Submitter : Organization : Mrs. Susan Davies

Restore Therapy Services

Category:

Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

TRHCA- Section 201: Therapy

CapS

TRHCA-- Section 201: Therapy CapS

In the rule, CMS discusses implementation of the therapy cap in 2008.

Comment: In the rule, CMS discusses implementation of the therapy cap in 2008. CMS states that in accordance with the statute, it will continue to implement the therapy caps, but the therapy cap exceptions process will no longer be applicable beginning January 1, 2008.

Restore is deeply concerned about the negative impact that implementation of the financial limitations on therapy services without the extension of the exceptions process will have on Medicare beneficiaries needing therapy services. As CMS is aware, the AdvanceMed study published in November 2004 indicated that in 2002 14.5% of patients would exceed the physical therapy cap. This is the population of patients that Restore Therapy provides skilled services to. Once the cap is exceeded, if there is no exceptions process in place beneficiaries will not receive services that are medically necessary unless they seek treatment from hospital outpatient departments or pay out-of-pocket for their care. It is specifically the frail older adult in nursing facilities who can not take advantage of either rof these options.

As a result, the cap can be expected to have a significant detrimental effect on beneficiaries needing rehabilitation services and could lead to complications, ultimately resulting in greater costs to the Medicare program. We recognize that it will take Congressional action to provide additional statutory authority and prevent the implementation of the therapy caps, and we continue to strongly urge Congress to take timely action to pass legislation that would repeal the therapy cap or extend the exceptions process if repeal is not feasible.

TRHCS-Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

The proposed rule includes a discussion of CMS plans to evaluate and test mechanisms for collecting quality measures from medical registries. This approach to reporting data would be an alternative to submitting data through the claims processing system. CMS describes 5 options for data submission from medical registries to CMS:

Comment: Restore Therapy has been disappointed with the agency's implementation of the Physician Quality Reporting Program (PQRI) in 2007 because it excluded cligible professionals providing covered therapy services to Medicare Part B beneficiaries in inpatient settings (i.e. SNFs, Rehab Agencies, outpatient HH) from participating in the program. The Tax Relief and Health Care Act of 2006 (TRHCA) specifically defined physical therapists, occupational therapists and qualified speech-language pathologists as eligible professionals, but those therapists providing care to some of the most medically complex Medicare patients are unable to report for two reasons: (1) the claims format does not allow providers in these settings to report the information to CMS—even though these professionals are providing interventions that currently qualify for PQRI (specifically the Falls screening), and (2) no measures have been approved for SLPs, which effectively blocks them out of the entire program.

Although there are many professional organizations that have recommended ways in which SNF-based quality reporting data could be collected, the PQRI program for 2008, as outlined in the proposed rule, would continue the exclusion of reporting from institutional settings. We believe that the restrictive means of quality reporting adopted by CMS undermines the validity of the therapy data that are being reported.

While Restore has serious concerns about the current state of the PQRI program, we are encouraged by the agency's proposal to evaluate and test mechanisms for registry-based reporting. We believe that the adoption of registry reporting could help alleviate the inequities that exist today. Restore Therapy also encourages CMS and its contractors (NQF & other consensus based groups) to adopt PQRI measures that are inclusive of all professionals outlined in the statute.

Therapy Standards and Requirements

Therapy Standards and Requirements

CMS proposes to update the personnel qualifications for physical therapists (PTs), physical therapist assistants (PTAs), occupational therapists (OTs), and occupational therapist assistants (OTAs). Specifically, CMS is proposing to broaden the current grandfathering requirements to recognize practicing physical therapists, occupational therapists, physical therapist assistants, and occupational therapist assistants who meet their respective state qualifications (e.g., have been licensed, certified, registered or otherwise regulated by their state as PTs, OTs, PTAs, or OTAs) before January 1, 2008, and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than two years. Individuals who begin practicing as physical therapists, physical therapist assistants, occupational therapists, and occupational therapy assistants after January 1, 2008, would be required to meet the new qualifications proposed in the

regulation at section 484.4.

Restore Therapy would encourage CMS to remove qualified physical therapists from this provision. All physical therapists currently practicing meet the education and licensure requirements included in section 484.4. No states have permitted licensure of physical therapists without successful completion of a curriculum in physical therapy after 1977 (the date currently specified under the grandfather clause). Therefore, it seems unnecessary to include qualified physical therapists in this new broadened grandfathering provision.

In the rule, CMS states that they believe therapy services should be provided according to the same standards and policies in all settings to the extent possible. Therefore, they revise the regulations (sections 409.17 and 409.23, etc) that pertain to services furnished at inpatient hospitals and skilled nursing facilities, and several other settings to state that physical therapy, occupational therapy or speech-language pathology services must be furnished by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants or speech-language pathologists who meet the requirements specified in 484.4

Comment: Restore supports the use of qualified personnel in the providing of physical therapy, occupational therapy & speech-language pathology services. With that consideration, Restore also recognizes that implementation of many of the standards that currently apply to services provided to Medicare B beneficiaries would necessitate significant changes for providers in Part A settings. It is important to fully consider the impact this might have and prepare for the changes by insuring provider education materials are accessible to all providers.

We also recommend that CMS distinguish services provided by a student and services provided by a therapy aide. Services by a student provided under line of sight supervision should be considered for payment across all settings, including settings where Medicare Part B beneficiaries receive care. Students who are in the process of obtaining degrees in Physical Therapy, Occupational Therapy and Speech Language Pathology demonstrate increased skill and ability Finally, we would ask that these changes be implemented over a 12-18 month period in order to allow providers and fiscal intermediaries to prepare for this significant change.

Plan of Care

CMS explains that since inpatient hospital services are always provided under the care of a physician, the agency believes that the physician s review and certification of the therapy plan of treatment is implied by the physician s review and approval of a facility plan that includes therapy services. Therefore, there would be no additional certification requirements for the inpatient hospital setting.

Comment: We encourage CMS to clarify that the following statement applies to the skilled nursing facility setting also. The physician s review and approval

CMS-1385-P-15550-Attach-1.DOC

August 31, 2007

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

Re: Comments submitted by Restore Management Company regarding revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008

Dear Acting Administrator Norwalk:

Restore Management Company, LLC is a provider of rehabilitation services (speech-language pathology, physical, and occupational therapy) for the skilled nursing, home health, and outpatient settings. We are pleased to have the opportunity to provide comments on behalf of our therapists on this proposed rule which will have a direct impact on the Medicare beneficiaries we serve.

We wish to comment on the six following areas in the 2008 Proposed Rule: (1) Therapy Standards and Requirements (page 38191) (2) Application of Consistent Therapy Standards (3) Plan of Care(4) Revisions to Payments for Therapy Services (5) Outpatient Therapy Certification Requirements (6) PQRI initiative. These comments are described in detail on the following pages.

Restore Management LLC would like to submit the following comments concerning CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008.

Therapy Standards and Requirements (page 38191)

CMS proposes to update the personnel qualifications for physical therapists (PTs), physical therapist assistants (PTAs), occupational therapists (OTs), and occupational therapist assistants (OTAs). Specifically, CMS is proposing to broaden the current grandfathering requirements to recognize practicing physical therapists, occupational therapists, physical therapist assistants, and occupational therapist assistants who meet their respective state qualifications (e.g., have been licensed, certified, registered or otherwise regulated by their state as PTs, OTs, PTAs, or OTAs) before January 1, 2008, and continue to furnish Medicare services at least part time without an interruption in furnishing services of more than two years. Individuals who begin practicing as physical therapists, physical therapist assistants, occupational therapists, and occupational therapy assistants after January 1, 2008, would be required to meet the new qualifications proposed in the regulation at section 484.4.

Restore Therapy would encourage CMS to remove "qualified physical therapists" from this provision. All physical therapists currently practicing meet the education and licensure requirements included in section 484.4. No states have permitted licensure of physical therapists without successful completion of a curriculum in physical therapy after 1977 (the date currently specified under the "grandfather clause"). Therefore, it seems unnecessary to include qualified physical therapists in this "new" broadened grandfathering provision.

Application of Consistent Therapy Standards

In the rule, CMS states that they believe therapy services should be provided according to the same standards and policies in all settings to the extent possible. Therefore, they revise the regulations (sections 409.17 and 409.23, etc) that pertain to services furnished at inpatient hospitals and skilled nursing facilities, and several other settings to state that "physical therapy, occupational therapy or speech-language pathology services must be furnished by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants or speech-language pathologists who meet the requirements specified in 484.4.

Comment: Restore supports the use of qualified personnel in the providing of physical therapy, occupational therapy & speech- language pathology services. With that consideration, Restore also recognizes that implementation of many of the standards that currently apply to services provided to Medicare B beneficiaries would necessitate significant changes for providers in Part A settings. It is important to fully consider the impact this might have and prepare for the changes by insuring provider education materials are accessible to all providers.

We also recommend that CMS distinguish services provided by a student and services provided by a therapy aide. Services by a student provided under line of sight supervision should be considered for payment across all settings, including settings where Medicare Part B beneficiaries receive care. Students who are in the process of obtaining degrees in Physical Therapy, Occupational Therapy and Speech Language Pathology demonstrate increased skill and ability

Finally, we would ask that these changes be implemented over a 12-18 month period in order to allow providers and fiscal intermediaries to prepare for this significant change.

Plan of Care

CMS explains that since inpatient hospital services are always provided under the care of a physician, the agency believes that the physician's review and certification of the therapy plan of treatment is implied by the physician's review and approval of a facility plan that includes therapy services. Therefore, there would be no additional certification requirements for the inpatient hospital setting.

Comment: We encourage CMS to clarify that the following statement applies to the skilled nursing facility setting also.

"The physician's review and approval of a therapy plan should be implied by the physician's review and approval of a facility plan that includes therapy services."

Revisions to Payments for Therapy Services

In the rule, CMS discusses implementation of the therapy cap in 2008.

Comment: In the rule, CMS discusses implementation of the therapy cap in 2008. CMS states that in accordance with the statute, it will continue to implement the therapy caps, but the therapy cap exceptions process will no longer be applicable beginning January 1, 2008.

Restore is deeply concerned about the negative impact that implementation of the financial limitations on therapy services without the extension of the exceptions process will have on Medicare beneficiaries needing therapy services. As CMS is aware, the AdvanceMed study published in November 2004 indicated that in 2002 14.5% of patients would exceed the physical therapy cap. This is the population of patients that Restore Therapy provides skilled services to. Once the cap is exceeded, if there is no exceptions process in place beneficiaries will not receive services that are medically necessary unless they seek treatment from hospital outpatient departments or pay out-of-pocket for their care. It is specifically the frail older adult in nursing facilities who can not take advantage of either rof these options.

As a result, the cap can be expected to have a significant detrimental effect on beneficiaries needing rehabilitation services and could lead to complications, ultimately resulting in greater costs to the Medicare program. We recognize that it will take Congressional action to provide additional statutory authority and prevent the implementation of the therapy caps, and we continue to strongly urge Congress to take timely action to pass legislation that would repeal the therapy cap or extend the exceptions process if repeal is not feasible.

Outpatient Therapy Certification Requirements

In the rule, CMS proposes to amend the regulations to change the plan of treatment recertification schedule. Currently, the physician must initially certify a plan of treatment at the time the plan is established or as soon thereafter as possible. If the need for treatment continues beyond 30 days, the plan of treatment must be recertified every 30 days. CMS proposes that the physician (or NPP as appropriate) would be recertified every 90 days.

