Submitter : Dr. Timothy Love **Date:** 08/24/2007

Organization : Love Chiropractic Center

Category : Chiropractor

Issue Areas/Comments

Technical Corrections

Technical Corrections

It is imperative that I be able to Order X-rays on Medicare patients. For the safety of our senior citizens I believe that a MEDICAL radiologist should be paid to examine chiropractic patients. How many tumors, cancers, and broken bones could be missed if this group of professionals are not accessible to our fixed income group.

Submitter : **Dr. Daniel Shaye** **Date: 08/24/2007**

Organization : **Performance Chiropractic, LLC**

Category : **Chiropractor**

Issue Areas/Comments

Technical Corrections

Technical Corrections

RE: file code CMS-1385-P -- Technical Corrections

To whom it may concern:

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

I once had a patient with severe hip pain after a fall. She was a senior on Medicare. Her PCP x-rayed her, and the films were negative. Her pain spiked 3 weeks later, and she came to see me. I had to go through the PCP to get the CAT scan done that confirmed my suspicion: hip fracture. Having Medicare set up any roadblocks to patient care from chiropractors seems unwise. It is ultimately the patient who will suffer.

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

By limiting a Doctor of Chiropractic from referring for diagnostic imaging studies, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal. Patients will NOT cease seeing chiropractors. We're here to stay, and we provide a unique and valuable service. It makes more sense to expand our inclusion in mainstream medicine, than to attempt to restrict that process.

I strongly urge you to table this proposal. Diagnostic imagine, when needed, are integral to the overall treatment plan of Medicare patients and. In light of the fact that the demonstration project, if carried forward into full-scope coverage, would be a step in the precise opposite direction from this new restriction, this proposed revision seems especially ill advised. Finally, it is ultimately the patient who will suffer should this proposal become standing regulation. On behalf of our millions of patients nationwide, I ask you to carefully and thoughtfully reconsider your proposal.

Sincerely,

Daniel A. Shaye, D.C., C.C.S.P., F.I.A.M.A.

Submitter : **Mr. Ted McFarlane** **Date: 08/24/2007**

Organization : **Johnson County Med-Act**

Category : **Local Government**

Issue Areas/Comments

Ambulance Services

Ambulance Services

We provide emergency ambulance services to the communities within Johnson County Kansas. We are part of local government. The proposed rule would have a negative impact on our operation and the high quality health care we provide to Medicare beneficiaries. In addition, we believe this proposed rule will inappropriately encourage paramedics to seek signatures from patients who are in need of medical care and under mental duress. Additionally, this proposed rule would have a negative impact on wait times in the emergency room impacting our operations and the operations of emergency rooms throughout the country. We therefore urgently submit comments on the problems with the proposed rule.

In summary, here are the points we would like you to consider:
? Beneficiaries under duress should not be required to sign anything;
? Exceptions where beneficiary is unable to sign already exist and should not be made more stringent for EMS;
? Authorization process is no longer relevant (no more paper claims, assignment now mandatory, HIPAA authorizes disclosures);
? Signature authorizations requirement should be waived for emergency encounters.

We understand that the proposed rule was inspired by the intention to relieve the administrative burden for EMS providers. However, the relief being proposed by CMS would have the unintended effect of increasing the administrative and compliance burden on ambulance services and the hospitals and would result in shifting the payment burden to the patient if they fail to comply with the signature requirements at the time of incident. Accordingly, we urge CMS to abandon this approach and instead eliminate entirely the beneficiary signature requirement for emergency ambulance services.

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.

Thank you for your consideration of these comments.

Sincerely,

Ted McFarlane
Chief

Submitter : **Anthony Geramita** **Date: 08/24/2007**

Organization : **Primary Health Network**

Category : **Chiropractor**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Please continue to reimburse for x-rays for patient safety for x-rays for patient under chiropractic care. Removing this provision only puts both the doctor and patient at risk. Please carefully take a look at this provision.

Submitter : **Dr. shayne monson** **Date: 08/24/2007**

Organization : **Monson chiropractic**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

CMS-1385-P

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

Re: TECHNICAL CORRECTIONS

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

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

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

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

Sincerely,

Shayne Monson, DC

Submitter : **Dr. Chad Anderson** **Date: 08/24/2007**

Organization : **Cich Chiropractic**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

Re: TECHNICAL CORRECTIONS

CMS-1385-P-7691-Attach-1.TXT

#7691

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

Re: "TECHNICAL CORRECTIONS"

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

Sincerely,

Dr. Chad M Anderson, D.C.
Chad.AndersonDC@gmail.com
763-843-6788

Submitter : **Dr. Tiffany Hardaway** **Date: 08/24/2007**

Organization : **Dr. Tiffany Hardaway**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Sincerely,

Tiffany Hardaway, M.S., M.D.
Division of Anesthesiology
Cleveland Clinic Foundation

Submitter : Dr. Prakash Navni **Date:** 08/24/2007

Organization : Chicagoland Early Intervention

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

As a physical therapist, I belive that no person other than physical therapist or physical therapy assistant is qualified to provide physical therapy. Physician Self referral should be stopped as It increases the potential of oversue and it will cost more federal and state government. On the contrary it has been difficult to get the prescription from the doctors for physical therapy services. The same doctors when they practice for self referral there is no problems. Physical therapist are qualified professional and they should be allowed to evaluate and treat like any other profession without any restrictions.

Submitter : **Dr. Shawn Pala** **Date: 08/24/2007**

Organization : **Pala Chiropractic, L.L.C.**

Category : **Chiropractor**

Issue Areas/Comments

Technical Corrections

Technical Corrections

It is critical for the correct diagnosis and corresponding treatment of Medicare patients that a doctor of chiropractic be permitted the referal capacity for radiology services. Please abolish the proposed recommendation eliminating payment or reimbursement to the Medicare Beneficiary for those services ordered and recommended by a doctor of chiropractic. This would only harm the Medicare patient.

