. Finally, we believe that any broad application of a new payment locality methodology should be accompanied by a firm commitment to re-examine the reasonableness of the new locality configuration at least every 5 to 10 years.

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Coding—Reduction in TC for Imaging Services

As required by Section 5102(b)(1) of the Deficit Reduction Act of 2005 (DRA), CMS caps the technical component (TC) of the PFS payment amount for imaging services (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). The DRA defines imaging services as "imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography."

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92285	External ocular photography with interpretation and report for documentation of medical progress (e.g., close-up photography, slit lamp photography, goniophotography, stereo-photography)
92286	Special anterior segment photography with interpretation and report; with specular endothelial microscopy and cell count

The College strongly opposes the addition of the six ophthalmic procedures to the list of imaging services subject to the DRA payment cap. We believe that CMS' initial decision with respect to these codes was the correct one. We do not believe that procedures involving photographic equipment or an angioscope (a type of microscope) can be considered "imaging" for purposes of the DRA provision any more than other procedures involving the use of microscopes or other forms of magnification should be so considered. None of the six ophthalmic procedures in question could reasonably be classified as X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy. Therefore, we urge CMS to reconsider this proposed change.

Professional Liability Insurance (PLI) RVUs (TC/PC) Issue

CMS is seeking input on how to address the apparent anomaly in the PLI values assigned to technical component (TC) and professional component (PC) services, in which TC codes may be assigned higher PLI RVUs than the PC codes. Two proposed methods—swapping PC and TC PLI RVUs or adjusting the PLI components of TC and PC services until their RVUs are equal--have been rejected by CMS on methodological grounds.

The College has been following the work of the AMA/Specialty Society RVS Update Committee (RUC) PLI Workgroup and agrees that it does not seem possible to separately identify professional liability costs for technical professionals. Indeed, we

believe that these costs are covered by the general practice setting liability insurance and so should already be included in payments made in both the facility and physician office settings. Consequently, we concur with the PLI Workgroup recommendation that CMS should reduce the PLI technical component to zero. The PLI RVUs should then be recalculated to ensure that they are redistributed across all physician services. This would be accomplished by modifying the budget neutrality adjustment applied as the last step in the methodology of assigning PLI RVUs. The total pool of available PLI RVUs would not change as a result of this proposal.

Coding—Multiple Procedure Payment Reduction for Mohs Surgery

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- Increased work RVUs for 10 of 11 proctosigmoidoscopy codes
- Decreased work RVUs for seven of nine anoscopy codes

We appreciate CMS' willingness to consider work value adjustments for these codes as part of the most recent 5-year review of relative values. While we might have minor disagreements about the work values being proposed for a few of the protosigmoidoscopy and anoscopy codes, we generally believe that the RUC process was fair and, therefore, we appreciate CMS' consideration of the RUC's recommendations.

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TRHCA—Section 101(b): PQRI

The proposed rule discusses in detail plans for implementing the second year (2008) of the Physician Quality Reporting Initiative (PQRI) for physicians, physical and occupational therapists, speech-language pathologists, and other practitioners billing under the physician fee schedule. CMS is proposing a significantly expanded list of clinical and structural measures from the following sources:

- 60 of the 74 2007 PQRI measures;
- 58 potential AMA-Physician Consortium for Performance Improvement measures;
- 11 measures currently under development by Quality Insights of Pennsylvania (the Pennsylvania quality improvement organization);
- Two structural measures related to the use of e-prescribing and electronic health records under development by Quality Insights of Pennsylvania;
- Six measures from the AQA starter-set not used in 2007;
- Seven measures endorsed by the National Quality Forum (NQF) but not used in 2007; and
- Three podiatric measures related to foot care for diabetics under development by the American Podiatric Medical Association (APMA).

With the exception of those measures previously endorsed or adopted by the National Quality Forum (NQF) or AQA, the proposed rule states that no measure will be used for the 2008 measure set that has not been endorsed by NQF or adopted by AQA by November 15, 2007. Thus, there could be as many as 147 quality measures available for reporting in 2008.

The preamble to the proposed rule includes a lengthy discussion of the criteria that must be met by organizations proposing quality measures. In essence, such organizations must be consensus organizations that develop measures through the use of a consensus-based process. The statute references two organizations–NQF and AQA–as examples of such organizations, but leaves the Secretary discretion to recognize other organizations. The proposed rule cites criteria from National Technology Transfer and Advancement Act (NTTAA) and OMB Circular No. A-119 as the basis for recognizing other organizations beyond NQF and AQA. The rule invites comments on other consensus organizations that use a consensus-based development process for quality measures. Further, the rule indicates that measures do not have to be developed by organizations controlled by physicians.

Finally, CMS notes that it plans to evaluate and test mechanisms for collecting quality measures from medical registries as an alternative to submitting data through the claims processing system. CMS describes five options for data submission from medical registries to CMS:

- Registries could provide measurement codes and beneficiary/service identifiers that could be linked with Medicare claims data;
- Registries could provide quality measure codes and diagnosis codes that could be linked to beneficiary claims data;
- Registries could calculate and submit directly to CMS measures and performance rates for Medicare beneficiaries by NPI and tax identifiers;
- Registries could provide all of the claims data elements using the Part B claims process; or
- Registries could provide their Medicare data ("data dump") to CMS.

The College would like to express its concerns about relying on NQF as the final arbiter of physician measures at this point in time. Dropping measures that were accepted by AQA, but not endorsed by NQF has led to the deletion of 14 measures after only six months of PQRI reporting. This means that physicians who have structured their billing systems to report on those 14 measures will have to re-tool their practice billing and reporting systems to report on alternative measures if they want to continue to participate in 2008. This is likely to discourage continued participation by those physicians who must modify their systems.

NQF does not have a substantial track record in evaluating and endorsing physician measures. Those physician-level measure sets that have been through NQF review have often received wildly varying assessments from different workgroups or when reviewed at different points in time. Further, its processes for reviewing and approving measures suffer from lack of transparency. At the same time, AQA (while recognized as a consensus organization in TRHCA) does not have a rigorously scientific process for evaluating measure sets or a structured voting/endorsement process. AQA's initial mission was to standardize performance measure implementation across payers and markets–not to create or endorse measures.

We strongly encourage CMS to maintain any measures that have been included in the PQRI program for two or three years before rotating them off the list of accepted measures. This will lead to greater stability of measurement, some possibility of examining trends, and a better ability to evaluate the reliability and validity of measures when many of them have had little pilot testing prior to adoption. In addition, maintaining stability in measures for multiple reporting periods will encourage more physicians to stay with the program over time.

The College also strongly supports CMS' plans to evaluate and test mechanisms for collecting quality measures from patient data registries as an alternative to submitting data through the claims processing system. Of the options proposed for testing, we believe option 3–where the data registry calculates and reports the quality information--presents the least opportunity for compromising beneficiary medical information and is most closely aligned with the intent of registry reporting. Clinical data and outcomes data captured in registries presents the best available alternative for moving beyond process measures and claims-based reporting to begin to measure true outcomes of care, and we encourage CMS to pursue these possibilities much more aggressively. Surgical care is particularly well-suited to outcomes measurement through data registries. The College currently has multiple operational data registries and a collaborative data registry development project underway through the Surgical Quality Alliance. We welcome the opportunity to collaborate with CMS in the testing of registries for reporting to the PQRI program.

We would also like to see CMS consider implementing a structural measure that recognizes a physician's participation in a national clinical data registry as a measure of quality.

