

**Submitter :** Mr. Scott Curington  
**Organization :** Jacksonville University  
**Category :** Other Health Care Professional

**Date:** 08/31/2007

**Issue Areas/Comments**

**Physician Self-Referral Provisions**

Physician Self-Referral Provisions

Dear Sir or Madam:

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

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

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

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

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

Sincerely,

Scott Curington, MS, ATC, LAT

**Submitter :** Mr. Conrad Kearns  
**Organization :** Pinellas County EMS/Fire Admin.  
**Category :** Local Government

**Date:** 08/31/2007

**Issue Areas/Comments**

**Beneficiary Signature**

**Beneficiary Signature**

Pinellas County EMS and Fire Administration thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule entitled Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E- Prescribing Exemption for Computer-Generated Facsimile Transmissions (the Proposed Rule ), 72 Fed. Reg. 38122 (July 12, 2007).

Pinellas County EMS and Fire Administration is the only ambulance service in Pinellas County.

Pinellas County EMS and Fire Administration commends CMS for recognizing that providers and suppliers of emergency ambulance transportation face significant hardships in seeking to comply with the beneficiary signature requirements of 42 C.F.R. 424.36. 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. The very reason they need ambulance transportation often contraindicates the appropriateness of attempting to obtain a signature from the beneficiary.

However, Pinellas County EMS and Fire Administration believes strongly 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 to instead eliminate the beneficiary signature requirement for ambulance services entirely.

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.

The Proposed Rule would create a new exception to the beneficiary signature requirements for emergency ambulance transport services. Under this exception, an ambulance provider would be permitted to submit a claim to Medicare for payment without the beneficiary's signature provided each of the following conditions was met:

1. The beneficiary was physically or mentally incapable of signing the claim at the time of service;
2. None of the individuals listed in 42 C.F.R. 424.36(b)(1) (5) was available or willing to sign the claim on the beneficiary's behalf at the time the service was provided; and
3. The ambulance provider maintains specific information and documentation for at least 4 years from the date of service. The required information and documentation includes:
  - a. A contemporaneous statement from an ambulance employee present during the transport, stating that the beneficiary was physically or mentally incapable of signing, and that no other authorized person was available or willing to sign the claim on the beneficiary's behalf.
  - b. Documentation providing the date and time of the transport, and the name and location of the receiving facility.
  - c. A contemporaneous statement from a representative of the receiving facility, which documents the name of the beneficiary and the date and time the beneficiary was received by that facility.

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.

**GENERAL**

**GENERAL**

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, Pinellas County EMS and Fire Administration does 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

**CMS-1385-P-15066**

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. Pinellas County EMS and Fire Administration 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.

Pinellas County EMS and Fire Administration also strongly objects 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 pr

CMS-1385-P-15066-Attach-1.DOC

15066

August 31, 2007

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

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

Dear Ladies/Gentlemen:

Pinellas County EMS and Fire Administration thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule entitled "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions" (the "Proposed Rule"), 72 Fed. Reg. 38122 (July 12, 2007).

Pinellas County EMS and Fire Administration is the only ambulance service in Pinellas County.

**BENEFICIARY SIGNATURE**

Pinellas County EMS and Fire Administration commends CMS for recognizing that providers and suppliers of emergency ambulance transportation face significant hardships in seeking to comply with the beneficiary signature requirements of 42 C.F.R. §424.36. 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. The very reason they need ambulance transportation often contraindicates the appropriateness of attempting to obtain a signature from the beneficiary.

However, Pinellas County EMS and Fire Administration believes strongly 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 to instead eliminate the beneficiary signature requirement for ambulance services entirely.

### 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

The Proposed Rule would create a new exception to the beneficiary signature requirements for emergency ambulance transport services. Under this exception, an ambulance provider would be permitted to submit a claim to Medicare for payment without the beneficiary's signature provided each of the following conditions was met:

1. The beneficiary was physically or mentally incapable of signing the claim at the time of service;
2. None of the individuals listed in 42 C.F.R. §424.36(b)(1) – (5) was available or willing to sign the claim on the beneficiary's behalf at the time the service was provided; and
3. The ambulance provider maintains specific information and documentation for at least 4 years from the date of service. The required information and documentation includes:
  - a. A contemporaneous statement from an ambulance employee present during the transport, stating that the beneficiary was physically or mentally incapable of signing, and that no other authorized person was available or willing to sign the claim on the beneficiary's behalf.
  - b. Documentation providing the date and time of the transport, and the name and location of the receiving facility.
  - c. A contemporaneous statement from a representative of the receiving facility, which documents the name of the beneficiary and the date and time the beneficiary was received by that facility.