Comment: We commend CMS for lifting the 30 day recertification requirement.

PQRI initiative

The proposed rule includes a discussion of CMS plans to evaluate and test mechanisms for collecting quality measures from medical registries. This approach to reporting data would be an

alternative to submitting data through the claims processing system. CMS describes 5 options for data submission from medical registries to CMS:

Comment: Restore Therapy has been disappointed with the agency's implementation of the Physician Quality Reporting Program (PQRI) in 2007 because it excluded eligible professionals providing covered therapy services to Medicare Part B beneficiaries in inpatient settings (i.e. SNFs, Rehab Agencies, outpatient HH) from participating in the program. The Tax Relief and Health Care Act of 2006 (TRHCA) specifically defined physical therapists, occupational therapists and qualified speech-language pathologists as eligible professionals, but those therapists providing care to some of the most medically complex Medicare patients are unable to report for two reasons: (1) the claims format does not allow providers in these settings to report the information to CMS – even though these professionals are providing interventions that currently qualify for PQRI (specifically the Falls screening), and (2) no measures have been approved for SLPs, which effectively blocks them out of the entire program.

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While Restore has serious concerns about the current state of the PQRI program, we are encouraged by the agency's proposal to evaluate and test mechanisms for registry-based reporting. We believe that the adoption of registry reporting could help alleviate the inequities that exist today. Restore Therapy also encourages CMS and its contractors (NQF & other consensus based groups) to adopt PQRI measures that are inclusive of all professionals outlined in the statute.

Submitter:

Mrs. lisa lee

Organization:

RIVERVIEW HOSPITAL

Category:

Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

Remove physical therapy from in-office ancillary services

Submitter:

Dr. James Moore

Organization:

UCLA Medical Center

Category:

Physician

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

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 the Director of District 11 of the California Society of Anesthesiologists. In this capacity I represent the interests of a diverse group of hundreds of physicians in the Los Angeles area. 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,
James M. Moore, MD
Associate Clinical Professor
Department of Anesthesiology
David Geffen School of Medicine at UCLA
Director, District 11, California Society of Anesthesiologists

Submitter:

Ms. Susan Rovnak

Organization:

Ms. Susan Rovnak

Category:

Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Re:Physician Self-Referral Issues Dear Mr. Weems:

Baltimore, MD 21244-8018.

I am writing regarding the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the in-office ancillary services exception. I have been a physical therapist for 20 years, beginning at Johns Hopkins Hospital in 1987, and now in private practice for the last 6 years.

My concern is the quality of physical therapy care for patients.

The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician-owned physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. 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, overutilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

A recent example of the abuse by physician owned practices is in a conversation I recently had with an old business colleague who mentioned he had physical therapy at a physican owned practice after his knee surgery. He reported to me that when he went in the therapist didn't say hello to him and he was told to grab a towel and get his own heat and do his exercises. This is certainly not physical therapy care and shows the potential abuse of the system by physicians.

I urge you to consider my concerns and remove physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws. I thank you for my patients, my family, and myself.

Susan Rovnak, PT License # 16168 Maryland

Submitter:

Dr. Peter Sybert

Organization:

Dr. Peter Sybert

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.

Peter E. Sybert, MD

Submitter:

Dr. Ronald Jasiewicz

Date: 08/31/2007

Organization:

Stony Brook University Medical Center

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter:

Dr. Brendan Frank

Organization:

Dr. Brendan Frank

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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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. Brent Stewart

Organization:

Dr. Brent Stewart

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)

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Thank you for your consideration of this serious matter.

Submitter:

Dr. Stephen Hays

Organization:

Vanderbilt University

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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Thank you for your consideration of this serious matter.

Stephen R. Hays, MD, FAAP Associate Professor, Anesthesiology & Pediatrics Vanderbilt University Medical Center Director, Pediatric Pain Services Vanderbilt Children's Hospital

Submitter:

Dr. Roderick Beer

Date: 08/31/2007

Organization:

Anesthesia Associates of Ann Arbor

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)

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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.

An upward adjustment to compensate for the years where the services were undervalued would be appreciated as well. I am very pleased that CMS has made the recognition of the work effort of anesthesiologists.

Thank you for your consideration of this serious matter.

Submitter:

Ms. Kelli Kyle

Organization:

Ms. Kelli Kyle

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer in Rochester, MN. I currently work for the Mayo Clinic Sports Medicine center doing outreach to John Marshall High School. This is the first time that this school has had an Athletic Trainer and they are extremely happy to have such a qualified person treating their athletes. I have been an Athletic Trainer for six years. I obtained my Bachelor of Science degree from Minnesota State University, Mankato and graduated Cum Laude. In my six years of being an Athletic Trainer, I have come to realize how vital our role is in the high school setting, as well as working with physicians whether that be in an outpatient physical therapy clinic or with the physicians directly.

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,

Kelli M. Kyle, ATC

Submitter:

Date: 08/31/2007

Organization:

Category:

Physical Therapist

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Physical Therapists have proven themselves as effective quality care providers to a variety of patients among the healthcare spectrum. We have direct access in over thrity-nine states and have proven ourselves as leaders in the field of rehabilitation.

Physicians are essentially referring patients to themselves when they use in-office ancillary services such as physical therapy which is promoting wasted healthcare money and overutilization of services. They have financial interest in their own companies, benefiting from the physical therapy services their patients are recieving, making them more likely to keep the patient past their appropriate discharge time. Physical Therapists are thoroughly trained, many receiving Masters and Doctorates in Physical Therapy, in determining when a patient should be discharged from our services. Some of these criteria include meeting their short term and long term goals as determined on initial evaluation, non-progression of further wellness, or non-compliance.

Many insurance companies do not pay for direct access and thus require a referral/ prescription from their physician in order to receive physical therapy services. If a physician has their own physical therapy practice, they will likely only refer to themselves, giving the patient little control over their own healthcare. Patients should be free to choose which physical therapist they could like to see, instead of being forced to go to their physican's office merely because they will not receive a presciption to another office secondary to their physician's interest.

The examples listed above are suggestive of abuse by physicians and impingement upon Physical Therapist practices. Please eliminate physical therapy as a designated health service under the in-office ancillry exception. Thank you for your consideration.

Submitter:

Dr. Tim Beger

Organization:

Anethesiologist

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:

1 am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. 1 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.

Timothy H Beger MD

Submitter:

Mrs. bobbie coit

Date: 08/31/2007

Organization:

heart and soul healthcare inc

Category:

Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

My comment is that medicare needs to realize the need for homehealth

for the elderly and disabled they need all the assistance you can provide, cutting of benefites only adds to the stress and health of the elderly. Most already do with out meds and other needs. Please consider they worked hard for their insurance.

Submitter:

Mr. Gerald Pedersen

Organization:

Lane Regional Medical Center

Category:

Other Health Care Professional

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.

I 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. I 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,

Gerald Pedersen CRNA

Submitter:

Miss. Achon Bell

Organization:

Lane Regional Medical Center

Category:

Other Health Care Provider

Issue Areas/Comments

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Achon Bell CRNA

Submitter:

Mr. Gregory Arnette

Organization:

Lane Regional MEdical Center

Category:

Other Health Care Professional

Issue Areas/Comments

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Gregory Arnette CRNA

Submitter:

Mr. Frank Ragsdale

Organization:

Lane Regional Medical Center

Category:

Other Health Care Professional

Issue Areas/Comments

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Frank Ragsdale CRNA

Submitter: Mr. James Chustz

Organization: Lane Regional Medical Center
Category: Other Health Care Professional

Issue Areas/Comments

Background

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
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James Chustz CRNA

Submitter:

Mr. Tom Butler

Organization:

Secaucus High School

Category:

Individual

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Thomas Butler and I am an Athletic Trainer at Secaucus High School in Secaucus, NJ. I take care of all the sports programs at the high school and make sure all of the athletes receive the proper medical care.

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

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

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

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

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

Sincerely,

Thomas J. Butler, ATC

Submitter:

Dr. Nancy High

Date: 08/31/2007

Organization:

Heartland Quality Anesthesia Professionals

Category:

Physiciai

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.

Nancy High, MD

Submitter:

Dr. Stephani Allison

_

Delaware Anesthesia Associates

Organization:
Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

Stephani R. Allison, MD Delaware Anesthesia Associates 424 Savannah Road Lewes, Delaware 19958

August 31, 2007

Leslic 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.

Sincerely,

Stephani R. Allison, MD

Submitter:

Mr. David cohen

Law Office of David S. Cohen

Organization:
Category:

Attorney/Law Firm

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am an attorney who practices health law. Before I became a lawyer, I worked for a number of years as an Athletic Trainer. My experience in healthcare and law has given me a unique perspective on many current and proposed CMS policies and their impact.

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.

While I now practice more as a lawyer than an Athletic Trainer, I am still very concearned about the proposed rule. 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.

Kindcst regards,

David S. Cohen, ATC, Esq.

Submitter:

Mr. Paul Bragenzer

Date: 08/31/2007

Organization:

Tim Bondy Physical Therapy

Category:

Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Certified Athletic Trainer working in an outpatient physical therapy clinic in an administrative position. Additional credentials include a Masters in Health Education and a Masters in Business Administration.

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Sincerely,

Paul Bragenzer, MA, MBA, ATC

Submitter:

Dr. Frank Politzer

Date: 08/31/2007

Organization:

Berks Cardiologists, Ltd.

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

As a practicing cardiologist in Pennsylvania, I respectfully request that current physician fee schedules for Medicare reimbursement be maintained in order to sustain current levels of patient care and delivery of adequate cardiac imaging and diagnostic services to serve our aging population in which cardiac disease is the number one cause of morbidity and mortality. To reduce fee schedules to levels currently suggested will only serve to hinder utilization of these essential imaging and diagnostic tools which to date have resulted in significant reductions in early diagnosis and treatment of heart disease and associated morbidity and mortality rates.

Submitter:

Ms. Sue Stanley

Organization:

Florida Southern College

Category:

Academic

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am the Athletic Training Program Director at Florida Southern College in Lakeland, FL. I am a Certified Athletic Trainer and have worked in the profession for over 25 years.

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.

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Sincerely,

Sue Stanley-Green, MS, ATC, LAT,

Submitter:

Ms. Albert Green

Date: 08/31/2007

Organization:

Florida Southern College

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

1 am the Head Athletic Trainer and Assistant Athletic Director at Florida Southern College in Lakeland, FL. I am a Certified Athletic Trainer and have worked in the profession for over 30 years.

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Sincerely,

Albert Green, MS, ATC, LAT,

Submitter:

Dr. W. Monteith

Organization:

Dr. W. Monteith

Category:

Physician

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Submitter:

Mr. philip chiaramonte

Organization:

Hines Veterans Hospital

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

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Dear Sir or Madam:

My name is Phil Chiaramonte and I am a certified athletic trainer and also a registered kinesiotherapist who has been employed at Hines VA hospital for 8 years providing care to our veterans.

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.

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Sincerely,

Philip Chiaramonte, ATC, RKT, MHA

Submitter: Date: 08/31/2007

Organization:

Category: Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I would like to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the in-office ancillary services exception. My comments are intended to highlight the abusive nature of physician-owned physical therapy services and support PT services removal from permitted services under the in-office ancillary exception.