Finally, with respect to these clinical data registries, we would note that many medical and surgical specialty organizations have put their plans to collect national health care quality and safety data on hold pending release of the regulations that would allow them to become patient safety organizations under the terms of the Patient Safety and Quality Improvement Act, which President Bush signed into law over two years ago. There can be no question that further delay in the implementation of this law, which the physician community overwhelmingly supported, is hampering our ability to collect and disseminate information that will improve the quality of healthcare for all patients.

TRHCA—Section 101(d): PAQI

TRHCA requires the Secretary to establish a Physician Assistance and Quality Improvement Fund (PAQI) to be available for physician payment and quality improvement. The statute appropriates $1.35 billion for this purpose in 2008. CMS notes that these funds may be used to "buy down" the scheduled 10 percent negative update to the physician fee schedule or to support a quality improvement program. The proposed rule indicates that CMS intends to use these funds to extend the PQRI for another year on the same basis as in place for the last 6 months of 2007. Funds from the PAQI Fund would be used to pay bonuses to physicians who satisfy the reporting performance standards. The rule estimates that the bonus payments would be between 1.5 percent and 2 percent of allowed charges for 2008 with payments actually made early in 2009. CMS states that reducing the scheduled negative adjustment to the fee

schedule conversion factor is not feasible because of the fixed pool of funds available ($1.35 billion), although it estimates that if the entire amount were applied to reduce the negative update it would fall by 2 percentage points.

The College does not support CMS' decision to use the Physician Assistance and Quality Improvement Fund (PAQI) for PQRI bonuses in 2008 (paid in 2009). We strongly believe that addressing the projected 9.9% cut in the physician fee schedule is a more appropriate use of the funds available and provides a greater incentive for continued participation in the Medicare program. It has been shown that improved quality can lead to greater efficiency and cost savings in health care delivery, therefore it is appropriate to continue to fund the PQRI bonus program from the Medicare Trust Fund and direct PAQI funds to minimizing the anticipated reduction in the physician fee schedule.

In-Office Ancillary Services Exception:

While CMS is not proposing to change the in-office ancillary exception (IOAE), we share concerns expressed by others about some of the language used to characterize the use of this exception. For example, CMS refers to "hundreds of letters from physical therapists and occupational therapists that the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices" without elaborating on the propriety or harm of this activity. In fact, when PTs and OTs work in a medical practice, patients have more provider options, potentially greater convenience, and often greater comfort knowing that their PT and OT works closely with their physician.

We request that CMS elaborate on its concerns in this area, engage in discussions with stakeholders on this issue, and analyze whatever data may exist to determine the relative cost-effectiveness of PTs and OTs in medical practices and in other settings.

We hope this input is helpful. If you have any questions regarding our comments or wish to discuss them further, please contact Cynthia Brown, Director of the Division of Advocacy and Health Policy, at 202-337-2701.

Sincerely,

Thomas R. Russell, MD, FACS
Executive Director

TRR:cb:wo

have the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated] to send and receive transactions compliant with the Foundation Standards, but such software becomes capable to send and receive transactions compliant with the Foundation Standards at any time after [insert date rule promulgated], then this exemption shall not apply with respect to such software twelve months after such software becomes capable to send and receive transactions compliant with the Foundation Standards.

2. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) is sending the transaction to a dispenser/prescriber who does not own, license, or otherwise use software that has the capability to receive transactions compliant with the Foundation Standards.*

3. *In the event any applicable law or regulation would prohibit the electronic transmission of the prescription and prescription related information using the Foundation Standards.*

4. *In the event there is a temporary communications failure, whether technological or otherwise, that would prohibit the electronic transmission of the transactions listed at Section 423.160(b)(1)(i) through (xii) using the Foundation Standards. Such temporary communications failures include, by way of example and not limitation, power outages, connectivity failures, or temporary outages of the either the prescriber's or dispenser's computer or management systems.*

Finally, we note that the receiver of a prescription message via a computer-generated fax likely will not have the ability to know whether or not the sender had the ability to send the message via NCPDP SCRIPT, but failed to do so in violation of the regulation. We propose that the rule state that receiver of a computer-generated fax should not be penalized for receiving such a fax, and the receiver should be free to act upon the message for the benefit of the patient and patient care.

Finally, with respect to the implementation date of the rule, we would suggest an effective date of April 1, 2009, rather than January 1, 2009. This date would coincide with the expected promulgation of additional standards under the MMA, and we believe that using coinciding dates for the elimination of the fax exemption will reduce confusion in the marketplace. However, if the promulgation of additional standards under the MMA were to be delayed past April 1, 2009, we would not support further delay of the

elimination of the fax exemption, and would suggest that the fax exemption be eliminated no later than April 1, 2009.

Of all parts of healthcare, the automation of the prescribing process is the most advanced and has made the most progress in the readiness to exchange information in electronic formats. We applaud CMS for its efforts to promote electronic prescribing pursuant to the NCPDP SCRIPT standard and for taking steps to eliminate barriers to adoption of the appropriate technology. If we may be of any additional assistance, please do not hesitate to contact Paul Uhrig, General Counsel and EVP, Corporate Development, of SureScripts at 703.921.2179 or paul.uhrig@surescripts.com.

Sincerely,

/s/ Paul Uhrig

Paul L. Uhrig
General Counsel, EVP – Corporate Development

Submitter : Mr. Byron Miller **Date:** 08/31/2007

Organization : N/A

Category : Other Health Care Professional

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Dear Sir or Madam:

I am a professional gentleman with 30 years in the education field and over 25 years as an Athletic Trainer. As an Athletic Trainer, I am certified by the NATA and hold state licensure in North Carolina. I have taught in the United States in the elementary, middle school, high school and community college levels. I have taught for several years out side the United States as well. I am currently teaching Adapted Physical Education on a k-12 system and serving as the head athletic trainer for a large high school in North Carolina. I work closely with Physical and Occupational Therapists in my teaching duties and with medical professionals in my athletic training duties. 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,

Byron Miller, ATC, LAT

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

Organization : **St. Xavier High School**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Michael Gordon, I am a certified athletic trainer with St. Xavier High School in Cincinnati, Ohio. I am also certified as a strength and conditioning specialist, and do a lot of work in rehab at our school.

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

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

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

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

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

Sincerely,

Michael Gordon, ATC, CSCS

Submitter : Dr. Daniel Wolfe **Date:** 08/31/2007

Organization : Pointe West Anesthesia P.A.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please note that Health Care is perhaps the single largest industry in the United States. Physicians are the small businessmen who drive the entire industry. The economic success of millions of citizens, and by extension the entire domestic economy, rests upon the collective viability of physicians' businesses. Like any other business, ours cannot support continued cuts or even stagnation in income in the face of increasing costs. Unlikc most businesses, the government controls physicians incomes via thc reimbursement schedules for funded health insurance. We cannot react to decreasing revenues like most businesmen. We rely on the government to revise the worth of our "product" in responsc to changing economic conditions in the full realization of the economic and social impact which the failure of our businesses would engender. These payment revisions are essential to the welfare of our businesses and therefore the welfare of our employees, our suppliers, the facilities we utilize, their employees and suppliers, and of course, our patients. Somc areas of The United States have already experienced shortages in health care providers as a result of growing economic pressures. We ask that you prevent further disruptions in the provision of health care by recognizing the increasing cost to providers and approve thc revisions to the payment schedule.

Submitter : **Dr. James Pisini** **Date: 08/31/2007**

Organization : **Dr. James Pisini**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P
Ancsthesia Coding (Part of 5-Year 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 reeognized the gross undervaluation of anesthesia services, and that the Ageney is taking steps to address this complicated issue.

Whcn 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 sincc 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 recommcnded by the RUC.

Thank you for your consideration of this serious matter.