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, Pinellas County EMS and Fire Administration does 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. Pinellas County EMS and Fire Administration **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.

Pinellas County EMS and Fire Administration also strongly objects 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.

### 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**

Pinellas County EMS and Fire Administration has no objection to CMS' proposal to revise 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. If you or your staff should have any questions, please contact me at 727-582-2000.

Sincerely,

Conrad T. Kearns, MBA, Paramedic  
Director, Pinellas County EMS/Fire Administration

**Submitter :** Teri Riding  
**Organization :** Teri Riding  
**Category :** Other Health Care Professional

**Date:** 08/31/2007

**Issue Areas/Comments**

**Physician Self-Referral Provisions**

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Teri Riding and I am a Certified Athletic Trainer. I have a Master's degree in Athletic Training. However, because of previous decisions made by your government program I am currently unemployed. I was working for a physical therapy clinic, since I cannot bill for the services I provided for my employer they could not cover my salary. I feel the current rule would do the same for other Certified Athletic Trainers working in other areas of the medical field and prevent me from getting another job.

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

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

As a Certified Athletic Trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national 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,

Teri Riding, MS, ATC



**Submitter :** Mrs. Amanda Anderson  
**Organization :** Glenbrook South High School  
**Category :** Other Health Care Professional

**Date:** 08/31/2007

**Issue Areas/Comments**

**Physician Self-Referral Provisions**

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer at Glenbrook South High School in Glenview, IL. I have a Bachelor's of Arts degree from North Central College in Naperville, IL in Athletic Training and have passed the Board of Certification exam.

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

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

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

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Sincerely,

Amanda Anderson, ATC, LAT

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
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. Craig Voll  
**Organization :** Purdue University  
**Category :** Other Health Care Professional

**Date:** 08/31/2007

**Issue Areas/Comments**

**Physician Self-Referral Provisions**

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Craig Voll and I am a certified athletic trainer currently working at Purdue University. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

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

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

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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,

Craig Voll, ATC

**Submitter :** Ms. Michelle Badertscher  
**Organization :** Fostoria Community Hospital  
**Category :** Other Health Care Professional

**Date:** 08/31/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Dear Sir or Madam:

My name is Michelle Badertscher and I am a certified athletic trainer licensed in the state of Ohio. I am employed through Fostoria Community Hospital located in Fostoria, OH within the outpatient physical therapy department. In addition to my clinical responsibilities, my job also allows me the opportunity to help educate, prevent, treat, and rehabilitate injuries that occur to young student athletes at Fostoria High School. My education consists of a Bachelor of Science degree from Ohio Northern University, located in Ada, OH and a Masters of Science degree in Exercise Science with a concentration in Biomechanics from The University of Toledo, Toledo, OH. I am an active member of The National Athletic Trainers Association and received my athletic training certification, which consists of a three part testing procedure.

Athletic training is an allied health profession that requires at least a bachelor degree and a certification from the National Athletic Trainers Association Board of Certification. Many states require a license to practice as a certified athletic trainer. Ohio is one of those states that mandate a license to practice. Athletic trainers are trained professionals in acute on-field emergencies, prevention and education of wellness and other health care topics, evaluating injuries with possible referral to physicians, in addition to rehabilitation of orthopedic-type injuries, the same injury diagnoses that one would treat at an outpatient rehabilitation clinic.

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

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

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

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

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

Sincerely,

Michelle L. Badertscher, MS, ATC

**Submitter :** Dr. Navtej Purewal  
**Organization :** Advanced Pain Management  
**Category :** Physician

**Date:** 08/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1385-P-15072-Attach-1.DOC



# ADVANCED PAIN MANAGEMENT

4131 W Loomis Road \* Suite 300 \* Greenfield, WI 53221 \* 414.325.PAIN \* Toll Free 1.888.901.PAIN \* Fax 414.325.3700  
August 31, 2007

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

Re: CMS-1385-P

Dear Mr. Weems:

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

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

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

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

## RESOURCE-BASED PE RVUs



## ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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

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



## ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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





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

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

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

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

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

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

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

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



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

\*\*\*

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

Sincerely,

Sincerely,

Navtej Purewal, MD  
Advanced Pain Management  
4131 W Loomis Road  
Greenfield, WI 53221

**Submitter :** Jeremy Simington  
**Organization :** King's College  
**Category :** Other Health Care Professional

**Date:** 08/31/2007

**Issue Areas/Comments**

**Physician Self-Referral Provisions**

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer who has been practicing for the past 11 years in a variety of settings, including college, high school, metropolitan hospital, and physician-supervised sports medicine clinic. I hold a Master of Science degree and national certification by the Board of Certification, Inc.