I am a physical therapist that has been practicing for 32 years with the last 30 of those years spent operating my own private practice in a rural community. My practice started when most doctors didn t even know what physical therapy was and we have grown along with the population growth in the area to the point where we now have 6 sites, 25 FT physical therapists, 14 PTA s, and about 24 other staff for reception, billing, administration, clinical aides, and cleaning. In the last several years, the ugly face of this problem has been rapidly expanding. I will give you 4 examples of situations we have encountered:

CMS-1385-P-15579-Attach-1.DOC

August 24, 2007

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

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

Dear Mr. Weems,

I would like to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception. My comments are intended to highlight the abusive nature of physician-owned physical therapy services and support PT services removal from permitted services under the in-office ancillary exception.

I am a physical therapist that has been practicing for 32 years with the last 30 of those years spent operating my own private practice in a rural community. My practice started when most doctors didn't even know what physical therapy was and we have grown along with the population growth in the area to the point where we now have 6 sites, 25 FT physical therapists, 14 PTA's, and about 24 other staff for reception, billing, administration, clinical aides, and cleaning. In the last several years, the ugly face of this problem has been rapidly expanding. I will give you 4 examples of situations we have encountered:

1. There is a group of occupational medicine doctors that were our biggest supporters for many years. They even encouraged us to grow and expand – saying that they had confidence in the work we did and wanted it to be more available throughout the county so that it would be more convenient for their patients. We did many projects with them and thought we had a close, quality based working relationship. When the rules changed to allow them to open their own PT service, they hired 2 of their own PT's to keep their referrals "in-house" and cut us off completely. They even had patients living in outlying areas drive past one or two of our offices just so that they could keep the business even though we have better facilities and more highly trained staff at our offices. When asked about it, they said it wasn't anything personal or about our skills, it was just a business decision based on what would be best for them. The PT's they hired had significantly less experience in orthopedic care than any of our staff (we know this because one of them later applied to work with us saying she was frustrated with the situation because she felt she was being taken advantage of [worked too hard] just to make the doctors bigger profits).

2. The next experience was with the largest organized group of doctors in the county – they have over 100 physicians including 6 orthopedists. This group opened a new large office in the main town at the center of the county. We were excited because 2 years ago they opened a new large "main" office on the lot right next to our office. Up until this time, this group of doctors was by far our main source of referrals with 7 of our top 10 referrers being from this group. Up until this point, this group had been doing things what we considered to be "the right way". By this I mean that they used a referral form that had the request for PT with pertinent information on one side and they had a list of all the PT offices in the region on the back of it (a list of more than 20 offices). They also had been willing to meet with us periodically during the year to discuss mutual topics related to the work they were doing and what treatment we were doing to support that care. Basically, they challenged us (and other PT offices) to "prove to us why we should recommend you to our patients". They challenged local PT offices to "earn" recommendations by providing better locations, better hours, better equipment, more advanced training/skills for staff, and outcomes showing better results in less visits/lower costs. We always were concerned about providing the best program we could to stay as good as or better than other choices in the area. It has been very frustrating to us that, when they opened the new office right next to us, they also opened a physical therapy office as part of it. As of that day, they cut off all referrals to us (and other local PT offices) and also stopped using the referral papers that show their patients that there are any other options other then themselves. They offer shorter hours of operation, have staff with less years of experience and less advanced training/certifications, have much less equipment, and have lower quality spaces (they only have cheap curtained areas for "rooms" while we have more rooms and they all have real walls and doors). Additionally, since one of their surgeons is a hand specialist and we had the only certified hand therapist in the area, they called her up and told her that they wanted her to come and work with them - and if she didn't, they would bring in a new CHT and would no longer be allowing any patients to go out to her. As a result, she felt she had not choice but to leave and go to work for them. Additionally, the typical referral we got from the orthopedists in this group was for treatments 2x weekly for 4 weeks. We have been told by many sources that the standard now is for 3x weekly for 6-8 weeks. This group had originally told us that they would only have 1-2 physical therapists, but within a year they had expanded to 5 full time PT's. This has been devastating for my office and has caused us to relocate some of our staff to other offices due to the resulting drop-off in business at that site. An additional example of the problem here is that a PT at a different clinic in a town 10 miles away was telling me that he was at a restaurant there in a booth next to where one of the orthopedists from this big group clinic was talking to a family practice doctor about this "great way to make extra money" with his PT office. He was giving the sales pitch to the family practice doctor asking him to send any of his patients needing PT to this new clinic and he would get some kind of compensation. At the end of the lunch, as they were leaving, he said "are we all on-board now?" and the other doc said it "sounded good". As an added side note, 3 of our independent PT clinic competitors have already had to close due to their loss of business. Also, we used to have periodic meetings with some of the doctors in this group, but we have been told by the doctors that their

corporate CEO has told them they are no longer allowed to have meetings with "outside" PT groups because it is a "conflict of interest" to their corporate goals (since they have their own PT service). I thought they were at least supposed to pretend that they were open to using other PT clinics to reduce the perception that there is a conflict of interest. We have also been told that they routinely have 2-3 week long waiting lists for patients to get in while we guarantee that new patients get started within 24 hours of them calling us. We do this by being willing to pay staff OT to get this done rather than make a patient in pain wait; the physician offices are not willing to pay OT and have it reduce their profit. In the last several months we were surprised that this group has started sending us some patients again. We are happy about this because we need the business, but we have found that the reason is that, due to complaints from patients about having to wait, they are sending out their Medicare and DSHS patients to us so that they will keep a higher percentage of private pay patients. We have always had a policy of taking everyone without bias to their insurance, but the physician owned offices will use their gatekeeper position to skim off the patients with lower reimbursements and let them go to others while not allowing the private pay group the same options.

- 3. The next example is another orthopedic group in our county has been formed in the last year. This is a group of 6 orthopedics that had been practicing in 5 different groups, but they said that they are following the "standard" set by the group described in case #2 above to come together as a group and they are also opening their own PT clinic where they intend to have all their patients go for the PT. This group just completed their reorganization in Aug of 2007, but have not opened their PT office yet because they had trouble finding PT's. As of this week we heard they finally have hired 2 PT's but they are having them take some orthopedic classes since they have only worked in nursing homes and do not have any experience in outpatient orthopedic settings. The frustrating thing here is that most of our PT's are Certified Orthopedic Specialists (board certified orthopedic specialists) and all of them are required to take several classes every year for continued advanced training. It is going to take these "new-to-orthopedics" PT's many years to gain the level of knowledge and experience our staff already has. These doctors have been utilizing us regularly for many years and have repeatedly been telling us how happy they are with the depth of knowledge and skill of our staff, yet they will now funnel all their business to PT's with clearly much lower levels of skill and experience – just so that they can make additional profit for themselves off of the physical therapy side of the treatment. They are not doing this for the benefit of patient quality of care; they are doing it for their own financial gain.
- 4. The last example is the only physiatrist (physical medicine and rehabilitation doctor) in the county. He has ownership in a rehab clinic that specializes in stroke, spinal cord, head injury, MS, and Parkinson's type problems. They do have a good reputation with those problems, so we have no problem with the quality of the work they do for this group of patients, but their PT's have little or no experience with orthopedic problems. When this doctor does occasionally get an orthopedic patient, he sends them to his clinic even if there are other more convenient clinics or clinics with more qualified PT's

that would be better for the patient. When a doctor has financial gain from things, it does create a bias that effects the decisions that he makes for the patients.

As you can see from my examples coming from just the county where I practice, the proliferation of the referral-for-profit situations has grown very rapidly and all because of the incentive for a physician to make extra profit off of physical therapy services. The reason for these doctors to offer these services has nothing to do with any desire for providing better quality of care or more convenience to customers because in all of my examples none of this happened. In actuality, it has resulted in a decrease in quality of care received by the customer and the only gain was financial gain to the referring physician. Many patients that live in outlying areas are being pressured by the physicians to drive significant distances (past many capable, quality clinics) to come to the clinic that the physician profits from even though these same physicians used to recommend these clinics when they didn't have any conflict of interest created by ownership in a PT service. Additionally, this situation has significantly compromised the business I have spent 30 years building based on a "quality of care comes first" standard. Because the physician's financial gain has come at our expense, it has caused us to be more "defensive" in our business practices. We have historically reinvested a much higher percent of our revenue back into our business (staff bonus', continuing ed, equipment, and community support/involvement, etc) because this is also an investment in our professional career. To the physicians, the PT business in just an investment and there is no reason for them to do it other than to make more money for themselves off of it. The quality programs are already here in the community and they already offer a higher standard of PT skill, equipment, facilities, and hours than the programs the physicians are creating. Physicians are not doing the programs because there is a lack of quality already.

Allowing these programs to continue has in fact resulted in a lower quality of care for many patients and has taken away the "competition incentive" from the marketplace. I am convinced that this has resulted in higher utilization, higher costs, and less convenience for patients. Physicians are no longer challenging us to provide a better program to earn their referral; they actually no longer care at all about what programs we have and are not willing to send patients to a better program if it means loss of revenue to them. Physician's without the bias of financial gain are a much better advocate in looking out for the best interest of the patient, while physician's with the bias of receiving financial gain will allow their personal financial gain to influence not just where the patient goes, but also how much they go there. It is not a healthy environment.

Thank you for consideration of my comments.

Sincerely,

Zip code 98370

Submitter:

Dr. Christine Harrison

Organization:

Austin Anesthesiology Group

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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.

CMS-1385-P

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. Kirk Steinam

Organization:

Dr. Kirk Steinam

Category:

Individual

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

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

Rc: 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.

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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.

Kirk Steinam, D.V.M.

Submitter:

Dr. Mark Hall

Organization:

Dr. Mark Hall

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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.

Simply put, this will determine the future of anesthesiology in Muncie, IN. The Medicare portion of our payor mix has grown about 1% each year for the past 15 years. Five talented anesthesiologists have left our practice in the last 3 years. We cannot compete with less Medicare-dependent practices, even within our own state.

Yours truly,

Mark A. Hall, MD

Submitter:

Mrs. Tanya Dargusch

Organization:

Mrs. Tanya Dargusch

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sirs,

I am a licensed and certified athletic trainer residing in Sewell, New Jersey. I have been a health care provider for over 20 years. I have worked as an athletic trainer in the industrial, clinical and now high school setting in a number of states. I am currently working at Washington Township High School and am responsible for the care of over 1500 students and patients.

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.

Sincercly,

Tanya M. Dargusch, ATC, ATR

Submitter:

Dr. Christina Noyes

Organization:

Emory University

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

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

Thank you for your consideration of this serious matter.

Submitter:

Mr. Andrew Henrichs

Organization:

Valley View Hospital

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 currently working at Valley View Hospital in Glenwood Springs, CO. My position includes assisting staff physical therapists in our outpatient rehabilitation clinic and sports coverage of two local high schools. While at the high schools, I work to prevent injuries within the sports. I also provide injury assessment, treatment, rehabilitation, and education services to the children who participate in all extracurricular sports at the schools.

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

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

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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 eonsider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Andrew Henrichs, ATC

Submitter:

Mrs. Marcey Keefer Hutchison

Therapeutic Associates

Organization: Category:

Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

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

RE: Physician Self-Referral Issues

Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

Dear Mr. Weems,

l am a physical therapist and director of a private, physical therapist owned clinic in Salem, Oregon. I have been a PT for 16 years specializing in orthopedics and sports medicine. I am writing to comment on the July 12 proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the in-office ancillary services exception.