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

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

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

Sincerely,
Shelena Pittman SRNA

Submitter : Ms. Marilyn Richmond **Date:** 08/31/2007

Organization : American Psychological Association

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1385-P-13625-Attach-1.DOC

AMERICAN PSYCHOLOGICAL ASSOCIATION

Practice Directorate

August 31, 2007

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

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

Dear Mr. Kuhn:

I am writing on behalf of the American Psychological Association (APA), the organization representing 148,000 members and associates engaged in the practice, research and teaching of psychology. APA wishes to offer comments on the proposed Medicare Physician Fee Schedule for 2008 published in the July 12, 2007 edition of the *Federal Register*.

Medicare Telehealth Services

Neurobehavioral Status Exam
We agree with the proposal by the Centers for Medicare and Medicaid Services (CMS) to add the Neurobehavioral Status Exam (CPT code 96116) to the list of covered telehealth services. Because the neurobehavioral status exam is primarily a clinical interview (similar to the psychiatric diagnostic interview, which already is a covered telehealth service) it is logical and consistent to also make this service available through telehealth.

Neuropsychological Testing
In addition, CMS asked for comments on the American Telemedicine Association's request to add neuropsychological testing (CPT codes 96118 – 96120) as to the list of telehealth services. This is definitely a service worthy of consideration for eligibility as a telehealth service and we would like to work with CMS on this possibility. While conducting neuropsychological testing via telehealth could improve access to testing services, especially in remote areas, we believe it is unclear whether the technology has advanced far enough to allow all neuropsychological testing to be provided via telehealth without compromising the quality of care. We have identified some issues that need to be considered and would like to investigate them further. Specifically, we believe more time is needed to assess how neuropsychological testing provided via telehealth would address:

- the variety of disorders and diagnoses that patients needing testing may have;
- the physical assistance that patients may need to complete tests; and

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E-mail: practice@apa.org
Web: www.apa.org

- the impact of face-to-face interactions with a psychologist or trained psychological technician during testing on the interpretation of test results.

We would appreciate CMS' willingness to work with us on this proposal. In addition, we believe that these considerations should include remote services for psychological assessment and testing (CPT codes 96101-96103).

Impact of the Budget Neutrality Adjuster

For 2007, CMS increased payments for physician evaluation and management (E/M) services under the 5-year review rule, raising Medicare costs by $4.5 billion. Required by law to keep its costs budget neutral, CMS offset the higher E/M payments by reducing the work relative value units (RVUs) for all Medicare services. This resulted in a 9% decrease in total Medicare payments for psychological services in 2007. Psychologists are bearing an unfair portion of the budget neutrality reduction because (1) the codes they bill are heavily weighted towards the work value and (2) they receive no benefit from the increased payments for E/M because CMS does not allow psychologists to bill for E/M services.

Now for 2008, CMS is proposing to apply an additional 1.8% budget neutrality adjustment to account for recent changes under the 5-year review due to increases in payments for anesthesia services. This adjustment, per Table 26 in the proposed rule, will result in an additional 3% decrease in payments to psychologists in 2008. This reduction is in addition to the 9% cut that psychologists incurred in 2007. Psychologists and social workers, who together provide almost all of the Medicare psychotherapy and testing services, cannot continue to bear the disproportionate and inequitable burden resulting from these additional adjustments. These cuts are certain to harm beneficiary access to outpatient mental health services.

Psychologists' Access to Evaluation and Management Services
We continue to believe that psychologists should have access to billing for E/M services. CMS' rationale for refusing to allow psychologists to bill for E/M services is that psychologists cannot perform each and every E/M function, specifically medication management, interpreting medical diagnostic studies, and taking medical histories. As we have discussed with CMS staff, psychologists routinely provide many of the elements of E/M services, including decision-making to establish diagnosis and treatment options, analysis of tests, records, and other information, counseling, and coordination of care.

Psychologists' services are defined by state scope of practice laws. Allowing psychologists to bill for the appropriate level of an E/M service will not interfere with other healthcare professionals' scope of practice. It would, however, ensure that psychologists are properly recognized for the "face time" and care management services that they provide to their patients. Psychologists, who are paid at 100% of the physician fee schedule, would be treated more equitably with physicians if they were allowed to furnish appropriate E/M services at the same time that they incurred reductions under the budget neutrality adjustor.

We are ready to work with CMS staff to advance our recommendations or answer any questions about psychologists' services. Please contact our Director of Regulatory Affairs, Diane M. Pedulla, J.D., at 202-336-5889 for further information.

Sincerely,

Marilyn S. Richmond, J.D.
Assistant Executive Director, Government Relations

Submitter : Dr. Kurt Mueller **Date:** 08/31/2007

Organization : Gundersen Lutheran Medical Center

Category : Physician

Issue Areas/Comments

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

I am a practicing Mohs surgeon serving a large rural population in southwestern Wisconsin. I am writing on behalf of myself, as well as many rural patients who travel as much as 200 miles or more round trip to visit our clinic.

I am certain that you are well aware of the longstanding history of exemption and the rational behind that and will not review that again; although, I certainly do ask that you consider that. On a more human note, I am asking that you consider the needs of skin cancer patients across the country and particularly our rural elderly for whom the expenses as well as logistics of travel create daily difficulties. It is a great benefit for me to be able to treat two, three, or even four or more cancers on these patients on the same day, and it would be disheartening to begin telling them that they have to make multiple trips for something that certainly could be managed more conveniently.

I ask that you consider the time, effort, and support necessary to treat individual cancer separately, whether it be on one visit or multiple visits. Additionally, I would ask that you consider issues facing many of our patients across the country and support their need to have medical care handled in a timely and efficient manner.

Many thanks for your consideration of this issue.

Submitter : Laura Darby McNally **Date:** 08/31/2007

Organization : Middlesex School

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 in a Secondary School. I have been working as an Athletic Trainer both in Secondary Schools and for National Teams for over 20 years. As a Certified Athletic Trainer in a School I provide needed daily care to my student-athletes, this propsed CMS change would greatly impact the care I am able to give my athletes on a daily basis.

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

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,

Laura Darby McNally, ATC, LAT, CSCS

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

Organization :

Category : **Physician**

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

As an Orthopaedic surgeon, I strongly support the proposal to extend the 30 day re-certification requirement to 90 days.

The 30 day re-certification is overly burdensome for physicians and is unnecessary.

I strongly support this change to ease the burden of unneccessary paperwork that does not positively impact patient care.

Submitter : Dr. Richard Whitten **Date:** 08/31/2007

Organization : Noridian Administrative Services

Category : Physician

Issue Areas/Comments

TRHCA-Section 110: Anemia
Quality Indicators

TRHCA-Section 110: Anemia Quality Indicators

Colleagues: It is logical and appropriate to collect data on the level of anemia present in patients for whom these very expensive and in some cases toxic medications are being used, yet it is illogical to collect the data in any manner that does not permit its AUTOMATED use. Requirements to place the data in the CMS 1500 "Box 19" or the electronic equivalent will NOT permit automated, electronic gathering and processing. If we are going to go to the extent of requiring reporting (which seems appropriate) we should do so using a mechanism such as the former Q codes that permit automated reporting of HCT level. Most logical would be a Q code that ends in the 2 digits corresponding to the most recent HCT. This will enable subsequent data analysis and use rather than just a reporting requirement that has little potential for economic use. Thank you for considering!
Richard W. Whitten, MD, MBA, FACP; Contractor Medical Director, Medicare B for AK, HI & WA

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

Organization : Brian Jones

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-13630-Attach-1.TXT

CMS-1385-P-13630-Attach-2.TXT

CMS-1385-P-13630-Attach-3.PDF

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 : **Dr. eugene segall** **Date: 08/31/2007**

Organization : **Dr. eugene segall**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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Anesthesia Coding (Part of 5-Year Review)

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.