Submitter : **Ms. Pam Dunlap** **Date: 08/24/2007**

Organization : **Oklahoma Society of Anesthesiologists**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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

Thank you for your consideration of this serious matter.

Submitter : **Dr. Jeffrey Philip** **Date: 08/24/2007**

Organization : **Perioperative Medical Consultants**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

Thank you for your consideration of this serious matter.

Submitter : **Dr. James Monks** **Date: 08/24/2007**

Organization : **American Chiropractic Association**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

This is in regard to CMS-1385-P. This should be considered under the headings "Technical Corrections" please see my attached letter. Thank you in advance for your time and understanding. Sincerely, Dr. James Monks

CMS-1385-P-7697-Attach-1.DOC

#7697

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

Re: "TECHNICAL CORRECTIONS"

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

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

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

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

Sincerely,

James Monks D.C.

Submitter : **Dr. Tom Hughes** **Date: 08/24/2007**

Organization : **Advantage Health**

Category : **Chiropractor**

Issue Areas/Comments

Coding--Reduction In TC For Imaging Services

Coding--Reduction In TC For Imaging Services

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P

Re: TECHNICAL CORRECTIONS

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Sincerely,

Dr. Thomas E. Hughes
Chiropractic Physician

Submitter : **Dr. kathryn nicol** **Date: 08/24/2007**

Organization : **alsip integrated medical center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: TECHNICAL CORRECTIONS

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

Sincerely,
Dr Kathryn Nicol

Submitter : **Dr. katy nicol** **Date: 08/24/2007**

Organization : **Dr. katy nicol**

Category : **Physician**

Issue Areas/Comments

Technical Corrections

Technical Corrections

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

Re: TECHNICAL CORRECTIONS

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

Sincerely,
Dr Kathryn Nicol

Submitter : **Dr. Dane Parker** **Date: 08/24/2007**

Organization : **none**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: TECHNICAL CORRECTIONS

As a Chiropractic physician, I must know that there no contraindications to adjustment (ie. abdominal aortic aneurysm, spinal instability from anomaly or fracture et.)
The issue of subluxation is one that is moot. I can assure you that costs will increase if every senior citizen that needs Chiropractic care has to be referred back to their primary to get this referral.

This is already a problem for MRI's and other imaging studies we so desperately need to have to render quality care.

Please don't make this same mistake with X-rays. It will jepardize the quality of care, and increase costs.

Dane V. Parker DC

Submitter : **Dr. Murray Smith** **Date: 08/24/2007**

Organization : **Dr. Murray Smith**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

Technical Corrections. CMS-1385-P.

I frequently use xrays performed at another facility for assessment of patient's conditions. Even if the films are, for example, 2 years old there can fruitful information to gained. To use existing films and the information from them is prudent and rational. Rember the purpose of HIPPA? Any reasonable person would do the same. Not being able to make use of that information is unreasonable. Perhaps we should throw out HIPPA for the same reason.

If the proposed change is made regarding xrays used by a chiropractor but taken by a radiologist or other physician is done it could add to the expense of chiropractic to the patient as well as the overall medical treatment costs. Additionally, ionizing radiation may subsequently be duplicated when xrays are performed. Every quality physician, DC and Phd will tell you that radiation has cumulative, deleterious effects and every effort to minimize harmful effects should be taken. Therefore, the proposed change would add expense and possible harm. Where is the benefit to the patient? Please do not let prejudice stand in the way of reason.

Submitter : **Dr. Andreas Schuster** **Date: 08/24/2007**

Organization : **ASA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Submitter : **Dr. Cailin Stubbs** **Date: 08/24/2007**

Organization : **Dr. Cailin Stubbs**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

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Thank you for your consideration of this serious matter.

Submitter : **Dr. Timothy Houseman** **Date: 08/24/2007**

Organization : **Eastern Shore Anesthesia**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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Thank you for your consideration of this serious matter.

Timothy W. Houseman, M.D.

Submitter : **Dr. Teresa Kelly** **Date: 08/24/2007**

Organization : **Eastern Shore Anesthesia**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Teresa K. Kelly, M.D.

Submitter : **Dr. Jeana Green** **Date: 08/24/2007**

Organization : **Eastern Shore Anesthesia**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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Jeana Green, M.D.

Submitter : **Dr. Blake Neal** **Date: 08/24/2007**

Organization : **Eastern Shore Anesthesia**

Category : **Physician**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Blake D. Neal, M.D.

Submitter : **Dr. William Womack** **Date: 08/24/2007**

Organization : **Eastern Shore Anesthesia**

Category : **Physician**

Issue Areas/Comments

GENERAL

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

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Thank you for your consideration of this serious matter.

William A. Womack, M.D.

Submitter : Dr. Aaron Milbank **Date:** 08/24/2007

Organization : Metropolitan Urology

Category : Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

As a practicing physician, the ability to rapidly diagnose and treat my patients is of paramount importance to me. I currently practice in a single specialty practice (Urology - 25 doctors). We offer on site laboratory services (state of the art) and I am able to receive the results sooner than I could through a third party lab. We also can offer imaging services. From a patient's perspective, this could not be better. If these regulations take effect, a typical patient of mine would come to my office where I would order labs and, if needed, a CT scan. They would then travel across town to have the lab studies, go elsewhere to have their CT scan, then perhaps be told by the CT facility that they have to have another series of labs since the facility cannot access the labs done elsewhere to ensure renal function is normal prior to administering the contrast for the CT. Then they have to make another appointment and see me to review the studies. In an ideal system, the physician's office would have state of the art laboratory facilities and imaging facilities. The patients could complete all of my ordered tests and I would have instantaneous access to the results. We currently have this system!
If the purpose of this proposed revision is to eliminate abuses associated with self-referral, there are better ways to go about reaching this goal. Physicians who are ordering unjustified studies should be appropriately reprimanded.
Let's not punish the patients when the problem lies not with them! I'd be happy to discuss these issues at length with any interested party.