I have watched physician referral for profit change the nature of referral practices in the town where I have my clinic. It is clear that when financial self-interest enters into the referral process the public s best interests are put in jeopardy. The trust a patient has in their physician is taken advantage of under the guise of perceived special care. In reality, patients are asked to travel unreasonable distances to receive therapy when services exist within blocks of their home or work. Moreover, patients are told they must attend therapy at the referral for profit clinic when indeed they have the right to choose which clinic and therapist they see. I see this happen on a weekly basis. This is bad public policy.

I respectfully and strongly request the removal of physical therapy as a designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.

Thank you for your consideration of this very important matter.

Marcey Keefer Hutchison, MSPT, ATC, CMP Director of Physical Therapy, Therapeutic Associates, Valley Physical Therapy Keizer

Submitter:

Organization:

Category:

Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See Attachment

CMS-1385-P-15587-Attach-1.PDF

CMS-1385-P-15587-Attach-2.DOC

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

Re: Physician Self-Referral Issues

Dear Mr. Weems,

I am a physical therapist that owns a small private practice in the mid-west. My practice has been open approximately six years. I am writing this letter in regards to my concerns on physicians self referral issues, with the Stark Loophole for physicians owned practices and the possibility of overuse. My concern is with the Stark Loophole for physician owned practices and the possibility of overuse. I have recently felt a big impact in my business since a large orthopedic group has opened a satellite clinic near mine. I have lost between 30-40% of my business since this has happened. The following are examples of situations that are of concerns to me.

- -I have lost several previous patients that were initially seen non-surgically that went in for surgery and followed with their physical therapy services. When I met them in passing, I have asked them how they are doing and wondered if there was anything I had done to dissuade them from returning. Their comments, with multiple people, have been that they did not realize they had a choice and they were just set up with the physical therapy immediately post operatively.
- -I have also had, on one occasion a patient come in to see my occupational therapist and she stated that the physician was trying to refer her out to their clinic and when she refused he actually stated that she probably didn't need any therapy and could do it independently at home. I have asked this individual to write a letter however, she is contemplating this and is concerned about upsetting her doctor and does not want to "rock the boat".
- I had been marketing with some family practice doctors and they stated that they were getting physical therapy in their office to generate more revenue. These statements seemed odd to me due to the fact that they "nonchalantly" brought this up as if I would not be impacted or concerned about this.
- -In another case there is a chiropractor who obviously is not able to bill Medicare but is an example of how the system may be affected. He was planning on hiring a physical therapist and asked me to come to his clinic to work for him until he found his therapist. I stated I would not do this however; he was more than welcome to send his patients down to me until he established his physical therapist in their clinic. I did not see anything from him. Since then I have found that he has had almost all his patients go to some physical therapy unless of course they're Medicare and then he tries to refer them out. Since we do not accept the chiropractor referral for Medicare because it is not reimbursable they have either refused these patients or asked them to see their family doctor in order to have them referred. I find this interesting in that prior to having his

own physical therapy clinic he did not have any justification for physical therapy and all of the sudden PT is now so much needed.

I feel these are perfect examples of how the system is flawed. It is not my place to say the physicians are going to be unethical however the current loopholes leave room for that opportunity and it has obviously happened in many cases.

I am basically just looking for having a more fair system in place. It would be nice if the patients knew that they did have a choice. Some physician's offices are stating that they are doing this however it is in the fine print of all the paperwork that the patient fills out at their initial visit. I am aware in my own clinic with our forms many patients do not read these but just sign them. I also feel that by having this statement of "they have a choice" it would be very hard for Medicare or other insurance companies to really check up on this to see if it is being done fairly and adequately enough.

I have also read many of the research articles there and studies that have shown that private practice PT get better outcomes and have fewer patient visits then those owned by physician practices. This may be a mere coincidence or as I feel part of the referral for profit issue. This letter may come across as a "sour grapes" letter since I am directly affected business and financially however there is more checks and balances when a physician has to refer a patient to an outside agency and we would have to show outcomes and progress in order to continue and that the physician would have to sign off on a continuation of PT orders. I wish to remain anonymous only due to the fact that I feel it could directly impact my business in that the physicians may feel I am actually accusing them of fraudulent behavior. I am only stating that there is greater potential for it and that I have heard through other patients and PT clinicians that this has occurred. I am again trying to get these pts to write letters so that we can have less "hearsay" and more proof to the detrimental effects that this could have on health care as a whole.

Sincerely,

51106

Submitter:

Mrs. Barbara Hall

Organization:

Mrs. Barbara Hall

Category:

Individual

Issue Areas/Comments

GENERAL

GENERAL

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.

I am 82 years old and a Medicare beneficiary. My son, Mark, is an anesthesiologist at Ball Hospital in Muncie, IN. He works 60+ hours per week, as his group is unable to recruit new partners. Several have left recently, including one who pulled me through a difficult back operation last summer. Mark tells me the practice is in trouble because they take care of a steadily increasing proportion of Medicare patients. Please help them continue providing seniors with the excellent care I was able to receive.

Yours truly,

Barbara L. Hall

Submitter:

Ms. Cynthia Clivio

Organization:

Ms. Cynthia Clivio

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

My name is Cynthia Clivio and 1 am a certified athletic trainer working in a private high school in Honolulu, HI. I am writing in opposition to the proposed revisions to 1385-P and the restrictions it places on who can provide services in hospitals and rural clinics. Certified Athletic Trainers are one of many healthcare professions who are skilled in providing a variety of treatments under the direction of a licensed physician. Physicians should be able to dictate which services and which professionals treat their patients. With access to healthcare at a critical shortage level in rural areas limiting who provides services may patients being denied access to necessary treatments. Please do not allow the physical therapy profession to create a monopoly which would result in increased cost and decreased access. Please reconsider the proposed revisions.

Submitter:

Joyce Anderson

Organization:

Joyce Anderson

Category:

Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

My comments are regarding potential changes to the In Office Ancillary Services Exception.

The American Physical Therapy Association has long been against physician-owned therapy centers. However, there has been no valid rationale for this, other than it cuts into their profits as the APTA is run by people owning freestanding therapy centers. In talking with many therapists, I have heard the consistent theme that freestanding centers tend to require therapists to see a higher volume of patients daily, and have them come for more visits. If a valid study were to be conducted comparing the number of visits required of therapists at freestanding centers vs. physician-owned centers, the data would most likely show the opposite of what the APTA espouses. Physican-owned clinics are more patient-focused whereas freestanding clinics are more dollar-focused.

Additionally I would like to point out the inadequacy of the methodology used in the OIG Report issued in May of 2006 titled Physical Therapy Billed by Physicians. The report analyzed 70 line items/CPT codes in 2002, of which 54 line items were from valid responses, leading to a total of \$1876 in improper payments. This result was then extrapolated to claims across the country with the perception that \$136 million were paid to physicians improperly. This result is extremely misleading and statistically invalid as it is based on the very small sample size of line items being actually studied (54).

I am requesting that CMS base its decision on valid data, not suppositions or opinions of vested interests regarding physician-owned therapy. Physican-owned therapy should be encouraged so patients get the best care.

Submitter: Dr. Dennis Higdon Date: 09/01/2007

Organization: Medical Anesthesia Group

Category: Physician Issue Areas/Comments

Coding-Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

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:

1 am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. 1 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:

Ms. brooke harvey

Organization:

Ms. brooke harvey

Category:

Other Health Care Provider

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

BRIEF INTRO ABOUT SELF ie. Where you work, what you do, education, certification, etc.

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,

Brooke Harvey, ATC

Submitter:

Organization:

Category: Individual

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.

Submitter:

Date: 09/01/2007

Organization:

Category:

Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I believe there are many problems with the ability for physician's to have the power to refer to themselves in the form of maintaining physical therapy in their offices. There is clearly a conflict of interest that challenges the ethics of the physician each time he or she refers to him or herself. When the referral is made out of the office without gain for the physician it changes the psychology of the referral with the patient's best interest is in mind. When monetary gain is involved in the referral it lends itself for impropriety even in the most honest of situations. We have had physicians in our area make it known that for no other reason they believe they are entitled to the monetary gain that goes along with placing some type of therapy in their office. There are studies that have been completed and submitted to the U.S. attorney general's office that have shown that it clearly costs the Medicare system significantly more money to have the loophole for physician referral to their own therapy department within their office. It seems this information is completely ignored in a time that we are in financial crisis to fund our Medicare program. The rules employed by the Medicare system place more scrutiny every year on free standing physical therapy practices. Fee schedule cuts seem inevitable. Why is nothing done when it comes to proven practices that are costing the system significantly more money when delivering the same service in another venue is much more cost effective. The physician's ability to self refer in the situation of a therapy clinic under their roof takes away any accountability necessary to ensure that best practices are employed in the delivery of physical therapy and the patient's ultimate well being is most important. It is imperative that the facts of this matter are what dictate the right course of action. A powerful lobby working for the american medical association cannot and should not be making the decision for you. Allowing the a physician to self refer to him or herself is bad

Submitter:

Dr. Aristides Koutrouvelis

Organization:

UTMB

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

CMS-1385-P - Please evaluate this fairly.

Submitter: Mr. David Damon Date: 09/01/2007

Organization: Kitsap Physical Therapy

Category: Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear representatives,

My name is David Damon & I am a physical therapist in private practice in Silverdale Wa. I am a clinic owner, and this letter is admittedly self serving as it is written on behalf of my profession, but certainly as you will hopefully realize it is also written on behalf of all American health care "consumers."

My concern is over the growing trend of physician owned physical therapy services. You may be aware that throughout the 80's and early 90's this practice was essentially prohibited by the Stark laws. Just as common sense tells a person that it would be a huge conflict of interest for a physician to own a pharmacy, in the same respect it was reasoned they should not own a physical therapy practice for profit. This common sense thinking was further justified by the Mitchell study which clearly showed increased utilization and cost of physical therapy when the service was owned by the referral source. In my town of Silverdale there have been 3 physician owned practices opened up in the past few years. Whatever amendment were made to the Stark laws seem to have opened the flood gates to this unnecessary practice. What has changed in how this practice is viewed? What has been the logic in making this now legal? I have experienced the unfair impact directly. Doctors who formerly chose to refer to myself and our staff have in some cases completely turned off the spicket as they now have a physical therapist that works for them. Though they formerly spoke very highly of our group they now only send patients who insist on coming to us or as we have also observed will tend to "cherry pick" and send financially challenged patients.

Though doctors are required by law to let their patients know they have a choice of where they go for therapy, this rarely occurs. The average person just goes where their doctor tells them to go, and of course this will usually be to the physical therapy department that enhances the doctors income.

This situation has created a very unfair playing field. As consistent with the Mitchell study findings, we have seen evidence that the doctors tend to refer much more liberally to their own practice. They send people more often and for more sessions with very questionable necessity at times. This will indeed result in tremendously higher costs to insurance companies, patients and tax payers in general while lining the pockets of the doctors who own these practices.