Eugene Segall, MD

Submitter : **Dr. Donald Santella** **Date: 08/31/2007**

Organization : **ASA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk,

I am writing in support of the proposed increase in anesthesia services under the 2008 Physician Fee Schedule.

There is currently a huge payment disparity for anesthesia services for our Medicare patient population. The $16.19 per unit we receive doesn t cover our operating costs. With our increasing elderly population we simply can t run a sustainable business with the current reimbursement.

In a step forward to correct this undervaluation of anesthesia services the RUC has recommended that CMS increase the anesthesia conversion factor that would result in a increase of nearly $4.00 per unit. To ensure our elderly population has access to quality anesthesia 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,

Donald Santella, MD
Albany, NY

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

Organization : **Brian Jones**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1385-P-13633-Attach-1.DOC

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

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

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

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

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

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

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

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

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

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

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

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

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

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

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

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

***

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

Sincerely,

Your Name
Address
City, State Zip

Submitter : **Dr. Sunavo Dasgupta** **Date: 08/31/2007**

Organization : **University of Pennsylvania**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dcar Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

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

Organization : Iris City Chiropractic Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

re: CMS-1385-P
Dear Sirs,
If you prevent payment for diagnostic tests (x-rays, MRIs) under Medicare just because they are referred by chiropractors, many cancers, aneurysms, and other life-threatening conditions will be missed. You believe that chiropractors can just refer to medical doctors for these procedures, but that may take weeks to get someone evaluated. This may cost lives. Please do not punish seniors in this manner./Robert A. Hayden, DC, PhD

Submitter : Ms. JOYCE LYELL **Date:** 08/31/2007

Organization : H.RHEA HOLLY, M.D.,P. C. (ANESTHESIOLOGY)

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I AM WRITING TO SUPPORT THE PROPOSED INCREASE IN ANESTHESIA PAYMENTS. THIS VITAL AND IMPORTANT SERVICE CONTINUES TO BE UNDERRATED AND THE REIMBURSEMENT FROM MEDICARE DECREASES EVERY YEAR. THIS PROPOSED INCREASE IS FAIR AND JUST AND SHOULD BE PAST.

Submitter : Dr. Thomas Hanlon

Date: 08/31/2007

Organization : Dr. Thomas Hanlon

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1385-P-13637-Attach-1.RTF

CMS-1385-P-13637-Attach-2.DOC

CMS-1385-P-13637-Attach-3.DOC

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

Re: CMS-1385-P

Dear Mr. Weems:

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

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

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

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

RESOURCE-BASED PE RVUs

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

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

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

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

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

CPT Code	Anesthesiologists - 05	Interventional Pain Management Physicians

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

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

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

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

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

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

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

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

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

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

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

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

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

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

***

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

Sincerely,

Thomas W. Hanlon, MD
14 Mountainwood Dr
Mountain Top, PA 18707
30 August, 07

Submitter : Dr. Carol Antonino **Date:** 08/31/2007

Organization : Antonino Chiropractic

Category : Chiropractor

Issue Areas/Comments

Medicare Economic Index (MEI)

Medicare Economic Index (MEI)

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-Ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal. I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, it is ultimately the patient that will suffer should this propsal become standing regulation.

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

Organization : Dahlonega Chiropractic Life Center

Category : Chiropractor

Issue Areas/Comments

Medicare Economic Index (MEI)

Medicare Economic Index (MEI)

August 31, 2007
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018
Re: "TECHNICAL CORRECTIONS"

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources, seniors may choose to forgo X-rays and thus, needed treatment. If treatment is delayed, illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

With kind regards,

G. Todd Holubitsky, D. C.

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

Organization : City of Lighthouse Point, FL

Category : Local Government

Issue Areas/Comments

GENERAL

GENERAL

CMS-1385-P

SEE ATTACHMENT

CMS-1385-P-13640-Attach-1.DOC

13640

Lighthouse Point Fire Rescue Dept.
3740 NE 22Ave. Lighthouse Point, Fl. 33064

Fire Chief David Donzella
(954) 941-2624

August 29, 2007

Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

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

Dear Ms. Norwalk:

Our organization provides emergency and non-emergency ambulance services to the communities which we serve. The proposed rule would have a direct impact on our operation and the high quality health care we provide to Medicare beneficiaries. We therefore greatly appreciate this opportunity to submit comments on the proposed rule.

BENEFICIARY SIGNATURE

Our organization commends CMS for recognizing that providers and suppliers of emergency ambulance transportation face significant hardships in seeking to comply with the beneficiary signature requirements. Ambulance services are atypical among Medicare covered services to the extent that, for a large percentage of encounters, the beneficiary is not in a condition to sign a claims authorization during the entire time the supplier is treating and/or transporting the beneficiary. Many beneficiaries are in physical distress, unconscious, or of diminished mental capacity due to age or illness. The very reason they need ambulance transportation often contraindicates the appropriateness of attempting to obtain a signature from the beneficiary.

We believe strongly, however, that the relief being proposed by CMS would have the unintended effect of increasing the administrative and compliance burden on ambulance

services and on the hospitals. Accordingly, we urge CMS to abandon this approach and instead eliminate entirely the beneficiary signature requirement for ambulance services.

Current Requirement

When the beneficiary is physically or mentally incapable of signing, the industry has been following the requirements listed in the CMS Internet Only Manual, Pub. 100-02, Chapter 10, Section 20.1.2 and Pub. 100-04, Chapter 1, Section 50.1.6(A)(3)(c). These sections require the ambulance provider or supplier to document that the beneficiary was unable to sign, the reason and that no one could sign for the beneficiary.

Summary of New Exception Contained in Proposed Rule

While the intent of the proposed exception is to give ambulance providers explicit relief from the beneficiary signature requirements where certain conditions are met, we note that the proposed exception does not grant ambulance providers any greater flexibility than that currently offered by existing regulations. Specifically, 42 C.F.R. §424.36(b)(5) currently permits an ambulance provider to submit a claim signed by its own representative, when the beneficiary is physically or mentally incapable of signing and no other authorized person is available or willing to sign on the beneficiary's behalf. If "provider" in this context was intended to mean a facility or entity that bills a Part A Intermediary, the language should be changed to also include "ambulance supplier". The proposed exception essentially mirrors the existing requirements that the beneficiary be unable to sign and that no authorized person was available or willing to sign on their behalf, while adding additional documentation requirements. Therefore, we believe that the new exception for emergency ambulance services set forth in proposed 42 C.F.R. §424.36(b)(6) should be amended to include only subsection (i), i.e. that no authorized person is available or willing to sign on the beneficiary's behalf.

It is important for CMS to realize that the first two requirements in the proposed sub-division (ii) are always met, as the ambulance crew will always complete a trip report that lists the condition of the beneficiary, the time and date of the transport and the destination where the beneficiary was transported. For this reason, we do not object to the requirements that an ambulance provider obtain (1) a contemporaneous statement by the ambulance employee or (2) documentation of the date, time and destination of the transport. Nor do we object to the requirement that these items be maintained for 4 years from the date of service. However, we do not see any reason to include these in the Regulation, as they are already required and standard practice.

The Proposed Rule would add a requirement that an employee of the facility, i.e. hospital, sign a form at the time of transport, documenting the name of the patient and the time and date the patient was received by the facility. Our organization **strongly objects** to this new requirement as:

- Instead of alleviating the burden on ambulance providers and suppliers, an additional form would have to be signed by hospital personnel.
- Hospital personnel will often refuse to sign any forms when receiving a patient.
- If the hospital refuses to sign the form, it will be the beneficiary that will be responsible for the claim.