Submitter : **Mr. Edward (Brady) O'Mara** **Date: 08/24/2007**

Organization : **Seven Summits Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Attn: Mr. Kerry N. Weems
Administrator Designate
CMS U.S. Dept. of Health & Human Services
P.O. Box 8018 Attn: CMS-1385-P
Baltimore, MD 21244-8018

Re: Physician Self-Referral Issues

Dear Mr.Weems, August 20, 2007

My name is Brady O'Mara, MSPT and I have been a physical therapist for ten years. I opened my physical therapy private practice in March 2005 in an affluent suburb of Philadelphia, which is the same town in which I live. I chose my location because it is six miles from two hospitals where I previously worked and seven miles from two other hospitals. I live and work in an area where most of the orthopedists (90%, 18/20) have their own outpatient physical therapy offices. And of course these orthopedists refer primarily to their own practices.

The in-office ancillary services exception has created an anti-competitive loophole that has resulted in the expansion of physician-owned arrangements that provide physical therapy services. These physicians have a captive referral base of physical therapy patients in their offices. This situation puts all independent practitioners at a significant competitive disadvantage.

I have been able to grow my practice slowly over the past two and a half years despite minimal referrals from these self-referring orthopedic practices. I have continued to grow my Direct Access patient referrals and caseload by marketing directly to the healthcare consumer. This type of marketing is a very expensive undertaking that I did not anticipate in starting my business. While my practice has grown slowly but steadily, I am still the sole physical therapist in my practice. I am a small businessman trying to make an honest living, to provide for my family, and to provide the best possible care to my patients. However, because of the abusive, monopolistic referral arrangements, I am unable to effectively compete with these Physician-owned practices (POPs).

The in-office ancillary services exception is currently defined so broadly in the regulations that it facilitates the creation and perpetuation of abusive referral arrangements. Due to the repetitive nature of PT services, it is no more convenient for the patient to receive services in the physician s office than an independent physical therapy clinic. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a

significant amount of programmatic abuse, over-utilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

In closing, I would like to thank you for your time and consideration of my comments.

Sincerely,

Brady O'Mara, MSPT
Owner, Seven Summits Therapy & Fitness, LLC

Submitter : **Dr. Paul Baird** **Date: 08/24/2007**

Organization : **Pinnacle Chiropractic & Spinal Rehabilitaion**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

Eliminating the reimbursement for Medicare x-rays, would severely hamper the ability for those who utilize Medicare to have adequate health care. Many of my patients would be required to pay for those services out of their own pocket, which could and would prevent some from receiving the appropriate care.

Submitter : **Dr. Christopher Schrepferman** **Date: 08/24/2007**

Organization : **Allied Urology, PSC**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I would like to voice strong opposition to the potential restriction involving in-office imaging (as opposed to off site imaging centers). Urologists have a long history of administering their own imaging (including prostate ultrasound in conjunction with biopsies), a refined skill set that would not be available outside our practice setting. In addition, patient after patient after patient thank us for providing imaging services in our office, reducing in some meaningful way the tremendous and at times preposterous hassle that the majority of patients experience in the health care marketplace. We believe strongly that office imaging has improved the care delivered to our patients - the physicians are available in the office and can troubleshoot patient problems and clarify orders for our technologists, eliminating unnecessary or redundant studies. We believe strongly that we have improved the patient experience greatly, offering web based image retrieval available via any web portal in the world. In our city, hospitals will not allow web portals to access images from competing facilities, a critically important shortfall when urgent or emergent surgery is required.

Our practice also recognizes the potential for abuse of office based imaging. Prior to the initiation of office CT imaging in our 16 man practice, we kept detailed records of our CT volume in order to compare our utilization once office imaging commenced. Our partners are well informed about their utilization - we believe self monitoring and appropriateness of care are critically important to maintaining a trustworthy and honest relationship with our patients.

I would like to suggest that CMS consider punishing over-utilizing practices rather than a blanket ban on office based imaging, a service that benefits the vast majority of patients. In addition, revenue generated on appropriate imaging allows retention of skilled and experienced nursing personnel within our practice. The ability to generate additional revenue allows our practicing physicians to care for indigent and complicated patients in our downtown practice location for little or no reimbursement. We have had serious discussions about this major practice problem and anticipate that we would need to restrict the number of patients we would be willing to take on charity, including no longer seeing state Medicaid patients.

We do not believe we can continue to absorb significant cuts to our office revenue, particularly after the ruling on office administered pharmaceuticals only a short time ago. Please consider the fact that the majority of MD's are principled, honest, and dedicated public servants. Assuming no excess utilization, allowing in-office imaging does not increase costs to the health care system - it certainly increase efficiency and patient satisfaction.

Sincerely,

Christopher G. Schrepferman, MD
Secretary, Allied Urology PSC
Louisville, KY 40202

Submitter : Ms. Ann-Marie Lynch **Date:** 08/24/2007

Organization : AdvaMed

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-7716-Attach-1.PDF

#7716.

701 Pennsylvania Ave., N.W., Suite 800
Washington, DC 20004-2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

August 24, 2007

Via Electronic and U.S. Mail

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

Re: 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 for Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions (CMS-1385-P)

Dear Mr. Kuhn:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies for Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions (CMS-1385-P, *Federal Register*, Vol. 72, No. 133, Thursday, July 12, 2007, p. 38122). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed appreciates the considerable effort you and your staff have put into the development of the proposed Medicare Physician Fee Schedule rule (PFS). While we are pleased with some of the proposed changes announced in the rule we remain concerned with others. AdvaMed supports the establishment of payment rates under the physician

fee schedule that are adequate and ensure access to advanced medical technologies by Medicare beneficiaries. We will comment on the following issues raised in the proposed 2008 PFS Rule:

1. Resource Based PE RVUS
   a. Discussion of Equipment Usage Percentage
   b. Equipment Interest Rate (Discussion)
   c. PE Proposals for CY 2008
   d. RUC Recommendations for Direct PE Inputs and Other PE Input Issues
      Transcatheter Placement of Stent(s)
      Arthroscopic Procedure Non-facility Inputs
2. Coding- Reduction in TC for Imaging Services
3. Clinical Laboratory Issues
4. TRHCA—Section 101(b): PQRI
5. Physician Self-Referral Provisions