I see email advertisements from management companies, that are intended for physicians, telling how easily they can help start up a turn key lucrative physical therapy practice. I fear this unfair practice may lead to the demise of private practice for my profession. In my practice we have nearly 30 physical therapists most of whom have advanced degrees (masters or doctorate), are board certified specialists or have other advanced credentialing. This does not seem to matter anymore to the doctor who has employed a willing technician to do "physical therapy" (this does in many cases occur) with their patients as this brings them more revenue. To be fair, some doctors do employ very competent physical therapists, but still the motive for in house referral is influenced by income.

I am asking you to re-look at the Stark laws. Look at what is going on and please, please consider making these physician referral for profit practices illegal once and for all.

Another way to help level the playing field would be to allow direct access of the patient to the physical therapist without a physicians referral. The level of training of a physical therapist is such that direct access is very safe and more cost effective. Physical therapists are trained to know the "red flags" in medical screening to refer on to physicians when a patient should be seen by an MD.

I appreciate and thank you for your consideration of this letter and the serious requests within.

David Damon PT, OCS, ATC

Submitter:

Dr. Dan Diep

Organization:

Dr. Dan Diep

Category:

Chiropractor

Issue Areas/Comments

Technical Corrections

Technical Corrections

Dear Centers for Medicare and Medicaid Services:

As a chiropractor caring for hundreds of Medicare patients per month, I want to write in strong opposition to proposed rule dated July 12, 2007 that would climinate reimbursement to non-treating physician (e.g. radiologist) from ordering x-ray for chiropractic patients. I feel this proposed rule do a disservice to Medicare beneficiaries and tax payers. In my own clinical experience, x-rays are required on many occasions to diagnosis misalignment of the spinal column (subluxation) before spinal manipulation can be safely rendered. Many spinal misalignments are very subtle to detected manually through palpation. For an example, minor slippage of one vertebra on the other (e.g. retrolisthesis) may pinch the exiting nerve root or causing spinal sternosis and some of these sternosis are asymptomatic in nature. Without the x-ray, this can be easily missed. The doctor delivered a spinal manipulation without noticing the present of spinal sternosis can be devastating and can cause the scrious complications such as nerve damage that may require more costly and invasive treatment (e.g. surgery). This would drive up the cost of care considerably. 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, c.g., orthopedist or rheumatologist, etc., for duplicative evaluation prior to referral to a radiologist.

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 who will suffer should this proposal become standing regulation.

Sinccrely,

Dan Diep, D.C. (626) 575-1211

Submitter:

Mr. Adrian Noble

Organization:

Resurgens Orthopaedics

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Hello, my name is Adrian Noble, MS, MBA, ATC, CSCS, EMT-I. I work in an outpatient physician owned orthopedic rehabilitation clinic in Atlanta, Ga. The regulation that CMS is trying to impose upon hospitals and rehabilitation clinics is unjust and unwarranted.

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. I can perform my job as well as any physical therapist if not better. 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

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,

Adrian Noble, MS, MBA, ATC, CSCS, EMT-I

Submitter:

Ms. Pat Graman

Date: 09/01/2007

Organization:

University of Cincinnati

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Athletic Training is an important practice for physicians in the health care of individuals. Athletic Training affects the health care of individuals in the community that could not otherwise be practiced by other health care individuals. I hope you take the time to fully investigate and pass this docket.

Submitter:

Mrs. Tracy Keller

Organization:

Mrs. Tracy Keller

Category:

Individual

Issue Areas/Comments

Ambulance Services

Ambulance Services

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

Anesthcsia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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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:

bradley smith

Organization:

bradley smith

Category:

Physical Therapist

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

I am both a physical therapist and athletic trainer. Your bill as written precludes athletic trainers from evaluating and subsequently treating Medicare beneficiaries. As I have both degrees for both professions I understand the academic preparation for each. An athletic trainer does NOT have the neurological academic preparation necessary for proper and thorough evaluation of in-patient or out-patient Medicare beneficiaries referred to long term rehab facilities, hospitals, CORF's or outpatient rehab facilities. Typical diagnoses referred to these facilities, ataxia, vestibular dysfunctions, CVA, peripheral neuropathy, traumatic head injury, dementia, etc., are best treated by physical and occupational therapists. They have received academic training, both didactic and residential education, that properly and confidently prepares them for such patients. Certified athletic trainers are essential in the care and management of athletic personnel in the academic institutional, high school, college and professional arenas. They are also very effective in the worker's compensation environment as they are well prepared to assist, triage, and manage the common acute and chronic orthopedic injuries related to this area. Please maintain your requirements for the Medicare beneficiares receiving treatment in the previously noted medical environments so competent evaluation and treatment is rendered.

Submitter: Miss. Christine Ames Date: 09/01/2007

Organization: Glasson Sports Medicine

Category: Other Health Care Professional

Issue Areas/Comments

GENERAL.

GENERAL

Dear Sir or Madam:

My name is Christine Ames. I work as an athletic trainer in a physician owned physical therapy clinic and I am contracted out to a local elite soccer club.

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,

Christine K. Ames, ATC

Submitter: Mrs. Penemarie Murphy Date: 09/01/2007

Organization: Physical Therapy Services

Category: Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please exclude Physical Therapy from in office ancillary services. I have a private practice and am continuously under scrutiny by payors for cost containment issues and potential overutilization of physical therapy services. Physician owned physical therapy services have traditionally billed out higher receivables due to the issues of the physician kick-backs and higher PT salaries to produce those kick-backs. Many of these physician offices are billing for "physical therapy services" which are performed in their offices by unlicensed personnel. Some of these physicians are employing staff whom have graduated from accredited programs but were unable to pass their state boards, therefore passing them off as trained Physical Therapists. Many of these physician are hiding these kick-backs in the form of high rents, or cost shifting for salaries for their referral staff. All of these issues result in higher pay out by the insurance companies, therefore increasing costs for all. Physical therapy services should not be allowed under the in office ancillary services exception.

Submitter: Dr. Daniel Hesler Date: 09/01/2007

Organization: Indiana University School of Medicine

Category: Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

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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.

Daniel M. Hesler, MD Resident, Indiana University School of Medicine Department of Anesthesia 4718 N. Evanston Ave. Indianapolis, IN 46205 (317) 946-0060 (cell) dhesler@iupui.edu

CMS-1385-P-15604-Attach-1.TXT

Daniel M. Hesler, MD Resident, Indiana University School of Medicine Department of Anesthesia 4718 N. Evanston Ave. Indianapolis, IN 46205 (317) 946-0060 (cell) dhesler@iupui.edu

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Thank you for your consideration of this serious matter.

Daniel M. Hesler, MD

Submitter:

Dr. Russell Schellhase

Organization:

Northwest Community Healthcare

Category:

Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified, licensed Athletic Trainer at Northwest Community Healthcare in Arlington Heights, Illinois. I also earned a PhD in Kinesiology and University of Illinois.

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,

Russell Schellhase, PhD, MS, ATC

Submitter:

Mr. Jorge Coronado

Organization:

SFA Graduate Student

Category:

Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

Dcar Sir or Madam:

My name is Jorge A. Coronado I am a Graduate Student at Stephen F. Austin in Nacogdoches, Texas. I am a full time student and I am pursuing a Master Degree in Athletic Training. I have a undergrduate degree from the Texas A&M International in Laredo, Texas. My undergraduate degree is in Fitness and Sports.

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.

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As an athletic trainer, I will be 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 will ensure that my patients receive quality health care. State law and hospital medical professionals will deem me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Sincerely,

Jorge A. Coronado SFA Ahletic Training Graduate Student

Submitter:

Dr. Phillip Lim

Organization:

Dr. Phillip Lim

Category:

Individual

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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Thank you for your consideration of this serious matter.

Submitter:

Dr. Bobby Mathew

Organization:

O'Connor Hospital

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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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.

Bobby Mathew, M.D. 310-430-3644

Submitter:

Dr. Benjamin Johnson

Organization:

Vanderbilt University

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Submitter:

Mr. Jason Bailey

Organization: C

Carolina Hurricanes

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

Hello, My name is Jason Bailey, and I work with the Carolina Hurrieanes. I am concerned about this legislation because it restricts our abilities to look for competitive jobs in Athletic Training. There is a wide varity of jobs that we can perform, limiting those to others with less experience and qualifications will be an injustice to the patients.

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,

Jason Bailey, MS ATC CSCS (and/or other credentials)

Submitter:

Dr. Robert timonen

Organization:

american society of anesthesiologists

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachement

CMS-1385-P-15611-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 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.

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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.

Respectfully,

Robert M. Timonen M.D.

Submitter:

Mrs. Mary Sullivan

Organization:

Mrs. Mary Sullivan

Category:

Other

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

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

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

I know Athletic Trainers are qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. Their education, clinical experience, and national certification exam ensure that their patients receive quality health care. State law and hospital medical professionals have deemed ATC's 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.

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Sincerely,

Mary Sullivan

Submitter:

Mr. Joseph Sullivan

Organization:

Mr. Joseph Sullivan

Category:

Other

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

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

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

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Sincerely,

Joe Sullivan

Submitter :

Krishana Mantravadi

Star Anesthesia

Organization:
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)

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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.

Sincerely, Krishana Mantravadi MD

Submitter: Dr. Rhonda Marvar Date: 09/01/2007

Organization: South Oakland Anesthesia Associates

Category: Physician

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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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Thank you for your consideration of this serious matter.

Submitter:

Dr. Peter Sperandio

Organization:

West Jersey Anesthesia Associates

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)

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Thank you for your consideration of this serious matter.

Submitter:

Dr. Ronald Brons

Date: 09/01/2007

Organization:

Bear Creek Anesthesiology Medical Group, 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)

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Thank you for your consideration of this serious matter.

Ronald Brons, MD Bear Creek Anesthesiology Medical Group, Inc. 301 E 13th St. Merced, CA 95340

Submitter:

Dr. Denise Hall-Burton

Organization:

Dr. Denise Hall-Burton

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)

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Thank you for your consideration of this serious matter.

Submitter:

Dr. Christian Gonzalez

Organization:

University of Massachusetts

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

Rc: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter:

Ms. Alys Staten

Utah State University

Organization: Category:

Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Alys Staten, and I have been working as a certified athletic trainer for over 10 years. I received my bachelors degree from Brigham Young University-Hawaii Campus and my masters in biomechanics from Boise State University. I am currently working as the athletic trainer for all of campus recreation for Utah State 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 would 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 arc 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.

Alys Staten, ATC, MS

CMS-1385-P-15621 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter: Dr. Thomas Rairdon Date & Time: 09/02/2007

Organization: Star Anesthesia

Category: Physician

Issue Areas/Comments

GENERAL

GENERAL

The Centers for Medicare and Medicaid Services (CMS), the government agency that runs the Medicare program, must make sure that Medicare beneficiaries have adequate access to care. ASA has well-founded concerns that current Medicare payment levels do not meet this standard and may have finally convinced CMS administrators that improved payment is essential.

Submitter:

Dr. Thomas Rairdon

. .

Star Anesthesia

Organization: Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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Submitter:

Miss. Jaclene Katchmark

Organization:

Miss. Jaclene Katchmark

Category:

Individual

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

A plea for assistance in providing quality PT care

CMS-1385-P-15622-Attach-1.DOC

8/31/2007

To Whom It May Concern:

Please remove physical therapy services from the allowed list of in-office ancillary services on the physician fee schedule.