- The ambulance provider or supplier would in every situation now have the additional burden in trying to communicate to the beneficiary or their family, at a later date, that a signature form needs to be signed or the beneficiary will be responsible for the ambulance transportation.
- Every hospital already has the information on file that would be required by this Proposed Rule in their existing paperwork, e.g. in the Face Sheet, ER Admitting Record, etc.

We also strongly object to the requirement that ambulance providers or suppliers obtain this statement from a representative of the receiving facility *at the time of transport.* Since the proposed rule makes no allowances for the inevitable situations where the ambulance provider makes a good faith effort to comply, but is ultimately unable to obtain the statement, we believe this requirement imposes an excessive compliance burden on ambulance providers and on the receiving hospitals. Consider what this rule requires—the ambulance has just taken an emergency patient to the ER, often overcrowded with patients, and would have to ask the receiving hospital to take precious time away from patient care to sign or provide a form. Forms such as an admission record will become available at a later time, if CMS wants them for auditing purposes.

Institute of Medicine Report on Hospital Emergency Department Overcrowding

The Institute of Medicine Committee on the Future of Emergency Care recently released a report citing hospital emergency department overcrowding as one of the biggest issues in emergency health care. According to that report, demand on hospital emergency departments (EDs) increased by 26% between 1993 and 2003. During that same period, the number of EDs fell by 425. Combined with a similar decrease in the number of inpatient hospital beds, this has resulted in serious overcrowding of our nation's ED. A further consequence has been a marked increase in the number of ambulance diversions, with 50% of all hospitals—and nearly 70% of urban hospitals—reporting that they diverted ambulances carrying emergency patients to a more distant hospital at some point during 2003.

The report recommended that hospitals find ways to improve efficiency in order to reduce ED overcrowding. However, the requirement that ambulance providers or suppliers obtain a statement from a representative of the receiving hospital at the time of transport would only compound the existing problem, by adding an additional paperwork burden. To meet this requirement, ambulance crews would be forced to tie up already overtaxed ED staff with requests for this statement. The Institute of Medicine report makes clear that this time would be more efficiently spent moving patients through the patient care continuum.

Purpose of Beneficiary Signature

a. Assignment of Benefits – The signature of the beneficiary is required for two reasons. The first purpose of the beneficiary signature is to authorize the assignment of Medicare benefits to the health care provider or supplier. However, assignment of covered ambulance services has been mandatory since April 2002. Furthermore, 42 C.F.R. §424.55(c), adopted November 15, 2004 as part of the Final Rule on the Physician Fee Schedule (67 Fed. Reg. 6236), eliminated the requirement that beneficiaries assign claims to the health care provider or supplier in those situations where payment can only

be made on an assignment-related basis. Therefore, the beneficiary's signature is no longer required to effect an assignment of benefits to the ambulance provider or supplier.

CMS recognized this in the Internet Only Manual via Transmittal 643, by adding Section 30.3.2 to Pub. 100-04, Chapter 1. As a result, the beneficiary signature is no longer needed to assign benefits of covered ambulance services.

b. Authorization to Release Records – The second purpose of the beneficiary signature is to authorize the release of medical records to CMS and its contractors. However, the regulations implementing the HIPAA Privacy Rule, specifically 45 C.F.R. §164.506(c)(3), permit a covered entity (e.g. an ambulance provider or supplier) to use or disclose a patient's protected health information for the covered entity's payment purposes, without a patient's consent (i.e. his or her signature). Therefore, federal law already permits the disclosure of medical records to CMS or its contractors, regardless of whether or not the beneficiary's signature has been obtained.

Signature Already on File

Almost every covered ambulance transport is to or from a facility, i.e. a hospital or a skilled nursing facility. In the case of emergency ambulance transports, the ultimate destination will always be a hospital. These facilities typically obtain the beneficiary's signature at the time of admission, authorizing the release of medical records for their services *or any related services*. The term "related services", when used by hospitals and SNFs, can mean more than only entities owned by or part of the facility. We believe that ambulance transport to a facility, for the purpose of receiving treatment or care at that facility, constitutes a "related service", since the ambulance transports the patient to or from that facility for treatment or admission. Therefore, we believe a valid signature will be on file with the facility. Additionally, for those transports provided to patients eligible for both Medicare and Medicaid, a valid signature is on file at the State Medicaid Office as a product of the beneficiary enrollment process.

Electronic Claims

It is also important to note that, as a result of section 3 of the Administrative Simplification Compliance Act and the implementing regulations at 42 C.F.R. §424.32, with very limited exceptions (e.g. providers or suppliers with less than 10 claims per month), ambulance suppliers must submit claims electronically. Thus, the beneficiary does not even sign a claim form. When submitting claims electronically, the choices for beneficiary signature are "Y" or "N". An "N" response could result in a denial, from some Carriers. That would require appeals to show that, while the signature has not been obtained, an alternative is accepted. As a result, many Carriers allow a "Y", even though the signature was not actually obtained, if one of the exceptions is met.

While this may be a claims processing issue, since you are now looking at the regulation, this would be a good time to add language indicating that the signature requirement will be deemed to be met if one of the exceptions to the requirement exists.

Program Integrity

It is important for CMS to realize that, for every transport of a Medicare beneficiary, the ambulance crew completes a trip report listing the condition of the patient, treatment, origin/destination, etc. AND the origin and destination facilities complete their own records documenting the patient was sent or arrived via ambulance, with the date. Thus, the issue of the beneficiary signature should not be a program integrity issue.

Conclusion

Based on the above comments, it is respectfully requested that CMS:

- Amend 42 C.F.R. §424.36 and/or Pub. 100-02, Chapter 10, Section 20.1.1 and Pub. 100-04, Chapter 1, Section 50.1.6 to state that "good cause for ambulance services is demonstrated where paragraph (b) has been met and the ambulance provider or supplier has documented that the beneficiary could not sign and no one could sign for them OR the signature is on file at the facility to or from which the beneficiary is transported".
- Amend 42 C.F.R. §424.36 to add an exception stating that ambulance providers and suppliers do not need to obtain the signature of the beneficiary as long as it is on file at the hospital or nursing home to or from where the beneficiary was transported. In the case of a dual eligible patient (Medicare and Medicaid), the exception should apply in connection to a signature being on file with the State Medicaid Office.
- Amend 42 C.F.R. §424.36(b) (5) to add "or ambulance provider or supplier" after "provider".

In light of the foregoing, we urge CMS to forego creating a limited exception to the beneficiary signature requirement for emergency ambulance transports, especially as proposed, and instead eliminate the beneficiary signature requirement for ambulance services entirely if one of the exceptions listed above is met.

AMBULANCE SERVICES – AMBULANCE INFLATION FACTOR

Our organization has no objection to revising 42 C.F.R §414.620 to eliminate the requirement that annual updates to the Ambulance Inflation Factor be published in the Federal Register, and to thereafter provide for the release of the Ambulance Inflation Factor via CMS instruction and the CMS website.

Thank you for your consideration of these comments.

Sincerely,

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

Organization : Metropolitan Ambulance Services Trust

Category : Health Care Provider/Association

Issue Areas/Comments

Ambulance Services

Ambulance Services

The Metropolitan Ambulance Services Trust (MAST) is a not-for-profit ambulance service providing 80,000 calls a year in Kansas City Missouri. We provide both the emergency and non-emergency services in our community.

We are writing today to comment on the difficulty our paramedics have in gettting signatures in both teh emergency and non-emergency settings.

Getting signatures in the emergency setting is very difficult. Our crews primary focus is patient care and yet they are expected to secure signatures from informed patients and family in such a difficult time.