PROVISIONS

I. Resource Based PE RVUS

AdvaMed supports CMS's decision to leave equipment utilization and interest rate assumptions unchanged for CY 2008. AdvaMed also encourages CMS to establish non-facility PE inputs for arthroscopic procedures done under local/regional anesthesia and furnished in the office setting. Our comments on these issues are discussed in more detail below.

a. Discussion of Equipment Usage Percentage

CMS acknowledges that it does not have sufficient empirical evidence to justify a change from its current assumption of a 50 percent utilization rate for imaging equipment. Some analysts cite a Medicare Payment Advisory Commission (MedPAC) survey of CT and MRI services provided by select physician offices and independent diagnostic testing facilities (IDTFs) as evidence for the need to change the CMS assumption about equipment use rates. When describing this survey during a public MedPAC meeting on April 19, 2006, a MedPAC professional staff member noted the following:

> "This survey is a first step in examining the use of imaging equipment. It was not nationally representative and it was not designed to determine equipment use rates. Its intent was to assess the feasibility of getting use rate data from the survey. It shows that a the [sic] short survey instrument can be used to collect information on how frequently equipment is operating while achieving a high response rate," and "I do want to caution that this survey is not representative [of] anything." (See MedPAC meeting transcript, pages 237, 242.)

Despite the limitations of the survey, the results formed the basis for MedPAC's discussion of equipment use rates in its June 2006 report.

At AdvaMed's request, United BioSource Corp (UBC) prepared an analysis of the MedPAC survey on imaging equipment utilization rates performed by the National Opinion Research Center (NORC) and Georgetown University.[1] The survey examined MRI and CT equipment use rates in physician offices and Independent Diagnostic Testing Facilities (IDTFs). UBC concluded that the survey results should not form the basis for evidence-based decision making due to limitations in the survey, which included:

- Low response rate;
- Lack of geographical representation in sample selection;
- Responses from physician offices and IDTFs that may not reflect the distribution of imaging service providers in many parts of the nation;
- Inclusion of only MR and CT equipment in the survey, which may not be representative of all imaging modalities.

As part of its analysis, UBC canvassed the literature for information about imaging equipment use rates. Like CMS, UBC found insufficient empirical evidence to inform evidence-based decision making about utilization rates.

AdvaMed supports CMS's decision to maintain the imaging equipment usage assumption at 50 percent until such a time as sufficient empirical evidence justifies an alternative proposal.

b. Equipment Interest Rate (Discussion)

In the proposed rule, CMS states its intention to maintain the interest rate on equipment at 11 percent , following their analysis of revised Small Business Administration data. AdvaMed concurs with the use of this data for verifying assumptions about the actual interest rates paid by physician offices and IDTFs and supports CMS's decision to retain the interest rate assumption used in the calculation of equipment costs at 11 percent.

c. PE Proposals for CY 2008

AdvaMed has some concerns regarding the potential impact of significant reductions in practice expense values on access to care, particularly in the case of some radiation therapy procedures (for example partial breast and High Dose Rate (HDR) brachytherapy). We ask that CMS consider the issue of beneficiary access to procedures in making any final determinations regarding practice expense reductions that impact the

1 Donald E. Stull and Craig A. Hunter, United BioSource Corporation, "Final Report: Evaluation and Critique of MedPAC's Survey on MRI/CT Utilization Included as Part of MedPAC's June 2006 Report to Congress" June 2007. National Opinion Research Center, "Survey of Imaging Centers: Use of MRI and CT Equipment in Five Markets," May 2006.

ability of physicians to offer certain treatment options to their patients.

d. RUC Recommendations for Direct PE Inputs and Other PE Input Issues

Transcatheter Placement of Stent(s)

In the proposed rule, CMS states that the PERC considered and approved direct PE inputs for the non-facility setting for transcatheter placement of stent(s) (CPT codes, 37205, 37206, and 75960). In the 2007 Final HOPPS/Ambulatory Surgical Centers Rule, CMS did not move forward with its proposal to add CPT codes 37205 and 37206 to the list of Ambulatory Surgical Center (ASC) approved procedures stating that,

> "Our medical advisors reconsidered our proposal to add CPT codes 37205 and 37206 to the ASC list and determined that it would be in the best interests of Medicare beneficiaries to continue to deny payment for them in ASC facilities. Our medical advisors believe that the procedures would require more than 4 hours of recovery time and would most often require an overnight stay in the facility. For these reasons, we are not finalizing our proposal to add CPT codes 37205 and 37206 to the ASC list for CY 2007."[2]

In the 2008 Proposed HOPPS/ASC Rule, CMS reiterated their safety concerns related to performing these transcatheter placement of stent procedures in ASCs.[3] AdvaMed urges CMS to consider these safety issues in making a determination regarding the appropriateness of developing direct PE inputs for the use of peripheral stent procedures in the non-facility setting.

Arthroscopic Procedure Non-facility Inputs

AdvaMed urges CMS to establish non-facility PE inputs for arthroscopic procedures done under local/regional anesthesia and furnished in the office setting. AdvaMed recommends that CMS work with physicians and manufacturers and use available data, including data received from manufacturers, in establishing new, interim non-facility PE RVUs. Establishing non-facility PE RVUs will help to ensure that patients have access to all physician services in the most appropriate setting.

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2 Federal Register, Vol. 71, No. 226, 68168 (Friday, November 24, 2006).

3 Federal Register, Vol. 72, No. 148, 42488 (Thursday, August 2, 2007).

II. Coding- Reduction in TC for Imaging Services

The proposed rule contains recommendations related to the technical component (TC) for imaging services under the physician fee schedule, which are currently subject to the DRA imaging cap. AdvaMed would like CMS to clarify that when an imaging service is packaged under the hospital outpatient prospective payment system, the cap will not apply to the TC of that service under the physician fee schedule.