I am a physical therapist assistant with 19 years of clinical experience, having worked in a variety of care settings. I have worked in multiple states, and have heard the same comments from patients all over the country regarding POPTS... "My doctor thought I should go to this clinic"... "My prescription was to their office"... "Well, that's where he/she sent me!"... Usually, patients do not even realize that the doctor owns the clinic to which they have been referred. Nor do they realize that they have the right to choose their PT care providers.

The consumer (the patient) is slowly learning to compare providers, prices and quality of care – but consumer education in the confusing world of medical care is woefully slow. In the meantime, patients continue to be referred to "Physical Therapy" services at physician owned clinics that sometimes do not even employ a licensed PT. How can one receive physical therapy in a clinic that does not employ a physical therapist?

We in the Physical Therapy field are proud of the unique services we provide. We are proud of our education, experience and commitment to our patients. We want to be evaluated and earn loyalty from our clients. Please help us encourage *quality* Physical Therapy care by removing physical therapy services from the allowed list of in-office ancillary services on the physician fee schedule.

Thank you.

Jaclene Katchmark, PTA

Submitter:

Dr. Robin Wieder

Organization:

private practice

Category:

Chiropractor

Issue Areas/Comments

GENERAL

GENERAL

Regarding CMS-1385-P, 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. This proposal will only interfere with patinet care in attempting to rule out red flags and itwill not save money. patients will be pushed tohave to go to another provider anyway to seek help and inthe end this will duplicate visits. Please oppose this proposed change

Submitter : Organization :

Dr. Tajammul Hussain

404

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:

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Thank you for your consideration of this serious matter.

Dr. Tajammul Hussain

Submitter:

Dr. James Day

Date: 09/02/2007

Organization:

St. John Anesthesia Services

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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Thank you for your consideration of this serious matter.

James S. Day, M.D.

Submitter:

Date: 09/02/2007

Organization:

Category: Physician

Issue Areas/Comments

Medicare Telehealth Services

Medicare Telehealth Services

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

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Anesthesia Coding (Part of 5-Year Review)

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Submitter:

Date: 09/02/2007

Organization:

Category:

Physician

Issue Areas/Comments

Medicare Telehealth Services

Medicare Telehealth Services

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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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.

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

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

Thank you for your consideration of this serious matter.

Submitter:

Mr. Gregg Everts

Organization:

Everts Enterprises. LLC

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a Ccrtified Athletic Trainer who works in the High School setting with many athletes.

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,

Gregg A. Everts, ATC/L

Submitter:

Dr. James Miller

Organization:

California Anesthesiology Associates

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

I have attached a comment letter.

CMS-1385-P-15629-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 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.

Most Sincerely.

James R. Miller, MD
Anesthesiologist
Long Beach Memorial Medical Center
Long Beach, CA

Submitter:

Dr. Ron Mov

Organization:

Moy-Fincher Medical Group

Category:

Physician

Issue Areas/Comments

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Sept 1, 2007

To The Honorable Herbert Kuhn, Acting Administrator of CMS:

I am a dermatologic surgeon and recent member of the California Medical Board. The planned changes in Medicare reimbursement policy by the Centers for Medicare and Medicaid Services (CMS) for Mohs Micrographic Surgery will have a significant negative impact on the healthcare of U.S. citizens and potentially add unnecessary cost to the delivery of healthcare in this country.

As you are probably aware, over a million Americans per year are diagnosed with skin cancer and over the last ten years the rate of new skin cancer diagnoses is growing at what many would call epidemic proportions. Mohs micrographic surgery is a common way of treating some of these cancers and is considered the gold standard among treatments for skin cancer, allowing the physician to examine 100% of the cancer margin to insure complete removal of the cancer with loss of as little normal skin as possible. Mohs surgery is an outpatient procedure that utilizes onsite laboratory analysis of excised tissue while the patient waits for the results. The critical component of Mohs surgery includes meticulous removal and microscopic examination of the entire edge and deep margin of the cancer, in which the same physician serves as both surgeon and pathologist. The procedure is particularly valuable in the treatment of skin cancers in cosmetically or functionally important areas such as the face, neck, hands, feet and genitalia. It is also valuable for large, aggressive, or ill-defined cancers and for those that have recurred after other previous treatment. After the cancer is removed, most patients undergo subsequent reconstructive surgery by the same doctor on the same day as the cancer removal

Exemption from the multiple surgery reduction rule would 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. If this proposed change is enacted, we will no longer be able to provide the same kind of high-quality, cost-effective services for our patients in need. We will be forced to change the way we deliver care in order to cover our costs of providing this 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, occurring in 10% of my referral practice population. 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, usually plastic, facial plastic, or oculoplastic surgeons, 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.

It is my hope that you will reconsider planned changes to Mohs codes.

Sincerely, Ronald L. Moy, MD 100 UCLA Medical Plaza Los Angeles, CA

CMS-1385-P-15630-Attach-1.PDF



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August 2, 2007

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Executive Office:

Fax: 414-276-2146

American College of Mohs Surgery

555 East Wells Street, Suite 1100 Milwaukee, WI 53202 Phone: 414-347-1103 800-500-7224

E-mail: info@mohscollege.org Website: www.mohscollege.org

The Honorable Herbert Kuhn Acting Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Washington, DC 20201

Phone: 202-690-6726

E-mail: herb.kuhn@cms.hhs.gov

Re: CMS 1385-P: 2008 Medicare Fee Schedule

Coding – Multiple Procedure Payment Reduction for Mohs Surgery

Dear Acting Administrator Kuhn:

As President of the American College of Mohs Surgery, I represent over eight hundred fellow-ship-trained Mohs surgeons in the United States, whose primary practice is the treatment of skin cancer. The College and I are deeply concerned regarding this proposed rule for multiple reasons. We appreciate this opportunity to offer comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule.

This proposal represents a dramatic reversal of sixteen years of the Centers for Medicare and Medicaid Services' (CMS) own determination that the Mohs codes are and should be exempt from the Multiple Procedure Reduction Rule (MPRR). Furthermore, because of the dual components of surgery and pathology associated with each Mohs surgery procedure, there is no gain in efficiencies when multiple, separate procedures are performed on the same date, making application of the reduction inappropriate. Third, this proposal is contrary to the Relative Value Update Committee's (RUC) own policy regarding procedures qualifying for exemption from this rule. Fourth, this proposal will negatively impact Medicare beneficiaries' access to timely and quality care. Fifth, application of this proposal will not likely generate significant cost savings and may paradoxically increase costs of providing care to these patients. Finally, we are concerned that the Proposed Rule reflects an alteration in the traditional role of the RUC in CMS policy formulation.

First, the Mohs surgery codes have had a longstanding and appropriate exemption from the Multiple Procedure Reduction Rule since 1991. In its Final Rule for the 1992 Medicare Fee Schedule (Federal Register November 25, 1991, volume 56, #227, p. 59602- copy enclosed), the CMS (then HCFA) included comment regarding Mohs micrographic surgery. CMS

Centers for Medicare and Medicaid Services Department of Health and Human Services August 2, 2007 Page Two

agreed at that time that the Mohs procedures "are a series of surgeries which, while done on the same day, are done at different operative sessions and are clearly separate procedures in a series of procedures....They will be paid separately with no multiple surgery reductions." This conclusion is still correct and applicable today.

At the request of CMS in 2005, the College, together with the American Academy of Dermatology, the American Society for Dermatologic Surgery, and the American Society for Mohs Surgery, worked through the AMA CPT/AMA RUC five-year review process and the AMA CPT/AMA RUC Modifier -51 Workgroup to develop site-specific codes for the Mohs procedure. Two new site-specific codes, 17311 and 17313, were accepted by AMA CPT/AMA RUC to differentiate Mohs excision of cancers in different anatomic areas. However, there has been NO CHANGE in the procedure or in the separate and distinct nature of the Mohs procedure from any other procedure which might be performed on the same day. We believe the revised code descriptors to differentiate anatomic sites, in the absence of a change in work associated with the procedure, does not support the change in the multiple procedure exemption status of the new Mohs codes.

Second, as noted in the Proposed Rule, "RVUs were developed for each Mohs surgery base code based on an assumption that each code is performed separately." This assumption is correct. Mohs micrographic surgery uniquely includes two distinct components, surgery and pathology, both of which are performed wholly by the Mohs surgeon, with the pathology component comprising half of the service. The nature of Mohs surgery requires that the entire procedure, including processing and interpretation of the histopathology slides, be completed before any consideration is given to the excision of additional tissue or to repair of the resulting defect. The intra-service work for 17311 was acknowledged by RUC to be 80% of the total physician work of the procedure (78% for 17313), including both the surgery and pathology. Even when two Mohs excisions are performed for a patient on the same date, there is no overlap in work for treatment of the second site, which requires all the same components of excision and tissue processing/interpretation as the first site. There are marginal gains in "efficiencies" when treating more than one tumor at the same time.

Likewise, there is no overlap between a Mohs procedure to remove a skin cancer and a subsequent, separate repair procedure that might be used to address the skin defect created by the Mohs procedure. The time required for the pathology component of the procedure results in an onsite waiting period for the patient. If a repair is performed, it requires return to an operating room, repositioning, re-anesthetizing, re-prepping, etc. It is performed with new instrumentation. It is typically performed in the same room as the prior Mohs procedure. There is no overlap of work or practice expense for clinical labor time, medical supplies, or medical equipment between the Mohs procedure and a repair procedure.

Centers for Medicare and Medicaid Services Department of Health and Human Services August 2, 2007 Page Three

Therefore, it is inappropriate to subject 17311 and 17313 to the multiple procedure reduction rule for repairs performed on the same day as the Mohs procedure or for multiple Mohs lesion excisions performed on the same day.

Third, the RUC -51 Research Subcommittee identified seven criteria to determine whether a code should be included on the Modifier -51 Exemption List: 1, RUC rationale supporting placement on the list; 2, Exemption from the CMS Multiple Surgery Reduction; 3, Limited amount of pre- and post-service time and limited number of visits; 4, No add-on codes; 5, No codes where payment logic would not reduce payment when performed with another procedure; 6, Service is typically adjunctive to another service but can be performed as stand-alone procedure; and 7, Service is performed with multiple other procedures that are so extensive that it is difficult to maintain a "Report With" list typically included in CPT.

Considering the arguments we present above, the Mohs codes meet three of the AMA CPT/AMA RUC Modifier -51 Workgroup criteria for procedures qualifying for exemption.

- 1. Mohs micrographic surgery was declared exempt by CMS in 1991. The procedure remains unchanged since then except for the new CPT code numbers described above.
- 2. The Mohs codes have very little pre- and post-service time and have a limited number of visits. As above, 78 80% of the total physician work of the Mohs codes is intra-service work. The pre- and post-service time for the Mohs codes is less on a percentage basis than that of the other codes remaining on the list of exemptions. The Mohs codes also have zero post-op visits embedded in the value of the codes.
- 3. The Mohs codes are typically adjunctive to a repair service but are often performed as stand-alone procedures, in cases when wounds are allowed to heal secondarily. Second-intention healing is typical for tumors in certain areas, especially the medial canthus, conchal bowl, and posterior ear, among others.

Meeting three of the seven RUC-developed criteria for exemption, any one of which merits consideration for inclusion on the list, appropriately justifies retaining the longstanding exempt status of the Mohs codes.

Furthermore, since the pathology component of Mohs surgery comprises half of the procedure, it is appropriate that the Mohs codes be treated similarly to other pathology codes, which are not subject to the multiple procedure reduction rule, since there is no overlap in work from reviewing one slide to another. To apply the reduction to the Mohs codes would be inconsistent with the exemption of application of this rule to other pathology codes.