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,  
Jeremy Simington, MS, ATC  
Director, Athletic Training Education Program  
King's College  
Wilkes-Barre, Pennsylvania

**Submitter :** Mr. Michael Minor  
**Organization :** Department of Veterans Affairs, VAMC  
**Category :** Other Health Care Professional

**Date:** 08/31/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

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

My name is Michael Minor, a Registered Kinesiotherapist with the Department of Veterans Affairs VA Medical Center, Washington DC the past 20 years. I have a B.S. degree with various certifications in Aquatics, Driver Rehab, Wheelchair clinics, FCE, CPR Instructor, Strength Training and Conditioning to name a few, and countless hours of additional training. The quality of life for many veteran patients' and their families would be vastly degraded without the expertise of a Kinesiotherapist.

I am writing today to voice my opposition to the proposed therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and other facilities proposed in Federal Register issue #1385-P. As a Kinesiotherapist, I would be excluded from providing physical medicine and rehabilitation services under these rules.

I am concerned that these proposed rules will create additional lack of access to quality health care for my patients. This is particularly important because my colleagues and I work with many wounded Veterans, an increasing number of whom are expected to receive services in the private market. These Medicare rules will have a detrimental effect on all commercial-pay patients because Medicare dictates much of health care business practices.

I believe these proposed changes to the Hospital Conditions of Participation have not received the proper and usual vetting. CMS has offered no reports as to why these changes are necessary. There have not been any reports that address the serious economic impact on Kinesiotherapists, projected increases in Medicare costs or patient quality, safety or access. What is driving these significant changes? Who is demanding these?

As a Kinesiotherapist, I am qualified to perform physical medicine and rehabilitation services. My education, clinical experience, and Registered status insure that my patients receive quality health care. Hospital and other facility medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards and accepted practices.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the health care industry. It is irresponsible for CMS to further restrict PMR services and specialized professionals.

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. Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to reconsider these proposed rules. Leave medical judgments and staffing decisions to the professionals. 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 Minor, RKT

**Submitter :** Dr. Douglas Keehn  
**Organization :** Advanced Pain Management  
**Category :** Physician

**Date:** 08/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1385-P-15075-Attach-1.DOC

15075



## ADVANCED PAIN MANAGEMENT

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August 31, 2007

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

Re: CMS-1385-P

Dear Mr. Weems:

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

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

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

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

**RESOURCE-BASED PE RVUs**



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

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

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

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

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

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

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



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### **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**

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

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

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



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

Sincerely,

Sincerely,

Douglas Keehn, DO  
Advanced Pain Management  
4131 W Loomis Road  
Greenfield, WI 53221

**Submitter :** Dr. Michael Champeau  
**Organization :** American Society of Anesthesiologists  
**Category :** Physician

**Date:** 08/31/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

See Attachment

CMS-1385-P-15076-Attach-1.DOC

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 possible support for the CMS proposal to increase payments to anesthesiologists under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services that has occurred since the implementation of the RBRVS in the early 1990's, 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. Much of the reason for this problem lies in methodological errors in the Hsiao study. 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. Our 11-physician practice was approximately 34% Medicare beneficiaries prior to the institution of the RBRVS methodology; over the last decade it has fallen to less than 10% Medicare beneficiaries. We simply cannot afford to take care of many Medicare patients since we live in an exceptionally high cost-of-living area.

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 extremely 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 W. Champeau, M.D.  
President, Associated Anesthesiologists Medical Group

**Adjunct Associate Professor of Anesthesia, Stanford University School of Medicine**  
**President-Elect, California Society of Anesthesiologists**

**Submitter :** Dr. Eric Werner

**Date:** 08/31/2007

**Organization :** West Central Anesthesiology Group, Ltd.

**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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Eric Werner, M.D.

**Submitter :** Dr. Thomas Lass  
**Organization :** Advanced Pain Management  
**Category :** Physician  
**Issue Areas/Comments**

**Date:** 08/31/2007

**GENERAL**

GENERAL

See Attached

CMS-1385-P-15078-Attach-1.DOC



## ADVANCED PAIN MANAGEMENT

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August 31, 2007

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

Re: CMS-1385-P

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**RESOURCE-BASED PE RVUs**





## ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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



## ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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



## ADVANCED PAIN MANAGEMENT

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

\*\*\*

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

Sincerely,

Sincerely,

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

**Submitter :** James Mili

**Date:** 08/31/2007

**Organization :** Worcester Academy

**Category :** Other Health Care Professional

**Issue Areas/Comments**

**Physician Self-Referral Provisions**

**Physician Self-Referral Provisions**

Dear Sir or Madam,

I am a certified athletic trainer at Worcester Academy, a private college preparatory school, grades 6 through 12.