III. Clinical Laboratory Issues

In this section, we offer comments relating to the pricing of clinical diagnostic laboratory tests. In contrast to several other payment systems, which have been significantly revised in the last several years, the procedures for operating the clinical laboratory fee schedule have remained relatively static. The applicable statute provides the Secretary opportunities to improve the system regarding specific details and to implement reasonable processes relating to new tests. Below we offer comments specific to the various aspects of the reconsideration proposal and suggest further improvements.

Reconsideration – Process

We commend CMS for proposing a reconsideration process for use in future new test payment determinations. Implementation of a reconsideration process would be a significant step in helping assure reasonable pricing decisions for new tests. At present, once CMS has established the payment amount for a new test, the decision is largely unchangeable. If significant questions arise later about either the basis for a decision to cross-walk or to gap fill a new test code, or a decision concerning the payment amount for the new test code, CMS and affected parties lack a regular process by which the decision can be revisited and revised.

We have a few questions and comments on the proposed reconsideration process:

- *Frequency of Public Meetings; Effective Date of Reconsidered Determinations.* We note that the Secretary has the authority under section 1833(h)(8)(D) to convene public meetings as the Secretary deems appropriate in order to receive public comments on payment amounts. However, the reconsideration process that is set forth in the proposed rule references the use of only the public meeting that is held typically in July to discuss new test payment for the following calendar year. We also note that the explanation of the proposed reconsideration process in the Preamble to the regulation appears to reference only the July public meeting to discuss comments regarding reconsidered determinations. This would mean that reconsiderations would only take place on an annual basis. Some reconsiderations may merit a speedier process. Because an improper payment rate could impact beneficiary access, we recommend that this option be built into the time lines associated with the reconsideration process. We recommend that CMS make public a summary of <u>all</u> recommendations for reconsideration by January 31st using a grid similar to the annual posting in September

which contains the recommendations made at the July public meeting and CMS's preliminary new test payment determinations. CMS could then accept public comments for at least 30 days, and make updates by the end of the first quarter of the calendar year. CMS could also elect to hold another public meeting, in addition to and in advance of the July public meeting, to consider public comment on the matters that are being reconsidered on this faster track. If CMS found that it needed additional time for reconsideration, any remaining codes could go through the July public meeting and be updated by January 1st of the following year.

- *Opportunity to Make Oral Public Comments.* The Preamble discussion of the proposed reconsideration process makes reference to a 60-day public comment period concerning either the basis for a decision (to price a new test code through either the cross-walk or gap fill process) or the amount of payment for the new test code. This discussion states that those members of the public who submit written comments during the 60-day comment period will also have the opportunity to comment orally at the next clinical laboratory public meeting. AdvaMed does not support restricting the comments made during the clinical laboratory public meeting. We recommend that CMS accept comments from entities who submitted written comments, during the 60-day comment period, AND other interested parties during the meeting.

- *CMS Rationale for Initiating a Reconsideration and for Deciding Whether to Change a Prior Determination.* AdvaMed appreciates CMS's clarification that its proposed reconsideration process would involve two steps: (1) deciding whether to reconsider a prior determination; and (2) deciding whether to change a prior determination. We note that the agency has stated that it will post information on the CMS website regarding its decision to reconsider a prior determination, as well as the results of the reconsideration. First, we urge the agency to enhance the transparency of its process by posting summaries of all recommendations to reconsider prior determinations. Second, we recommend that CMS provide information regarding the rationales underlying its decisions to either accept or decline reconsideration requests submitted by external requestors. Third, after a reconsideration has begun, we urge CMS to include information in its web postings regarding the basis or rationale for deciding whether to change a prior determination. In particular, we recommend that the postings provide a succinct explanation for the determination, indicating the information that the agency found persuasive or important. The current tracking sheets used in the national coverage process provide a useful model for presenting the agency's rationale for its decisions.

Pricing New Test Codes by Cross-walking

AdvaMed urges the agency, when cross-walking payment for a new test, to set the payment amount at the national limitation amount (NLA) of the test on the Clinical Laboratory Fee Schedule to which the new test is cross-walked.

When electing to price a new test code by cross-walking it to an existing test code on the

fee schedule, the agency is making a single decision with national applicability, rather than subjecting the test to a fresh assessment by multiple contractors. The decision is presumably based on both the similarity of the tests and the resources needed for their delivery. Under these circumstances, we submit that the choice being made is in effect based on a national rate, the NLA, without significant attention to the local carrier-specific rates that might be below that national value.

Some of these carrier-specific amounts below the NLA are improbably low, and may compromise access to these tests in some carrier jurisdictions. Assigning such inappropriately low rates to new tests would compound any potential access problem. We believe that the statute affords the Secretary the opportunity to set appropriate policy in this area, and we urge the Secretary to exercise this discretion by setting payment amounts at levels sufficient to encourage the ready availability of new tests for beneficiaries throughout the country.

Pricing New Test Codes by Gap Fill

CMS's gap fill proposal, while valuable, could be improved in a number of ways. The proposal appears to confine the gap fill pricing process to a single calendar year. Once a decision is made to gap fill, claims-payment contractors (carriers or Medicare Administrative Contractors (MACs)) would start, as at present, to use carrier-specific amounts on any claims starting January 1. As we understand the proposal, the contractors would establish preliminary carrier-specific amounts by April 1, and CMS would post these amounts for public review by April 30. Final carrier-specific amounts would then be collected by CMS by September 30. After this, CMS would either let the NLA calculated on the basis of these carrier-specific amounts stand or would revise the NLA "based on comments received."

AdvaMed endorses the proposed change that could result in revisions to the otherwise applicable NLAs based on consideration of further information, if the process for doing so adequately allows for transparency and public input. As proposed, the new process deprives the agency of the advantages of fully-informed comments and could lead to questionable results.