The multitude of demands upon the patient and family during emergency situations means that this process is grossly inaccurate at best. Cumbersome is another good term. You want us to provide quality serivces yet we also must demand of our paramedics that they be up-to-date on Medicare billing issues so that they can answer questions for the patient and family as they seek to make an informed decision regarding the signing.

We often have troubles with signatures for non-emergency serivces as well. Confusion around patients with variuos physical or mental issues. Again issues where a paramedic whose primary function is patient care is also needign to be fluent in Medicare issues in order to answer the many questions which are often asked.

The proposal that ambulance crews get additional forms signed by hospital staff is a big problem.

Hospitals around KC are on Diversion 20-30% of the time. This means the ED's are very busy. This means the staff do not have time for what they are to be doing today and to expect them to read, understand and then sign a new form is silly.

We have trouble now getting hosptial staff to sign the medical report. We either seem to have hospital staff that sign anything in order to move our paramedics along (rare) or the need for a signature means that the hospital staff has another reason to be stressed and unhappy.....leading to poor services.

We woudl request that CMS Amend 42 CFR 424.36 and / or Pub 100-02, Chapter 10, Section 20.1.1 and Pub 100-04, Chapter 1, section 50.1.6 to state that "good cause for ambulance services is demonstrated where paragraph (b) has been met and the ambualcne provider or supplier has documented that the beneficiary could not sign and no one could sign for them OR the signature is on file at the facility to or from which the beneficiary is transported".

Amend 42 CFR 424.36 to add an exception stating that ambualnce providers and suppliers do not need to obtain the signature of the beneficiary as long as it is on file at the hospital or nursing home to or from where the beneficiary was transported. In the case of a dual eligible patient (Medicare and Medicaid), the exception should apply in connection to a signature being on file with the State Medicaid Office.

Amend 42 CFR 424.36 (b) (5) to add "or ambulance provider or supplier" after "provider".

Thank you very much for your consideration.

Sincerely,

Jason White
Director of Compliance / Government Relations

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

Organization : **University of Wisconsin-Milwaukee**

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 at the University of Wisconsin-Milwaukee as a Graduate Assistant Athletic Trainer. I am beginning my second year in the position and my second year as a Certified Athletic Trainer and will finish my graduate studies in the upcoming academic year.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P. While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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

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

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

Sincerely,

Joseph W McBeth, ATC/LAT

Submitter : Dr. Alan Harvey **Date:** 08/31/2007

Organization : Brigham and Women's Hospital/Harvard Medical Schoo

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.
Alan M. Harvey, MD

Submitter : Dr. Joel Stein **Date:** 08/31/2007

Organization : Dr. Joel Stein

Category : Physician

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

RE: Docket #1385-P Therapy Standards and Requirements, Physician Self-Referral Provisions

Dear CMS:

I am an Osteopathic Physician, board certified in three areas including Family Practice, Osteopathic Manipulative Medicine and Sports Medicine. I am a member of a five doctor multispecialty group which includes physiatrists and family physicians, all limiting our practices to physical and sports medicine, with Osteopathic Manipulative Medicine and interventional pain management.

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

As a practitioner for 25 years in our community, manual therapy has always until recently been a big part of patient care. Our physical therapists do not have the skills that the manual therapists/massage therapists do for treating a variety of neuromusculoskeletal disorders, especially those rooted in soft tissue pathology. I surely respect the APTA and have only employed physical therapists to maintain compliance with CMS. I prefer to not own or employ physical therapists, but let them be independent as they are able to be reimbursed on their own accord. I have however employed Manual Therapists, which are not able to be reimbursed and have used them in the past incident to our physicians' work. These therapists are much better at treating soft tissue injury and non-articular rheumatism that conventional physical therapists, who are better at developing joint range of motion, stretching programs and implementing therapeutic exercise prescriptions with my input.

Many of our patients simply do not get better from the efforts of what CMS deems "Qualified Therapist". In fact, in our practice, it is not the exception, but the rule that patients have typically already been to PT and have not succeeded in resolving their problems or being helped at all. Of course there are still the holdour PT's that have manual therapists as 'incident to' pratitioners in their clinics, but this is not appropriate according to an April 4th CMS Website Notice.

With the last several years changes in reimbursement patterns from CMS, we have had to charge recipients cash for what they really should be getting according to the physicians recommendations. It is understandable that CMS is being held responsible for fiscal involvement in our governments circumstances while we are at war. And, the money must come from somewhere, but our patients' have noted that their benefits should not be encumbered by poor Washington decision making regarding expenditures. I know this seems to be mixing up government policies, but the money comes only from one source...the people of our United States. It is obvious that the current state cannot support the healthcare of our populace and the destruction of the middle east.

CMS has offered no explanation as to why these significant changes to Hospital Conditions of Participation are necessary. These changes 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.

I am qualified to perform physical medicine and rehabilitation (PMR) services; physical therapy is only a small subset of PMR. 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.

Thank you for your consideration in this matter.

Dr. Stein 33308

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

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

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

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

Organization : East Pennsboro Ambulance Service, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

East Pennsboro Ambulance Service, Inc.
A Community Ambulance Service
P.O. Box 47
Enola, PA 17025

Phone (717) 732-5552
Fax (717) 728-9501
E-Mail epems@comcast.net

August 30, 2007

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

Re: CMS-1385-P: Geographical Price Cost Indices

Dear Mr. Kuhn:

This letter serves as our comments on the Geographical Price Cost Indices section of the Proposed Rule (CMS-1385-P). Our organization strongly opposes any reductions in Medicare reimbursement for ambulance service providers which would have an adverse impact on patient access to vital emergency and non-emergency ambulance care. The Proposed Rule would unfortunately cause that exact effect in areas where providers would receive lower reimbursement as a result of the updated Geographical Priee Cost Index (GPC) figures.

While we recognize the statutory requirement for CMS to update the GPCI, any reductions in reimbursement would be in direct contradiction to the findings of the May 2007 Government Accountability Office (GAO) report entitled Ambulance Providers: Costs and Expected Medicare Margins Vary Greatly (GAO-07-383) which determined that Medicare reimburses ambulance service providers on average 6% below their costs of providing services and 17% for providers in super rural areas. For those ambulance service providers who would receive lower reimbursement as a result of the changes to the GPCI, the Proposed Rule will further exacerbate the problems already caused by below-cost Medicare reimbursement.

The GAO recommended that CMS monitor the utilization of ambulance transports to ensure that negative Medicare reimbursement does not impact beneficiary access to ambulance services particularly in super rural areas. We believe that the Proposed Rule would have a considerable impact on beneficiary access in all areas adversely affected by the changes in the GPCI. We implore CMS to take this into consideration as it finalizes the Proposed Rule and alleviate any harmful impact these changes in the GPCI will have on providers while ensuring that those providers who would benefit from the changes receive the proposed increases which are desperately needed.

Thank you for your consideration of these comments

Sincerely,

David W. Hayes, President
East Pennsboro Ambulance Service, Inc.

CMS-1385-P-13646-Attach-1.PDF

1366

East Pennsboro Ambulance Service, Inc.

"A Community Ambulance Service"

P.O. Box 47
Enola, PA 17025

Phone (717) 732-5552
Fax (717) 728-9501
E-Mail epems@comcast.net

August 30, 2007

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

Re: CMS-1385-P: "Geographical Price Cost Indices"

Dear Mr. Kuhn:

This letter serves as our comments on the "Geographical Price Cost Indices" section of the Proposed Rule (CMS-1385-P). Our organization strongly opposes any reductions in Medicare reimbursement for ambulance service providers which would have an adverse impact on patient access to vital emergency and non-emergency ambulance care. The Proposed Rule would unfortunately cause that exact effect in areas where providers would receive lower reimbursement as a result of the updated Geographical Price Cost Index (GPC) figures.