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

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

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

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

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

Sincerely,

James R. Mili, ATC

**Submitter :** Dr. Camille Mason  
**Organization :** American College of Mohs Surgery  
**Category :** Physician

**Date:** 08/31/2007

**Issue Areas/Comments**

**Coding--Multiple Procedure  
Payment Reduction for Mohs  
Surgery**

**Coding--Multiple Procedure Payment Reduction for Mohs Surgery**

As of July 1st of this year, CMS has planned a change in payment policy that in my opinion has the potential to negatively impact the care of my patients and could add significant cost to an already stressed healthcare budget. This planned change would remove Mohs surgery from a longstanding exemption from the multiple surgery reduction rule (MSRR, indicated by CPT modifier -51). This is a departure from a longstanding exemption agreed to by CMS and virtually all private insurance carriers since 1991. The change proposed would eliminate the exemption and decrease reimbursement by 50% for either the Mohs excision or for the associated repair, and for Mohs excision of any additional cancers treated on the same day; such a decrease in reimbursement would not cover the cost of providing the service.

In its review of the Mohs codes in 1991, CMS agreed that Mohs excisions are separate staged procedures; they will be paid separately with no multiple surgery reductions. This rule was placed in the Federal Register at that time (Federal Register, November 25, 1991, volume 56, #227, pg 59602). In 2004, the Mohs codes were added to the CPT Appendix E list of codes exempt from the -51 modifier and the multiple surgery reduction rule, to eliminate the occasional carrier misunderstanding when the multiple surgery reduction was applied to these codes. The July 2004 CPT Assistant article reviewed the rationale. For Mohs surgery greater than 80% of the work is intraservice work that does not overlap when two or more procedures are performed. The pathology portion of Mohs surgery constitutes a large portion of this total and also is not reduced with multiple procedures. The preservice and postservice work values are small because there is a zero-day global period. Together there is very little overlap or reduction in work when two or more tumors are treated on the same patient on the same day. Therefore, Mohs surgery codes are exempt from the use of modifier 51.

The exemption of the Mohs codes from the MSRR has been maintained by CMS since 1992 and was not questioned during the CMS mandated five-year review of the Mohs codes undertaken in October 2006.

The consequence of applying the multiple surgery reduction rule to the Mohs codes would be a reimbursement reduction to a value less than the cost of providing the service. Therefore, providers will no longer be able to perform more than one Mohs procedure on any patient on a single day. Multiple tumors are commonly diagnosed on one visit. Treatment of only one tumor per day will inconvenience many patients and their friends and families who accompany them for treatment. It will also inconvenience employers when workers are absent from work more frequently for multiple treatments. More importantly, delays in treatment will further increase risk for high-risk patients such as organ transplant patients with multiple squamous cell carcinomas, and for patients with syndromes such as basal cell nevus syndrome. In addition to its application to multiple cancers treated on the same day, the MSRR would apply to repairs performed on the same day as Mohs surgery. According to this new proposal, when Mohs surgery is reimbursed less than a reconstructive procedure on the same day, even the first Mohs code will be subject to the multiple surgery reduction rule. Since costs would not be covered, this may require patients to have their Mohs surgery and their reconstruction done on separate days, or to be referred to other physicians for reconstruction who work primarily in hospitals or ambulatory care centers where costs of care are higher. The result would be that healthcare costs will be higher than they are under the current policy of payment.

I am asking that you re-consider this change that negatively impacts appropriate care for the patient and appropriate physician reimbursement for services provided. Sincerely, Camille Mason, MD.

**Submitter :** Dr. Steven Behr  
**Organization :** American Society of Anesthesiologists  
**Category :** Physician

**Date:** 08/31/2007

**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.

Simply put, anesthesiology practices stay in the black with third party insurance reimbursement. In many practices, Medicare insured cases are considered charity work, as the reimbursement falls far short of covering overhead costs of liability insurance premiums, staffing for scheduling and billing, and credentialing.

Older patients on average have more medical problems and when surgery is indicated have higher risks with their anesthetics. Combined with the increased risks of more complicated surgeries in these aging patients, we find that Medicare patients have the greatest risks while reimbursing the least.

I assure you this cannot continue. As the Medicare population grows and represents more of the payer mix, anesthesiologists trying to cover their practice costs will try harder to avoid these patients and the disproportionately low reimbursement they bring.

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.