Under the proposal, it appears that CMS would have access to comments based on the April 30 preliminary carrier-specific amounts. Contractors would have four months to establish these amounts. The amounts will inevitably be less reliable than those available today. As stated in the proposed rule, "it takes approximately 9 months for our carriers to establish carrier-specific amounts". See 72 FR 38163. Thus the agency will examine the carrier-specific amounts it harvests on September 30 using comments based on preliminary amounts harvested five months earlier. While we appreciate the willingness of the agency to receive and react to comments, we urge creation of an opportunity for comment on the September 30 amounts.

We appreciate the timing difficulties such an opportunity might present in establishing

final gap fill payment amounts by January 1. However, we believe the importance of achieving reasonable pricing decisions outweighs the need to establish a final amount by that date. We urge CMS to consider a revision to the proposed process that would allow gap fill prices to be revised, even if that requires retaining contractor prices for some period of time into the next year, or establishing an interim NLA to be used starting January 1 and permitting revision of that NLA sometime over the ensuing year.

The proposed changes offer a welcome opportunity to revisit payment amounts established by gap fill, but promise no significant effect on the quality of the payment decisions initially made by contractors. If reasonable payment amounts can be established at the start of the process, the need to rework decisions through a reconsideration process could be avoided. We have repeatedly urged CMS to provide clear and detailed instructions and improve the transparency of the process. In addition, we urge CMS to provide the information on which the contractors base their decisions to the public. Specifically, contractors should be directed to consider a number of factors, including: (1) the resources involved in acquiring the equipment and materials needed to perform the new test; (2) the staff expertise and skill required to perform the new test; (3) the time associated with performing the test or method; and (3) the potential value of the test or method. We continue to believe such steps would be valuable, and we urge the agency to update its instructions and make information used in the decision process readily available to the general public. In addition, considering several recent experiences with gap fill pricing of new test codes, we are concerned with several additional aspects of this process.

- First, it appears that contractors have sometimes misunderstood or misinterpreted CMS's existing instructions. In particular, contractors have arrived at carrier-specific amounts for a gap fill test that appear to be cross-walked to the payment amounts for a similar test, even when the agency has explicitly rejected cross-walking in the particular instance.

- Second, contractors are frequently unfamiliar with clinical aspects of new tests. Developing a payment rate using gap-fill is resource-intensive from the contractors' perspective because they need to learn the details about the nature, use, expected outcomes, and needed resources of a new test to price it appropriately. This is a particularly challenging dilemma when some new tests may only be performed in one or a few laboratories nationwide, and thus many contractors may have no claims experience with such tests at all.

- Third, contractors may be unfamiliar with the gap-fill process because it is employed infrequently and represents a very small portion of a given contractor's overall workload.

The first of these problems might be addressed by CMS examining compliance with its instructions or by exclusion of ostensibly cross-walked payment amounts from the NLA

calculations. The agency may wish to consider such steps. We would, however, urge the following changes in the approach to gap fill pricing that could help to address many of these concerns.

CMS should consider limiting the number of contractors involved in the gap-fill process for clinical laboratory services because it will enable greater attention to this process and improve overall quality in gap-fill decision-making. This limitation in the number of contractors should only apply to the gap-fill process, not other aspects of clinical lab services reimbursement. Section 1833(h) of the Social Security Act gives the Secretary the authority to establish regions for laboratory services, and it appears to provide sufficient latitude for this purpose. The resulting payment amounts would prevail for an entire region and would serve as the basis for the NLA in due course. This activity could be added as a specific task to one of the MAC contracts in each region. Having the task explicitly described and funded with appropriate resources would be vital. In turn, the concentration of resources should afford the chosen contractors the ability to develop more sophisticated capacity in making payment decisions. Such resources could be used, for example, to obtain staff knowledgeable in matters related to clinical lab services. Further, the relevant contractors could more easily be held accountable for following CMS's instructions and for the transparency of their activities. We believe that this approach would yield high quality, reliable decisions more consistently than the existing approach where all carriers are called upon to engage in gap fill pricing.

This approach would still cause concern in instances where a new test is performed only in a single location. As more high-technology, molecular tests aimed at genetic characteristics are developed by the industry and become available to Medicare beneficiaries, more instances are likely to arise in which the test is done in only one or a few select locations. In these circumstances, some contractors would, under either the existing arrangement or the alternative discussed above, be required to establish prices for tests whose claims will never be processed in their jurisdictions. The exercise would be abstract for those contractors; whatever advantages might be thought to result from a carrier's familiarity with local circumstances would be missing and the consequences of its decisions would have no immediate impact in its area.

For tests performed in only one location, we recommend having the single contractor with claims experience take the lead role in gap fill pricing. If CMS concludes that the statute does not permit the resulting payment amount to stand as the NLA without further steps, perhaps the lead entity's proposed payment amount and the associated information on which it is based could be shared with the other contractors for their review and consideration.

As a further step, we believe that the entire process could be better informed by making use of an advisory committee of laboratory experts which could advise the agency on molecular (including genetic) tests. Some of the tests, while very valuable and cost-effective in informing clinical decisions regarding use of potentially expensive or risky therapies, are likely to be quite expensive (per test). Failure by Medicare to set

appropriate payment rates could have a chilling effect on the availability of these tests for current and future Medicare beneficiaries. AdvaMed believes that the information needed to fairly assess the uses, resource costs, and value of these tests is often complex and challenging to marshal effectively in brief remarks at a public meeting or even in written comments. Establishing a panel of experts, including clinicians, laboratory experts, and representatives of the public, could help the agency develop and assess relevant information fairly and more reliably. The interaction of knowledgeable experts in such an advisory forum could significantly improve the information base available to CMS and its contractors. Recommendations of such a panel could help inform both the entities making gap fill pricing decisions and also CMS as it considers all of the decisions, including the basis for pricing and the possibility of reconsideration, relating to such tests.

The Secretary clearly has the authority to establish such a committee in accord with the Federal Advisory Committee Act. While we are mindful of the administrative resources needed to operate such a panel, we believe that these costs should be weighed in comparison to the difficulty and significant effect of the decisions the agency will be required to make in this area.