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Thank you for your consideration of these comments

Sincerely,

David W. Hayes, President
East Pennsboro Ambulance Service, Inc.

Submitter : Dr. Catheirne Cheung **Date:** 08/31/2007

Organization : Northeast Anesthesia & Pain Spcialist, PA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Seaa attachment

CMS-1385-P-13647-Attach-1.PDF

13647

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

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

Organization : Parkland Medical Center

Category : Physical Therapist

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

CMS is proposing to amend the regulations to change the plan of treatment re-certification schedule. Currently, the referring physician must certify the initial plan of care and re-certify every 30 days thereafter.

CMS proposes to change the re-certification period to 90 days.

I strongly support the proposal to extend the 30 day re-certification requirement to 90 days.

The 30 day re-certification is overly burdensome for physicians and physical therapists is costly and is not an effective means of controlling utilization of therapy services.

CMS has adequate other requirements in place (referral, certification of the initial plan of care, specific medical necessity requirements, extensive documentation requirements, Local Coverage Determinations, Therapy Caps, CCI edits, etc.) and does not need the 30 day re-certification process in order to manage appropriateness of therapy care and utilization.

This regulation alone causes me to hire a clerical person to track, insure compliance for 40 hours per month. A large cause is calling the physician office to 'remind" them of the regulation and to sign the appropriate re-certication. This is a waste of medical system dollars.

Submitter : Dr. Stephanie McGuire **Date:** 08/31/2007

Organization : Duke University Medical Center

Category : Physician

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Submitter : Mr. John Morr **Date:** 08/31/2007

Organization : The University of Alabama

Category : Other Health Care Professional

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

In-Office Ancillary Services Exception
Therapy Standards and Requirements
? 482.56 Condition of participation:
Rehabilitation services.

CMS-1385-P-13650-Attach-1.PDF

#13650

Dear Sir or Madam:

My name is John W. Morr and am employed at The University of Alabama as an Athletic Trainer, Certified by the NATABOC and currently licensed in the State of Alabama to practice Athletic Training. I have a Bachelors' degree from Eastern Illinois University and a Masters Degree from the University of Kentucky.

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

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

Based on the following statement in your proposal this should include athletic trainers that are certified by a national independent body and either state licensed or certified would meet these requirements. Why would you not include them in this proposal?

Therefore, we believe it would be appropriate to broaden the current grandfathering clauses for practicing PTs, OTs, PTAs, and OTAs. We propose to revise our requirements to recognize PTs, OTs, PTAs, or OTAs who meet their respective State qualifications (or have received State recognition as PTs, OTs, PTAs or OTAs) before January 1, 2008. Individuals who furnish physical or occupational therapy services but have not met State qualifications (or received State recognition as PTs, OTs, PTAs and OTAs) before January 1, 2008, would be required to meet the updated qualifications in § 484.4.

With regards to the section :**§ 482.56 Condition of participation: Rehabilitation services.**

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,

John W. Morr, M.S.,ATC

Submitter : Dr. Richard Whitten **Date:** 08/31/2007

Organization : Noridian Administrative Services

Category : Physician

Issue Areas/Comments

Background

Background

Colleagues: In your section on the history of the RVS you correctly point out that Section 1848(c)(2)(B)(i) of the Act requires CMS review all RVUs no less often than every five years. Note, please, that our manner in doing so at (the maximal) five-year intervals has contributed - I believe significantly - to the tendancy for RUC revaluations to be somewhat inflationary over time, as has been pointed out by MedPAC and others. Specialty societies are continuously able to identify and work within their committees and with staff to identify potentially undervalued codes, which are then brought forward at successive five-year reviews. Since the call from CMS for potantially over-valued codes has only gone out at the successive five-year intervals, however, the identification of these has been sporadic, poorly coordinated and with little ongoing discussion and feedback. The RUC has identified this as a concern and established an ongoing subcommittee mechanism to collect and review potentially mis-valued codes (including newer technologies whose initial valuations may well need reassessment at intervals). CMS should identify a mechanism to solicit, receive and encourage the submission of such concerns on an ONGOING basis. Submissions should be in a format that encourages careful presentation of the evidence for possible misvaluation (again, similar to the criteria for evidence the RUC has prepared). These could be transmitted for review and discussion by the RUC on an ongoing basis and then sent again more formally (unless resolved) at the five-year major review when it occcurs. This will help assure there is continuing input from CMDs as well as from the private sector and may go a considerable ways to help address the issue of MedPAC's concern. Thank you for considering! Richard W. Whitten, MD, MBA, FACP;
Contractor Medical Director, Medicare B for AK, HI & WA

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

Organization : **Tufts University School of Medicine**

Category : **Physician**

Issue Areas/Comments

Medicare Economic Index (MEI)

Medicare Economic Index (MEI)

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Michael H. Entrup, MD
Chair, Department of Anesthesiology
Tufts University School of Medicine

Submitter : Ms. Marisa Lund **Date:** 08/31/2007

Organization : Ms. Marisa Lund

Category : Other Health Care Professional

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam:

My name is Marisa Lund. I am a certified athletic trainer. I have a B.A. in athletic training and a M.S. in Biomechanics. I work in an outpatient physical therapy clinic with additional responsibilities at a local high school and college.

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

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

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

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

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

Sincerely,

Marisa Lund, MS, ATC

Submitter : Ms. Christy Hawley **Date:** 08/31/2007

Organization : Catawba College

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My Name is Christy Hawley and I work as an assistant athletic trainer at Catawba College in Salisbury, North Carolina. I am currently working with the field hockey team and during the winter season with both men s and women s basketball. I received my B.S. in athletic training from The University of North Carolina at Charlotte and my M.S. in Sports Health Care from A.T. Still University, The Arizona School of Health Sciences. I have been licensed to practice in the states of Arizona and North Carolina.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Christy Hawley, ATC, LAT

Submitter : Dr. Mark Lema **Date:** 08/31/2007

Organization : American Society of Anesthesiologists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-13655-Attach-1.PDF

AMERICAN SOCIETY
OF ANESTHESIOLOGISTS

Office of Governmental Affairs
1101 Vermont Avenue, N.W.
Suite 606
Washington, DC 20005
(202) 289-2222
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mail@ASAwash.org

August 29, 2007

Herb Kuhn
Acting Director
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1385-P
Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY2008

Dear Mr. Kuhn:

The American Society of Anesthesiologists (ASA) appreciates the opportunity to comment on several of the issues included in the Proposed Rule referenced above.

Anesthesia Coding (Part of 5-Year Review)

The American Society of Anesthesiologists commends the Centers for Medicare and Medicaid Services (CMS) for recognizing the undervaluation of anesthesia work. **We urge CMS to increase the value of the work component of anesthesia services by 32% as proposed in the July 12, 2007 Federal Register (Vol 72, No 133, pp 38148-38149).**

Since the implementation of the Resource Based Relative Value System (RBRVS) in 1992, ASA has consistently argued that the conversion factor used by CMS has undervalued anesthesia care. A 2005 ASA survey of 267 anesthesia groups showed that the median conversion factor used by private payers was $50 per unit. In contrast, the 2005 Medicare conversion factor was $17.76—35.5% of private. This gap has grown in the last two years. A 2007 ASA survey of 284 anesthesia groups showed that the median private payer conversion factor is $55 per unit, while the 2007 Medicare conversion factor fell to $16.19—a mere 29.4% of private. Meanwhile, Medicare's rates for medical/surgical procedures paid under the RBRVS methodology are typically equal to about 80% of private payer rates.