Steve Behr, M.D.  
Tucson, AZ

**Submitter :** Mr. Chip Hewgley  
**Organization :** Emory Healthcare/Sports Medicine  
**Category :** Physical Therapist

**Date:** 08/31/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Dear Sir or Madam:

I've been a staff physical therapist at Emory Sports Medicine since 2002. A native of Oak Ridge, TN. I earned my Master s of Physical Therapy from The University of St. Augustine for Health Sciences (St. Augustine, FL) in 2000. I received my Bachelor s of Science in Sports Performance from Berry College (Rome, GA) in 1996. While at Berry, I was a member of the Varsity Baseball Team.

Before coming to Emory Sports Medicine, I spent two years with the Atlanta Braves as the organization s physical therapist. I'm currently working towards a specialty certification in Sports Physical Therapy as well as a Manual Therapy certification. My special interests include working with throwing athletes with shoulder and elbow injuries. I'm also a member of the American Physical Therapy Association Sports Section and am licensed in the State of Georgia.

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

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

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

Chip Hewgley, MPT



**Submitter :** Dr. Edward Bentley  
**Organization :** Santa Barbara County Medical Society  
**Category :** Physician

**Date:** 08/31/2007

**Issue Areas/Comments**

**Geographic Practice Cost Indices  
(GPCIs)**

Geographic Practice Cost Indices (GPCIs)  
see attached comments

CMS-1385-P-15083-Attach-1.DOC

15085



SANTA BARBARA COUNTY MEDICAL SOCIETY

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Santa Barbara, California 93111  
(805) 683-5333 FAX (805) 967-2871  
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August 31, 2007

Leslie Norwalk, Esq.  
Acting Director  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-P "GEOGRAPHIC PRACTICE COST INDICES (GPCIs)"  
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 "GEOGRAPHIC PRACTICE COST INDICES (GPCIs)"

Dear Ms. Norwalk:

I am writing on behalf of the Santa Barbara County Medical Society in response to solicitation of comments on proposed rules regarding Medicare physician payment localities (72FR38122) and GPCI's. Since 1997, our county has been adversely affected by CMS locality decisions. We have extensively studied the problem and have discussed solutions with CMA, CMS, MedPAC, GAO and Congressional leaders. It is appropriate, therefore, that we comment on the most recent proposal.

#### Background

The intent of current Medicare law is to reimburse providers according to the cost of providing services, make adjustments for geographic differences in those costs, and distribute payments accordingly. Since payments within localities are uniform, costs within localities should also be uniform. In 1997, HCFA applied a 5 percent iterative threshold to existing localities to consolidate them into comparable cost areas creating our current national physician fee schedule structure (61FR59494). In the ruling, there was no provision for future locality revision. In response to comments regarding managing future cost changes, it was stated "while we do not plan to routinely revise payment areas as we implement new GPCIs, we will review the areas in multiple locality States if the newer GPCI data indicates dramatic relative cost changes among areas." (61FR59497).

Since 1997, dramatic relative cost changes within current localities have occurred (CMS county data). The Government Accountability Office recently reported that more than half of the current payment localities contained counties with a large payment difference between locality payments and practice costs (GAO-07-466). A disproportionate number of these Counties are located in California. The GAO recommended that "the Administrator of CMS examine and revise the physician payment localities using an approach that is uniformly applied to all states and based on the most current data". It was also recommended that CMS "examine and, if necessary, update the physician payment localities on a periodic basis, with no more than 10 years between updates".

The GAO analyzed three options for Locality revision (County-based iterative, County-based GAF ranges, and MSA-based iterative) where payment accuracy could be improved without significantly increasing the administrative burden to CMS (GAO-07-466). The County-based GAF ranges option had the greatest payment accuracy, reducing the national average payment difference by 52 percent. The County-based iterative option, a variant of what we have been advocating for several years, had the second greatest payment accuracy, reducing the national average payment difference by 35 percent, and had less negative impact, less adjacent Locality GAF difference, and more statewide localities than the County-based GAF ranges option. The number of localities generated by the County-based iterative option could be reduced by consolidating single-county localities with similar costs. Such consolidation would result in minimal loss of payment accuracy.

CMS-1385-P offers three variations of GAO options for locality revision in California (72FR38140). The impact in California will be evaluated before a more broad application is considered in the future. We appreciate the attention to a problem that has troubled our physicians since 1997 and welcome the opportunity to pilot an appropriate proposal for the rest of the nation.