In addition to the above recommendations, we urge CMS to enhance the transparency and openness of the gap-fill process overall. We recommend that CMS make available for public inspection and comment the proposed new gap-filled national payment amount. Additionally, we recommend using informal mechanisms for requesting comment, such as the agency's web site for the following:

- To facilitate meaningful comment, provide the data and methodology upon which the gap-filled amount is based;
- If based on claims data, provide specific information on the number of claims, and the localities from which those claims were filed;
- Provide principles to be employed to ensure that the data used by carriers are statistically significant and alternatives to follow if statistically significant data are unavailable; and
- Provide rationales and any other information or data that was factored into the decision-making.

We also recommend that CMS make open for comment any proposals to switch from gap-fill to cross-walk (or vice versa). After taking into account additional data and comments received, we recommend that CMS publish the final national payment amount for the new test, with a clear explanation of the basis for its determination, again using informal publication mechanisms, such as the web site.

On a separate note, to date, CMS has not clarified how carrier fee-schedule amounts below the NLA will be adjusted as carriers are phased out and their functions are moved to Medicare Administrative Contractors (MACs). Leaving the existing set of carrier fee schedules in place, even as the MAC jurisdictions transcend old carrier localities, appears

to be unnecessarily complicated. In establishing MAC amounts, the agency appears to have the ability to choose an appropriate policy. We believe that in virtually all cases, the majority of carrier-specific amounts in each MAC jurisdiction will be at or above the NLA for each test. In a few cases, amounts will be below the NLA. The NLA for all old tests is set at 74 percent of the median of carrier-specific amounts, already a low figure, and the few instances where tests are paid amounts below the NLA may lead to access problems. We urge CMS to establish the payment amount for the MAC jurisdictions, as the new MACs are implemented, at the NLA.

Finally, as an editorial point, we suggest that CMS may wish to reconsider the use of the term "carrier-specific amount" in the regulation text. Carriers as such are being phased out in favor of MACs, and the retention of the word "carrier" in this section may contribute to confusion in the future.

V. TRHCA—Section 101(b): PQRI

CMS began its Physician Quality Reporting Initiative (PQRI) in 2007, with physicians beginning to report on quality in July for a bonus payment in 2008. CMS proposes to continue its PQRI program in 2008 by allocating $1.35 billion from the Physician Assistance and Quality Initiative Fund.

CMS is required to use measures for 2008 that have been endorsed or adopted by a consensus organization and have been developed through the use of a consensus-based process. CMS identifies the National Quality Forum as a consensus organization but concludes that the AQA Alliance is not a consensus organization. AdvaMed concurs with this interpretation.

We appreciate the efforts of CMS to implement the PQRI. We especially applaud the agency for the extensive discussion in the Proposed Rule of the process and the measures proposed for 2008, as well as for its extensive outreach efforts to help explain this initiative. One area of the PQRI about which AdvaMed would like to comment is the measure development process. The description provided in the Proposed Rule was very helpful in understanding the roles of the National Quality Forum (NQF) and the Ambulatory Quality Alliance (AQA) in the measure endorsement process. Nonetheless, the Proposed Rule also demonstrates the many routes that physician quality measures may take during the measure development process (e.g., the American Medical Association Physicians Consortium for Performance Improvement, Quality Insights of Pennsylvania, etc). This array of sources for new measures makes it very difficult for anyone trying to stay informed about the development and review of new measures.

Therefore, we encourage CMS to actively consider ways to ensure that this critical measure development process is fully transparent. In that regard, we would encourage the agency to consider establishing on its web site an updated listing of measures under formal consideration by the various organizations. To promote further transparency and input from multiple stakeholders, including consumers, CMS could require measure developers

to institute public comment periods on their measures. CMS could post information about the measures and the comment periods on the CMS web site. CMS could consider not including in the PQRI any measure that does not go through a public comment period during its development stage. In addition, CMS could post information about measures under consideration for endorsement by the NQF and AQA.

CMS would be the logical collection point for this information, and it could be a requirement for inclusion in the PQRI that each organization make this information available to CMS for posting on its site. AdvaMed would also encourage CMS to continue managing the PQRI process in a manner that allows input from the public, especially patient advocacy groups and device manufacturers.

AdvaMed applauds CMS for considering the feasibility and utility of accepting clinical quality data submitted from electronic health records (EHRs) as an alternative to claims-based reporting. We believe that using EHRs will reduce reporting costs, reporting errors, and enhance the value of the data reported.

VI. Physician Self-Referral Provisions

AdvaMed would like to respond to the request for comments related to the in-office ancillary services exception. We are concerned that modifications to this exception may hamper ease of access to ancillary care for Medicare beneficiaries. AdvaMed does not support CMS's statement that "these types of arrangements appear to be nothing more than enterprises established for the self-referral of DHS". Instead we view the in-office ancillary services exception as a mechanism for ensuring continuity of care. Therefore, AdvaMed encourages CMS to not limit the services that qualify for the exception.

Providing in office ancillary services greatly facilitates immediate clinical care, patient compliance, and patient convenience by eliminating the need for Medicare beneficiaries to travel long distances or see providers with whom they are not familiar. Better diagnostic and preventive health care is facilitated by allowing access to necessary services in surroundings that are comfortable and familiar to the beneficiary. The early and accurate diagnosis of critical health issues or the ruling out of the need for any additional medical intervention saves the healthcare system the cost of more expensive, unnecessary, and high-risk invasive procedures.

Across the board restrictions on the use of the in-office ancillary services exception to curb abuse and over utilization is not necessary at this time. In fact, limiting use of the exception could in some cases deprive Medicare beneficiaries of convenient access to necessary health care. AdvaMed urges CMS to maintain the in-office ancillary services exception in its current form and to seek alternative means to manage perceived abuses.

Conclusion

AdvaMed urges CMS to carefully consider our comments as well as those submitted by

our member companies, as they provide a unique source of information in developing appropriate PFS and clinical diagnostic lab test payment rates. We appreciate the opportunity to submit comments on the Proposed 2008 PFS rule, and look forward to working with CMS to address our concerns.