ASA has brought the problem of anesthesia work undervaluation to all three Five Year Reviews conducted since the RBRVS system was adopted. At the conclusion of the third Five-Year Review, the RUC unanimously agreed that anesthesia work is undervalued and recommended that CMS increase Medicare's anesthesia conversion factor to rectify this situation. We are both relieved and pleased that the Agency has recognized this undervaluation and intends to address this inequity in the 2008 Physician Fee Schedule effective January 1, 2008. Physicians still face many challenges to reasonable and adequate payment, some relevant to all of medicine and others specific to anesthesiologists); however, this update will help defray some of the costs associated with providing the expert anesthesiology medical care our nation's seniors deserve.

In preparing for the 2005 Five Year Review, the ASA considered the 2000 Five Year Review. The RUC's Anesthesia Workgroup divided an anesthesia service into five subparts:

- Pre-service work
- Equipment/Drug/Supply preparation
- Induction period procedures
- Post-induction period procedures
- Post-procedure work.

ASA determined that the RUC's 2000 Workgroup did a rather accurate job in valuing the anesthesia work involved in all the above subparts except for the post-induction procedure period. To address this subpart, the ASA developed a linear regression model which posited that the higher the base unit value, the greater the work of the pre- and post-procedures periods and *the greater the intensity of the work during reportable anesthesia time.* The ASA and the RUC agreed that the intensity of the post-induction period should range from that assigned to the values the RUC recommended for second provider moderate sedation up to that assigned to a critical care service. Ultimately the RUC Workgroup used the ASA model to value the post-induction period and created a building block approach to determine the values for the other subparts. This approach demonstrated that the work element of an anesthesia service is undervalued by 32%.

We would like to take this opportunity to acknowledge the efforts of the AMA/Specialty Society RVS Update Committee (RUC) in regard to the valuation of anesthesia work. The RUC examined the relationship between values assigned to anesthesia services and the values assigned to other medical/surgical services on three separate occasions. With the possible exception of the recent review of Evaluation and Management services, no other single issue has received such rigorous review. While the process had some difficult moments, we appreciate the RUC's perseverance and willingness to review the issue.

Resource –Based Practice Expense (PE) Relative Value Units (RVUs)

CMS is continuing its implementation of a "bottom up" methodology which greatly impacts many specialties – including anesthesiology. Last year was the first of a 4-year transition period. The American Medical Association (AMA) along with more than 70 specialty societies is conducting a Physician Practice Information survey. This survey will provide reliable, current and consistent measures of the elements that make up Practice Expenses for ALL specialties. The results of this survey should be applied to CMS's PE methodology, providing a much needed update to aged and likely inaccurate data. We anticipate that these results will be ready in time for them to be reviewed and incorporated into the 2009 fee schedule. Since 2009 will be the third year of this 4-year transition period, we strongly encourage CMS to make appropriate adjustments, by specialty, to the Practice Expense components of the physician fee schedule when those results are available.

RUC Recommendations for Direct PE Inputs and Other PE Input Issues– Cardiac Catheterization Procedures

We support the Agency's proposal to accept the PERC recommendations for code 93503 – *Insertion and placement of flow directed catheter (eg, Swan –Ganz) for monitoring purposes.* We agree that this service would not be performed in an office setting and concur that the fee schedule should not list PE RVUs for this code in the non-facility setting.

Physician Self-Referral Provisions

The proposed rule contains a series of proposals and requests for comment relating to proposed changes and clarifications in the physician self-referral ("Stark") law and regulations. ASA appreciates the fact that CMS is seeking input as it attempts to address concerns relating to certain arrangements that may have been designed to circumvent the Stark restrictions and that present the potential for abuse. At the same time, we urge CMS to consider carefully how its proposals would have unintended adverse effects on legitimate arrangements that do not present the potential for abuse.

"Set in advance" and percentage arrangements

Many of the Stark exceptions relating to compensation arrangements require that the compensation be set in advance and some of the arrangements that anesthesiologists enter into with hospitals may be viewed as percentage-based compensation arrangements. CMS proposes that percentage-based compensation arrangements may be used only to pay for personally performed physician services. ASA is concerned that this proposal will preclude arrangements relating to anesthesiologists' services that are performed in a care-team setting, whether in an academic setting with residents, or in a private practice setting with nurse anesthetists or

anesthesiologist's assistants. Care-team practice is common in many areas of the country and ASA does not believe that CMS intends to implement a change in Stark that would preclude compensation arrangements involving physicians who work with residents, nurse anesthetists, and/or anesthesiologist's assistants.

ASA urges CMS to revise its proposal to recognize that physician services include services personally performed by a physician and physician services in circumstances in which the physician is medically directing or medically supervising "qualified individuals," as those terms are defined in 42 C.F.R. § 414.46, as well as physician services in circumstances involving other allowable means for reporting anesthesia services.

Burden of proof
CMS proposes to clarify that the burden of proof to establish that a referral fits into an exception is on the entity submitting the claim, not on CMS or its contractors. ASA believes that this "clarification" represents a fundamental change in position that may have a chilling effect on legitimate arrangements. ASA urges CMS to reconsider this proposed change and allow this issue to be resolved by the finders of fact. Otherwise, it would create an inducement for Fiscal Intermediaries and Carriers to increase denials based on alleged Stark violations and concurrently exacerbate concerns over potential noncompliance with respect to the many grey areas of the law.

TRHCA – Section 101(b): PQRI

We request the Agency note the following comments in regard to its proposals for the 2008 Physician Quality Reporting Initiative:

AMA-PCPI Measures
CMS is proposing to include in the 2008 PQRI program measures under development by the AMA-Physicians Consortium for Performance Improvement (PCPI) pending NQF or AQA endorsement of the measures. We request correction of a mis-stated measure listed in *Table 17 – AMA/PCPI Measures* in the proposed rule. The PCPI measure cited "Prevention of Catheter-Related Bloodstream Infections" is not limited to ventilated patients and the phrase "in ventilated patients" should be deleted.

> *Prevention of Catheter-Related Bloodstream Infections ~~in Ventilated patients~~ Catheter Insertion Protocol.*

Addressing a Mechanism for Submission of Data on Quality Measures Via a Medical Registry or Electronic Health Record

We are pleased that the Agency acknowledges the advantages of implementing a method to allow eligible professionals to submit PQRI data via a registry. We suggest that it is fair to assume that PQRI quality measures reflect elements of clinical performance important to the specialty sponsors of the registries, and therefore are incorporated among the registry data elements. We agree with the agency that separate reporting on these measures is likely to be duplicative and inefficient and an integrated process is desirable. Option #3, as described on p. 38203, appears to have the advantage of also eliminating duplicative calculation of performance rates by relying on a registry function to accomplish this, with results transmitted to CMS. With respect to development of validation methodologies, we would request consideration of a similar effort to avoid redundancy. Clinical registries typically incorporate costly validation strategies and audits. As CMS moves forward in integrating registry activity with its quality improvement agenda, a method by which registry audit and validation can be "deemed" authoritative with respect to CMS data submission would be desirable.

We further note that the capacity of registries to transmit PQRI data merely scratches the surface of the potential of this activity. Clearly, the Society of Thoracic Surgeons (STS) registry experience demonstrates substantial benefit to patient care by physician benchmarking on elements of care identified by the specialty. This observation should lead CMS to define physician participation in a qualified clinical registry *per se* as a recognized structural quality measure under PQRI or related programs. Doing so would represent a more potent stimulus to proliferation of clinical registry-based quality improvement than the approach described in the Notice that is limited to PQRI data transmission.

We thank you for your consideration of our comments. If you have any questions or need any additional information please do not hesitate to contact Sharon Merrick at s.merrick@asawash.org.

Sincerely,

Mark J Lema

Mark J. Lema, M.D., Ph.D.
President