In the past, CMS has stated that it would consider locality revision if it had the “overwhelming support” of the state medical association and physicians from areas that are positively and adversely affected by the revision. Such support could be demonstrated by a resolution adopted by the state medical association, the number of licensed actively practicing physicians in the state and the number that were society members, the number of society members in each local (county) medical society, and letters from the local societies representing physicians in areas experiencing a payment decrease indicating the level of support for the change (59FR63416). The California Medical Association House of Delegates meets annually in October. The sixty day comment period for this proposal does not allow sufficient time for this to be addressed at that meeting. A resolution supporting one of the three proposals, therefore, is not possible. Furthermore, there are counties within the CMA that have expressed their opposition to any proposal that would result in payment reductions. Therefore, CMA does not have the overwhelming support that CMS has previously required for any of the proposed options. We have previously commented that State Medical Association input is important for locality revisions but support should not be a requirement. Congress intended CMS, not State Medical Associations, to have the final authority in locality decisions.

In anticipation of locality proposals this year, the Santa Barbara County Medical Society introduced a resolution to the 2006 California Medical Association House of Delegates establishing principles for locality revision that were adopted as CMA policy. The resolution states that CMA must apply the following principles in supporting revised Medicare Geographic Payment localities:

- 1) the methodology for revision is applied consistently;
- 2) payment accuracy within the locality is improved;
- 3) there is a mechanism for future revision of localities that is formula driven;
- 4) implementation of the revision minimizes payment reduction in each payment locality;

5) evaluation of any revision is based on accurate data gathered by CMA which shows that the revision minimizes any negative effect on access to care in California.

#### Alternative Proposal and Comment on Option 1 & 2

We would like to propose a variation of Option 1 and 2 of CMS-1385-P for consideration. We have extensively studied payment localities and have advocated that the 5% iterative methodology be applied (as described in GAO-07-466 County-based iterative option and Option 1 5%i (61FR34618)). Unlike the GAO and HCFA application, however, we advocate the methodology be applied to existing localities. The iterative methodology compares the highest GAF County to the weighted average (GAF) of the remaining counties of the locality. The 5% (non iterative) methodology proposed in Option 1 and 2 compares the highest GAF County to its Locality GAF. The highest GAF County is, therefore, included in the calculation of the Locality GAF to which it is being compared. As described by HCFA in 1996 (61FR34618) the 5% iterative methodology is preferred because mid sized areas in large states and large areas in small states with considerably higher input prices have difficulty meeting the threshold (see description p34618 Federal Register July 2, 1996). For example, San Diego County in Rest of California Locality has considerably higher input prices than the Rest of California (72FR38141-2). San Diego County contributes about 20% to the calculation of the Rest of California's GAF. As San Diego County's GAF increases to the threshold, the Rest of California's GAF also increases disproportionately, raising the payment error for all counties. San Diego County is not included in Option 1 or 2, we believe, because the 5% iterative methodology was not applied. If the same methodology is applied more broadly than California, areas exist where a county is so heavily weighted in the locality average that the threshold can never be met, unless they are compared separately (refer to CMS US County GPCI data).

We prefer the 5% iterative methodology to Option 1 and Option 2 of the CMS Locality proposal. Our comparison of the three options shows greater payment accuracy with our 5% iterative option. If implemented over two to three years, the impact on remaining counties is minimized and may be offset by conversion factor increases. In our opinion, the 5% iterative methodology applied to existing localities best fulfills our principles of locality revision. Administration could be simplified by consolidating single county localities with similar GAF's or Metropolitan Statistical Areas (MSA's) into Localities. Census data used for the Work and PE GPCIs for many areas is derived from MSAs. MSAs provide a logical basis for consolidation. Furthermore, there is greater payment accuracy than the 5% iterative county-based option reported by the GAO because the methodology is applied to existing localities rather than states. Such an application creates less disruption among existing localities with high payment accuracy.

We are troubled that the methodology consolidating counties in Option 2 (after the threshold is applied) is not clearly stated. Combining the Counties into one locality has less payment accuracy than Option 1. The three Counties are not geographically contiguous and reside in separate MSAs. It is not clear how such a consolidation would occur on a more broad application. We would propose that consolidation of Counties be based on MSAs (if the 5% iterative threshold is not exceeded within the MSA) or a 1% range as suggested in the GAO report. At the very least, CMS should clearly define the methodology (threshold) used to consolidate counties with similar cost structures into one new locality. We oppose an arbitrary consolidation of counties for administrative simplification at the expense of payment accuracy.