Fourth, removing the exempt status of the Mohs codes will negatively impact Medicare beneficiaries' access to timely and quality care. Currently, 10% of patients undergoing Mohs micrographic surgery have more than one tumor treated with Mohs on the same day.

Centers for Medicare and Medicaid Services Department of Health and Human Services August 2, 2007 Page Four

Application of the proposed rule to a second tumor treated on the same day will mean that reimbursement for the second procedure does not cover the cost of providing the service. This will affect Medicare beneficiaries disproportionately, since the incidence of skin cancers peaks in Medicare-age patients, who are most likely to have multiple tumors. Additionally, patients who are immunosuppressed from organ transplantation, cancer chemotherapy, infection or other diseases are at significantly higher risk for skin cancers and often have multiple tumors; many of these patients are also Medicare beneficiaries. These immunosuppressed patients are not only at higher risk for cancers but also at higher risk for potential metastases and possibly death from skin cancers, especially squamous cell carcinoma.

Fifth, although perhaps intended as a cost-saving measure, application of this rule will not likely generate significant cost savings and may paradoxically increase cost of providing care to these patients. When Mohs procedures are performed with higher-valued repairs such as flaps or grafts, application of the MPRR to the Mohs codes will result in reduced reimbursement for Mohs that doesn't cover the cost of the procedure. Likewise, for lower-valued repairs such as intermediate and complex layered closures, which are the most commonly performed repairs, reduced reimbursement will not cover the cost of the repair.

Finally, we support the RUC process and recognize the value it brings to the annual physician fee schedule development. As initially charged, the RUC has done an exceptional job over the years in expressing opinions regarding relative values for procedures. In doing this the RUC defied the predictions of critics who claimed that agreement would not be possible among the various stakeholders. The RUC and CMS also prevailed against the legal challenge that the RUC amounted to a Federal Advisory Committee. In defending against that allegation it was persuasive to the court that the RUC only provides opinions on relative values and that CMS retains the authority to make policy decisions. The RUC, it was noted, is independent and is only one source of CMS input on relative values. All policy decisions have undergone full development by CMS in the public notice and comment process.

The policies adopted by CMS such as multiple surgical reductions, bundled services, and prohibition against operating surgeons from separately billing for anesthesia and assistant at surgery restrictions are all examples of policy decisions by CMS. They do no strictly represent issues of relative value but rather they represent policy formulations that guide payment and medical practice. To have the RUC engaged in these policy formulations in a forum which is not open or accessible to the public is unfair to the Medicare beneficiaries affected and threatens the RUC process.

We disagree with using the RUC for this purpose but if CMS believes the RUC role should be expanded it should only be done by giving the RUC a public and well-articulated charge to take on this task.

Centers for Medicare and Medicaid Services Department of Health and Human Services August 2, 2007 Page Five

In light of the concerns raised above, the American College of Mohs Surgery respectfully requests reconsideration of the proposed rule. We provide the above rationale in support of the Mohs procedure base codes, 17311 and 17313, as appropriately exempt from the multiple procedure reduction rule, as are the other add-on Mohs codes. We therefore request permanent exemption from the MPRR.

We would appreciate the opportunity to meet with CMS to discuss this issue as soon as possible. Please feel free to contact me at 412/466-9400.

Respectfully,

David G. Brodland, M.D.

President, American College of Mohs Surgery

cc:

Terrence Kay, Director, Hospital and Ambulatory Policy Group

Amy Bassano, Director, Practitioner Services Division

Diane Baker, MD, President, American Academy of Dermatology

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

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

Enclosures -1992 Medicare Fee Schedule: Final Rule (Federal Register, November 25, 1991, vol.

56, #227, pg 59602)

CPT Assistant, July, 2004

CPT Assistant, November, 2006

Submitter:

Dr. Wade Foster

.

Moy Fincher Medical Group

Organization: Category:

Physician

Issue Areas/Comments

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Sept 1, 2007 To The Honorable Herbert Kuhn, Acting Administrator of CMS; I am a dermatologic surgeon in Los Angeles, CA. The planned changes in Medicare reimbursement policy by the Centers for Medicare and Medicaid Services (CMS) for Mohs Micrographic Surgery will have a significant negative impact on the healthcare of U.S. citizens and potentially add unnecessary cost to the delivery of healthcare in this country. As you are probably aware, over a million Americans per year are diagnosed with skin cancer and over the last ten years the rate of new skin cancer diagnoses is growing at what many would call epidemic proportions. Mohs micrographic surgery is a common way of treating some of these cancers and is considered the gold standard among treatments for skin cancer, allowing the physician to examine 100% of the cancer margin to insure complete removal of the cancer with loss of as little normal skin as possible. Mohs surgery is an outpatient procedure that utilizes onsite laboratory analysis of excised tissue while the patient waits for the results. The critical component of Mohs surgery includes meticulous removal and microscopic examination of the entire edge and deep margin of the cancer, in which the same physician serves as both surgeon and pathologist. The procedure is particularly valuable in the treatment of skin cancers in cosmetically or functionally important areas such as the face, neck, hands, feet and genitalia. It is also valuable for large, aggressive, or ill-defined cancers and for those that have recurred after other previous treatment. After the cancer is removed, most patients undergo subsequent reconstructive surgery by the same doctor on the same day as the cancer removal. Exemption from the multiple surgery reduction rule would 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. If this proposed change is enacted, we will no longer be able to provide the same kind of high-quality, cost-effective services for our patients in need. We will be forced to change the way we deliver care in order to cover our costs of providing this 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, occurring in 10% of my referral practice population. 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, usually plastic, facial plastic, or oculoplastic surgeons, 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. It is my hope that you will reconsider planned changes to Mohs codes. Sincerely, Wade Foster, MD/PhD, MD 100 UCLA Medical Plaza Los Angeles, CA

CMS-1385-P-15631-Attach-1.PDF



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Executive Office:

American College of Mohs Surgery 555 East Wells Street, Suite 1100

Milwaukee, WI 53202 Phone: 414-347-1103 800-500-7224

Fax: 414-276-2146

E-mail: info@mohscollege.org Website: www.mohscollege.org The Honorable Herbert Kuhn Acting Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Washington, DC 20201

Phone: 202-690-6726 E-mail: herb.kuhn@cms.hhs.gov

Re: CMS 1385-P: 2008 Medicare Fee Schedule

Coding - Multiple Procedure Payment Reduction for Mohs Surgery

Dear Acting Administrator Kuhn:

As President of the American College of Mohs Surgery, I represent over eight hundred fellow-ship-trained Mohs surgeons in the United States, whose primary practice is the treatment of skin cancer. The College and I are deeply concerned regarding this proposed rule for multiple reasons. We appreciate this opportunity to offer comment on section II.E.2 (P-122) of the 2008 Medicare Fee Schedule Proposed Rule.

This proposal represents a dramatic reversal of sixteen years of the Centers for Medicare and Medicaid Services' (CMS) own determination that the Mohs codes are and should be exempt from the Multiple Procedure Reduction Rule (MPRR). Furthermore, because of the dual components of surgery and pathology associated with each Mohs surgery procedure, there is no gain in efficiencies when multiple, separate procedures are performed on the same date, making application of the reduction inappropriate. Third, this proposal is contrary to the Relative Value Update Committee's (RUC) own policy regarding procedures qualifying for exemption from this rule. Fourth, this proposal will negatively impact Medicare beneficiaries' access to timely and quality care. Fifth, application of this proposal will not likely generate significant cost savings and may paradoxically increase costs of providing care to these patients. Finally, we are concerned that the Proposed Rule reflects an alteration in the traditional role of the RUC in CMS policy formulation.

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Centers for Medicare and Medicaid Services Department of Health and Human Services August 2, 2007 Page Two

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At the request of CMS in 2005, the College, together with the American Academy of Dermatology, the American Society for Dermatologic Surgery, and the American Society for Mohs Surgery, worked through the AMA CPT/AMA RUC five-year review process and the AMA CPT/AMA RUC Modifier -51 Workgroup to develop site-specific codes for the Mohs procedure. Two new site-specific codes, 17311 and 17313, were accepted by AMA CPT/AMA RUC to differentiate Mohs excision of cancers in different anatomic areas.. However, there has been NO CHANGE in the procedure or in the separate and distinct nature of the Mohs procedure from any other procedure which might be performed on the same day. We believe the revised code descriptors to differentiate anatomic sites, in the absence of a change in work associated with the procedure, does not support the change in the multiple procedure exemption status of the new Mohs codes.

Second, as noted in the Proposed Rule, "RVUs were developed for each Mohs surgery base code based on an assumption that each code is performed separately." This assumption is correct. Mohs micrographic surgery uniquely includes two distinct components, surgery and pathology, both of which are performed wholly by the Mohs surgeon, with the pathology component comprising half of the service. The nature of Mohs surgery requires that the entire procedure, including processing and interpretation of the histopathology slides, be completed before any consideration is given to the excision of additional tissue or to repair of the resulting defect. The intra-service work for 17311 was acknowledged by RUC to be 80% of the total physician work of the procedure (78% for 17313), including both the surgery and pathology. Even when two Mohs excisions are performed for a patient on the same date, there is no overlap in work for treatment of the second site, which requires all the same components of excision and tissue processing/interpretation as the first site. There are marginal gains in "efficiencies" when treating more than one tumor at the same time.

Likewise, there is no overlap between a Mohs procedure to remove a skin cancer and a subsequent, separate repair procedure that might be used to address the skin defect created by the Mohs procedure. The time required for the pathology component of the procedure results in an onsite waiting period for the patient. If a repair is performed, it requires return to an operating room, repositioning, re-anesthetizing, re-prepping, etc. It is performed with new instrumentation. It is typically performed in the same room as the prior Mohs procedure. There is no overlap of work or practice expense for clinical labor time, medical supplies, or medical equipment between the Mohs procedure and a repair procedure.

Centers for Medicare and Medicaid Services Department of Health and Human Services August 2, 2007 Page Three

Therefore, it is inappropriate to subject 17311 and 17313 to the multiple procedure reduction rule for repairs performed on the same day as the Mohs procedure or for multiple Mohs lesion excisions performed on the same day.

Third, the RUC -51 Research Subcommittee identified seven criteria to determine whether a code should be included on the Modifier -51 Exemption List: 1, RUC rationale supporting placement on the list; 2, Exemption from the CMS Multiple Surgery Reduction; 3, Limited amount of pre- and post-service time and limited number of visits; 4, No add-on codes; 5, No codes where payment logic would not reduce payment when performed with another procedure; 6, Service is typically adjunctive to another service but can be performed as stand-alone procedure; and 7, Service is performed with multiple other procedures that are so extensive that it is difficult to maintain a "Report With" list typically included in CPT.

Considering the arguments we present above, the Mohs codes meet three of the AMA CPT/AMA RUC Modifier -51 Workgroup criteria for procedures qualifying for exemption.