Sincerely,

Ann-Marie Lynch
Executive Vice President

cc: Terry Kay
Liz Richter

Submitter : **Date: 08/24/2007**

Organization :

Category : **Chiropractor**

Issue Areas/Comments

Technical Corrections

Technical Corrections

Re: TECHNICAL CORRECTIONS

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

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

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

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

Submitter : Mr. John Sorenson **Date:** 08/24/2007

Organization : Department of Anesthesiology, Univ of Wisconsin

Category : Academic

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Please see attachment

CMS-1385-P-7718-Attach-1.PDF

#7718

University of Wisconsin
SCHOOL OF MEDICINE
AND PUBLIC HEALTH

John W. Sorenson, MBA
Administrator
Department of Anesthesiology

August 24, 2007

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to register 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 longstanding, complicated issue.

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

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

I work for a Department of Anesthesiology based in an Academic Medical Center where we are privileged to train future anesthesiologists. As part of that training we provide some of the business basics such as billings, collections, expenses, contracting, etc. The patient population we serve has slightly more than a 25 percent Medicare representation, not a disproportionate level when compared to what warmer climate areas of the country may experience. However, these future anesthesiologists are disheartened by the current level of

B6/319 Clinical Science Center
608/263-8115
600 Highland Avenue
Madison, WI 53792-3272
FAX 608/263-8111

Medicare reimbursement as compared to the work elements involved especially when linked to the demographic projections of the growth of the senior population. To ensure that our Medicare patients nationwide have continued access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

John W. Sorenson

John W. Sorenson, MBA

B6/319 Clinical Science Center
608/263-8115

600 Highland Avenue

Madison, WI 53792-3272
FAX 608/263-8111

Submitter : **Dr. Steven Hauf** **Date: 08/24/2007**

Organization : **Dr. Steven Hauf**

Category : **Chiropractor**

Issue Areas/Comments

Technical Corrections

Technical Corrections

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

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

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

Sincerely,
Dr. Steven Hauf, D.C.

Submitter : Mr. David Berkheimer **Date:** 08/24/2007

Organization : AANA

Category : Other Health Care Provider

Issue Areas/Comments

Background

Background

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.

Submitter : **Ms. Katheryn Courville** **Date: 08/24/2007**

Organization : **Ms. Katheryn Courville**

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

I am a registered nurse in a graduate program for nurse anesthesia in Houston. I am training side by side with anesthesiologists and I see how our practice can directly impact safety for patients undergoing surgery. Nurse anesthetists practice all over the country, in most rural, underserved areas and should be reimbursed for the incredibly important work they do. Their skills and knowledge save lives every day. Please reward them accordingly.

Submitter : **Dr. Blaise Glodowski** **Date: 08/24/2007**

Organization : **Gibbstown Chiropractic Center**

Category : **Chiropractor**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

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

Re: TECHNICAL CORRECTIONS

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

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

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

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

Sincerely,

Blaise K. Glodowski D.C.

Submitter : Dr. Scott Schreiber **Date:** 08/24/2007

Organization : Dr. Scott Schreiber

Category : Chiropractor

Issue Areas/Comments

Technical Corrections

Technical Corrections

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

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

Sincerely,

Scott Schreiber, DC, MS

Vice President-Delaware Chiropractic Society

Submitter : **Dr. Jeffrey Jackson** **Date: 08/24/2007**

Organization : **Dr. Jeffrey Jackson**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Jeffrey Jackson M.D.
602 W. 2nd Street
Bloomington, Indiana 47403

Submitter : **Dr. Richard Santucci** **Date: 08/24/2007**

Organization : **ANJC**

Category : **Chiropractor**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Dear Sirs; I have been in practice for 30 years and have treated many Medicare patients. The efficacy of Chiropractic care has saved much suffering; unnecessary testing and surgeries; and monies charged to the Medicare system.

It is absolutely necessary, in many cases, to have the availability of x-rays for the patient's own protection. To disallow reimbursement for those x-rays, even when taken by another practitioner and viewed by a Chiropractor is a travesty and an injustice to a segment of the population that in many cases cannot afford to pay for them themselves and many times have put their lives on the line defending this country.

I trust that the powers that be will do the right thing for the people that helped build this country.

Very truly yours,
Richard Santucci, D.C., D.A.C.B.O.H.

Submitter : **Dr. Brian Bledsoe** **Date: 08/24/2007**

Organization : **Dr. Brian Bledsoe**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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Thank you for your consideration of this serious matter.

Brian Bledsoe, M.D.

Submitter : **Mrs. Nicole** **Date: 08/24/2007**

Organization : **Mrs. Nicole**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

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

Re: TECHNICAL CORRECTIONS

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

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

Sincerely,

Dr. Nicole DC

Submitter : **Date: 08/24/2007**

Organization :

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1385-P-7728-Attach-1.TXT

#7728

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

Re: "TECHNICAL CORRECTIONS"

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Sincerely,

Gerard DeBernardis, DC

Submitter : **Dr. Kathryn Webb** **Date: 08/24/2007**

Organization : **Dr. Kathryn Webb**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

MEI

Re: TECHNICAL CORRECTIONS

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

The patient already is burdened with the cost of E&M codes payable to other physians and is unreasonable.

Submitter : **Dr. Sami Zamzam** **Date: 08/24/2007**

Organization : **Sierra Anesthesia, Inc.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Sincerily,

Sami Zamzam, M.D.

Submitter : **Date: 08/24/2007**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

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I am writing to urge the CMS to accept the RUC recommendations for amending Medicare payments. The RUC recommendation was based on compelling evidence that, over the years, anesthesia work has been chronically undervalued. Please take this step at righting this inequity.

Submitter : **Dr. Willard Chumley Jr. MD** **Date: 08/24/2007**

Organization : **Anesthesiologist**

Category : **Physician**

Issue Areas/Comments

GENERAL

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

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