### Comment on Option 3

We prefer our 5% iterative county-based methodology to GAO's County-based GAF ranges and both methods for CMS Option 3 (5% or 0.05 range). Option 3 (5% or 0.05 range) has greater payment accuracy than our 5% iterative option. It creates a favorable locality for Santa Barbara County in 2007 if implemented. In California, it creates fewer payment areas (5 for 5%; 6 for 0.05). However, it creates payment error in localities that have high payment accuracy. Six of the nine payment areas in California have 100% payment accuracy (costs, as measured by county GAF, are the same as locality payment). Option 3 creates payment errors in these six localities. Option 3 creates localities with counties that are not geographically contiguous. The locality border difference is higher in County-based GAF range option than the 5% iterative county-based methodology reported by GAO. In addition, counties of the same MSA (and similar cost indices) are assigned different localities. Methodology used to create Option 3 would be difficult to apply for future revision without potentially disrupting all payment localities. One potential solution to this problem would be to create fixed ranges of .05 or 5% difference based on absolute numbers rather than "highest sequence" County GAFs.

Our greatest concern with Option 3 in a budget neutral proposal such as CMS 1385-P is the negative impact to low cost rural Rest of California Counties. These Counties will receive 4.9 to 7.3% payment reductions in the setting of rising costs, no payment updates for five years and a 9.9% conversion factor reduction. In our opinion, such payment reduction would unquestionably affect access of care to Medicare beneficiaries in these areas. We are unable to calculate the negative impact of our 5% iterative methodology without updated county GPCI's and RVUs but estimate that it will be significantly less than Option 3, particularly if implemented over a two to three year period.

We believe Option 1 5% iterative methodology provides the best balance of payment accuracy and negative impact in a budget neutral proposal. In addition, it is less disruptive to existing localities with high payment accuracy and would be more effectively applied to future revision. We recommend that you modify Option 1 and 2 of your proposal to include iterative methodology with consolidation of Counties into MSA derived localities (if the 5% threshold is not exceeded) and/or localities with 1% ranges.

### Comment on the proposed GPCI Update (72FR38136).

In past years, budget neutrality adjusting factors were described in the proposed update (69FR47504). Changes observed in the physician work GPCI update for 2009 were due to minor changes in utilization and budget neutrality factors (72FR38138) however these were not specified. In the interest of transparency, we recommend that this adjustment factor be published. We also recommend that all data used to calculate GPCI's be available to interested parties.

We would like to make two general comments about our observation of GPICs in California.

First, there is a high probability that calculation errors are occurring that effect payments and may effect locality revisions. We have observed discrepancies in other California County GPICs and GAFs that could effect locality revisions and locality GPCI calculations. Errors are expected considering the nearly 20,000 figures (three GPICs and three corresponding RVUs for each of the greater than 3000 counties) used to determine locality payments. Those errors could be minimized if the data used for the

calculations were available to interested parties. Errors in GPCIs to the third decimal point can affect payment of millions of dollars to an area. It is appropriate that the Administrator make this information as transparent as possible. We recommend that you make all data used to develop GPCIs and GAFs available to interested parties.

Second, there is considerable volatility in the HUD FMR data (used to generate rent indices for the PE GPCI) that makes us question its validity as a proxy for office rents. Santa Clara physicians did not see a 29% reduction in office rent relative to the national average. The GAO recommended in its 2005 report on GPCIs that CMS "consider the feasibility of replacing the practice expense GPCI's current rent index with a commercial rent index; if using a commercial rent index is not feasible, consider a residential rent index directly based on ACS data"(GAO-05-119). If the HUD FMR data is still considered the best proxy for office rents, we recommend that it be modified to adjust for the volatility in rental units that physicians are not seeing in their practice overhead.

#### Comment on Administrative Burden of Locality Proposal

We cannot identify any significant administrative burden to our practices as a result of locality revisions.

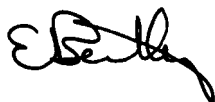
#### Summary

In summary, we recommend that

- 1) 5% iterative methodology be used in CMS proposed Option 1 with consolidation of Counties within the same MSA or a 1% range as the best option for budget neutral locality revision for California and other areas
- 2) Data used to develop GPCI's and GAF's is made available to interested parties.
- 3) CMS consider alternative methods to develop indices for office rent.

Thank you for the opportunity to comment on this very important proposal.

Sincerely,



Edward S. Bentley MD  
Senior Medicare Analyst  
Santa Barbara County Medical Society

Submitter : Mr. Raymond Meier  
Organization : AANA  
Category : Other Practitioner

Date: 08/31/2007

Issue Areas/Comments

Background

Background

August 20, 2007  
Office of the Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)  
Baltimore, MD 21244 8018 ANESTHESIA SERVICES  
Dear Administrator:

As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

This increase in Medicare payment is important for several reasons.

1 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.

1 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.

1 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,  
Raymond S.Meier

\_\_\_\_\_  
Name & Credential  
2308 26 1/2 Ave.South  
Address  
\_\_\_\_\_  
 Fargo, North Dakota 58103  
City, State ZIP

**Submitter :** Ms. Rebekah Grube  
**Organization :** University of Texas at Tyler  
**Category :** Other Health Care Professional

**Date:** 08/31/2007

**Issue Areas/Comments**

**Physician Self-Referral Provisions**

**Physician Self-Referral Provisions**

Dear Sir or Madam:

My name is Rebekah Grube and I am the head athletic trainer at the University of Texas at Tyler. I have been in athletic training for over eight years now and strongly believe in our professions' goals and objectives. Athletic training is a profession which seeks to improve the lives of the physically active through prevention, evaluation, treatment and rehabilitation of injuries as well as provide emergency care and education to the people we treat. This is a growing field that has been recognized by the American Medical Association as an allied health profession. Colleagues that I am acquainted with are some of the hardest-working, most dedicated professionals you will find. Athletic trainers go through rigorous academic programs, extensive internships and must successfully pass extremely difficult board exams. A large majority of athletic trainers have also obtained graduate-level degrees and are required to have ongoing continuing education to remain in good standing. It would be a shame to not have athletic trainers as part of the medical community in certain settings. We bring a wealth of knowledge and experience that is difficult to duplicate. Please help us by protecting the athletic training profession as it now stands.

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

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

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that 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,

Rebekah C. Grube, MSED, LAT, ATC  
Head Athletic Trainer  
The University of Texas at Tyler  
3900 University Blvd  
Tyler, TX 75799



**Submitter :** Dr. Harry Tagalakis  
**Organization :** Advanced Pain Management  
**Category :** Physician

**Date:** 08/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1385-P-15086-Attach-1.DOC

15086



## ADVANCED PAIN MANAGEMENT

4131 W Loomis Road \* Suite 300 \* Greenfield, WI 53221 \* 414.325.PAIN \* Toll Free 1.888.901.PAIN \* Fax 414.325.3700  
August 31, 2007

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

Re: CMS-1385-P

Dear Mr. Weems:

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

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

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

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

**RESOURCE-BASED PE RVUs**



## ADVANCED PAIN MANAGEMENT

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

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

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

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

CPT Code	Anesthesiologists -05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
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62311 (Inject spine l/s (cd))	78%	8%

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



## ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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



## ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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

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



## ADVANCED PAIN MANAGEMENT

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

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

Sincerely,

Sincerely,

Harry Tagalakis, MD  
Advanced Pain Management  
4131 W Loomis Road  
Greenfield, WI 53221

**Submitter :** Ms. Maggi Souris  
**Organization :** Bryn Mawr School  
**Category :** Other Health Care Professional

**Date:** 08/31/2007

**Issue Areas/Comments**

**Physician Self-Referral Provisions**

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Maggi Souris and I have been the Certified Athletic Trainer at The Bryn Mawr School for the past ten years taking care of athletes ranging from age 12 to 18. I have a Bachelor's of Science in Physical Education and a Master's of Science in Athletic Training.

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,

Maggi V. Souris, MS,ATC,CSCS

**Submitter :** Don Elswick  
**Organization :** OSF Holy Family Medical Center  
**Category :** Other Health Care Professional

**Date:** 08/31/2007

**Issue Areas/Comments**

**Background**

**Background**

August 31, 2007

Office of the Administrator Centers for Medicare & Medicaid Services

Department of Health and Human Services

P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT) Baltimore, MD 21244 8018 ANESTHESIA SERVICES

Dear Administrator:

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1 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.

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Sincerely,

Don Elswick, CRNA  
1129 Kimberly Dr  
Monmouth IL 61462



**Submitter :** Dr. Kostandinos Tsoufas  
**Organization :** Advanced Pain Management  
**Category :** Physician

**Date:** 08/31/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1385-P-15089-Attach-1.DOC



## ADVANCED PAIN MANAGEMENT

4131 W Loomis Road \* Suite 300 \* Greenfield, WI 53221 \* 414.325.PAIN \* Toll Free 1.888.901.PAIN \* Fax 414.325.3700  
August 31, 2007

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

Re: CMS-1385-P

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**RESOURCE-BASED PE RVUs**



## ADVANCED PAIN MANAGEMENT

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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.

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## ADVANCED PAIN MANAGEMENT

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

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

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

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

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

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

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

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



## ADVANCED PAIN MANAGEMENT

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

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

Sincerely,

Sincerely,

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**Date:** 08/31/2007

**Organization :** West Central Anesthesiology Group, Ltd.

**Category :** Physician

**Issue Areas/Comments**

GENERAL

GENERAL

See Attachment

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CENTERS FOR MEDICARE AND MEDICAID SERVICES  
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