- 1. Mohs micrographic surgery was declared exempt by CMS in 1991. The procedure remains unchanged since then except for the new CPT code numbers described above.
- 2. The Mohs codes have very little pre- and post-service time and have a limited number of visits. As above, 78 80% of the total physician work of the Mohs codes is intra-service work. The pre- and post-service time for the Mohs codes is less on a percentage basis than that of the other codes remaining on the list of exemptions. The Mohs codes also have zero post-op visits embedded in the value of the codes.
- 3. The Mohs codes are typically adjunctive to a repair service but are often performed as stand-alone procedures, in cases when wounds are allowed to heal secondarily. Second-intention healing is typical for tumors in certain areas, especially the medial canthus, conchal bowl, and posterior ear, among others.

Meeting three of the seven RUC-developed criteria for exemption, any one of which merits consideration for inclusion on the list, appropriately justifies retaining the longstanding exempt status of the Mohs codes.

Furthermore, since the pathology component of Mohs surgery comprises half of the procedure, it is appropriate that the Mohs codes be treated similarly to other pathology codes, which are not subject to the multiple procedure reduction rule, since there is no overlap in work from reviewing one slide to another. To apply the reduction to the Mohs codes would be inconsistent with the exemption of application of this rule to other pathology codes.

Fourth, removing the exempt status of the Mohs codes will negatively impact Medicare beneficiaries' access to timely and quality care. Currently, 10% of patients undergoing Mohs micrographic surgery have more than one tumor treated with Mohs on the same day.

Centers for Medicare and Medicaid Services Department of Health and Human Services August 2, 2007 Page Four

Application of the proposed rule to a second tumor treated on the same day will mean that reimbursement for the second procedure does not cover the cost of providing the service. This will affect Medicare beneficiaries disproportionately, since the incidence of skin cancers peaks in Medicare-age patients, who are most likely to have multiple tumors. Additionally, patients who are immunosuppressed from organ transplantation, cancer chemotherapy, infection or other diseases are at significantly higher risk for skin cancers and often have multiple tumors; many of these patients are also Medicare beneficiaries. These immunosuppressed patients are not only at higher risk for cancers but also at higher risk for potential metastases and possibly death from skin cancers, especially squamous cell carcinoma.

Fifth, although perhaps intended as a cost-saving measure, application of this rule will not likely generate significant cost savings and may paradoxically increase cost of providing care to these patients. When Mohs procedures are performed with higher-valued repairs such as flaps or grafts, application of the MPRR to the Mohs codes will result in reduced reimbursement for Mohs that doesn't cover the cost of the procedure. Likewise, for lower-valued repairs such as intermediate and complex layered closures, which are the most commonly performed repairs, reduced reimbursement will not cover the cost of the repair.

Finally, we support the RUC process and recognize the value it brings to the annual physician fee schedule development. As initially charged, the RUC has done an exceptional job over the years in expressing opinions regarding relative values for procedures. In doing this the RUC defied the predictions of critics who claimed that agreement would not be possible among the various stakeholders. The RUC and CMS also prevailed against the legal challenge that the RUC amounted to a Federal Advisory Committee. In defending against that allegation it was persuasive to the court that the RUC only provides opinions on relative values and that CMS retains the authority to make policy decisions. The RUC, it was noted, is independent and is only one source of CMS input on relative values. All policy decisions have undergone full development by CMS in the public notice and comment process.

The policies adopted by CMS such as multiple surgical reductions, bundled services, and prohibition against operating surgeons from separately billing for anesthesia and assistant at surgery restrictions are all examples of policy decisions by CMS. They do no strictly represent issues of relative value but rather they represent policy formulations that guide payment and medical practice. To have the RUC engaged in these policy formulations in a forum which is not open or accessible to the public is unfair to the Medicare beneficiaries affected and threatens the RUC process.

We disagree with using the RUC for this purpose but if CMS believes the RUC role should be expanded it should only be done by giving the RUC a public and well-articulated charge to take on this task.

Centers for Medicare and Medicaid Services Department of Health and Human Services August 2, 2007 Page Five

In light of the concerns raised above, the American College of Mohs Surgery respectfully requests reconsideration of the proposed rule. We provide the above rationale in support of the Mohs procedure base codes, 17311 and 17313, as appropriately exempt from the multiple procedure reduction rule, as are the other add-on Mohs codes. We therefore request permanent exemption from the MPRR.

We would appreciate the opportunity to meet with CMS to discuss this issue as soon as possible. Please feel free to contact me at 412/466-9400.

Respectfully,

David G. Brodland, M.D.

President, American College of Mohs Surgery

cc: Terrence Kay, Director, Hospital and Ambulatory Policy Group
Amy Bassano, Director, Practitioner Services Division
Diane Baker, MD, President, American Academy of Dermatology
Alastair Carruthers, FRCPC, President, American Society of Dermatologic Surgery
Sharon Tiefenbrunn, MD, President, American Society for Mohs Surgery

Enclosures -1992 Medicare Fee Schedule: Final Rule (Federal Register, November 25, 1991, vol. 56, #227, pg 59602)

CPT Assistant, July, 2004

CPT Assistant, November, 2006

Submitter:

Dr. Curt Theo

Organization:

Dr. Curt Theo

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

file ./T/ELECTRONIC%20COMMENTS/ELECTRONIC%20COMMENTS/E-Comments/...tive%20Files/Milling%20file1.txt

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

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

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

Submitter:

Mr. Adam Annaccone

Date: 09/02/2007

Organization:

Clarion University Sports Medicine

Category:

Health Care Provider/Association

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Adam R. Annaccone, M.Ed, ATC, PES. I am an Assistant Athletic Trainer at Clarion University of Pennsylvania. I am also an Approved Clinical Instructor for our Athletic Training Education Program.

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,

Adam R. Annaccone, M.Ed, ATC, PES

Submitter:

Ms. Caitlen Shirk

Organization:

Marietta College

Category:

Academic

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

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

As an athletic training student, I, under the supervision of an ACI, perform evaluations on injured athletes and assist in rehabilitation programs. I have hopes of graduating in 2009 with a degree in athletic training. I recently learned that athletic trainers would no longer be reimbursed for their services on people that are on Medicarc and Medicaid.

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 get rid of the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely, Caitlen Shirk ATS

Submitter:

Dr. John Franz

Date: 09/02/2007

Organization:

Stept and Arnehim Urologic Associates

Category:

Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

As a urologist in a seven physician, three PA/NP group practice in three offices spanning almost fourty miles practicing in an area with one of the hightest median ages in the country I am writing to comment on the proposed changes to the physician fee schedule rules that were published on July 12, 2007 that concern the Stark self-referral rule and the reassignment and purchased diagnostic test rules. Our area is dominated by the monopoly of Highmark Blue Cross Blue Shield that is now attempting to spread across the whole state. They have billion dollar reserves at a time when half the licensed nurses in this state are not practicing, when those who do are tremendously stressed from overwork, and when surgeons can not be recruited because fee based practices can not compete economically to hire new partners. These restrictions will guarantee that hospitals will be employing salaried surgeons because those surgeons will be worth more to the hospital than to themselves. That then contributes to the monopoly power of the hospitals, the finest example of which is the UPMC Health Care system with its own striking reserves. Such power restricts innovation and competition. The changes proposed in these rules will restrict the ability to bring to our practice and hospital technology that is expensive, infrequently used or requires specialized technologists for its use. We have a shared lithotriptor that spends two days per month at our hospital, laser systems for prostate surgery and urinary calculi that are used a few times monthly on an as needed basis. We gave up doing urine cultures in our office because the income did not justify the costs. We and our patients lost by that move because without intimate connection with the microbiology laboratory the physician and the staff will evaluate and treat urine infections less accurately. The in-office ancillary services exception should not be limited in any way. New technologies will provide less expensive office and out patient services. It is important for urologists to have the ability to provide pathology services in their own offices. The urologist must be able to do his own needle biopsies of the prostate with ultrasound guidance and have control on the handling and interpretation of the results with a pathologist with whom he has trust and good communication. Most radiologists do not understand the intricacies of postate cancer and are not comfortable doing needle biopsies of the prostate. In addition they do not treat those complications of prostate biopsies which do occur. It is equally important for urologists to work with radiation oncologists in a variety of ways to provide ratiation therapy to patients. The urologist makes the diagnosis, decides the treatment in conference with the patient and possibly in consultation with the radiation oncologist, and ultimately it is the urologist who treats complications and follows the patient response to treatment long term. The sweeping changes to the Stark regulations and the reassignment and purchased diagnostic test rules go far beyond what is necessary to protect the medicare frogram from fraud and abuse. They will only further to continue the deliverance of health care to the likes of the CEO of UPMC medical system who told an audience of physicians at Shadyside Hospital that they were fools not to have monopolized the health care system. Unfortunately he did not take the Hippocratic oath or spirit. While I know of colleagues who are thieves, they are generally shunned. The value of beneficience must be paramount in our minds, especially as we care for the aging, frail Medicare population which dominates southwestern Pennsylvania. We need your help to maintain the independence necessary to support these values which are crueial to our own future care as well. I turn 65 in two months. This care is my care for myself and my patients. We are one.

Submitter:

Dr. Luu Nguyen

Organization:

Dr. Luu Nguyen

Category:

Physician

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding -- Additional Codes From 5-Year Review

Re: CMS-1385-P Anesthesia Coding

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule.

Anesthesia work has been significantly undervalued compared to other physician services, resulting in a huge payment disparity for anesthesia care. Medicare payment for anesthesia services at the current rate of just \$ 16.10 per unit imposes a huge financial burden to provide anesthesia care to our senior citizens; this situation forces anesthesiologists away from areas with high Medicare populations.

The RUC recommended that CMS increase the anesthesia conversion factor to offset the work undervaluation in anesthesia serivces. I support full implementation of the RUC's recommendation.

It is important that CMS implement the anesthesia conversion factor increase as recommended by the RUC to ensure that our patients will have access to expert anesthesia care.

Thank you for your consideration.

Submitter:

Dr. gene rosenberg

Organization:

associated university urology

Category:

Physician

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

see attachment

CMS-1385-P-15637-Attach-1.TXT

Gene Rosenberg MD 20 Prospect Avenue, Suite 719 Hackensack, New Jersey 07601

Herbert Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid services
Department of Health and Human Services
Attention: CMS-1385-P
Post Office Box 8018
Baltimore, Maryland 21244-8018.
Sunday, September 2nd, 2007

Dear Mr. Kuhn:

I am a urologist who practices in a small group setting. I see a large portion of my patients are Medicare based and many of them have prostate cancer and prostate issues. I am writing to comment on the changes that are been proposed to the physician fee schedules rules. These were published on July 12, 2007, that involved the Stark self-referral rule and the use of purchased diagnostic test rules.

The changes proposed in these rules, will have a significant negative impact on the way my partner and I practice medicine and will not lead to ideal medical practices. We perform a significant number of the ultrasound examinations in our office and consider them an extension and part of the physical examination, for many patients. This allows us to rapidly diagnose bladder tumors, kidney stones as well as kidney tumors and prostate malignancies. With respect to the in-office ancillary services exception, the definition should not be limited in any way. It is equally important for patient care, for urologists to have the ability to provide pathology services in their own offices. We have been seriously consider providing CT scan services for our patients as well, but are not doing so as yet. The provisions of this proposal would certainly impact that decision. Cryosurgical ablation is a commonly utilized modality for treating prostate cancer in our patient population. We find it to be a low morbidity and high efficiency treatment that serves both the patients and Medicare dollars that are being well spent in an efficient cost-effective manner.

The proposed changes in the reassignment and purchased diagnostic test rules, will make it difficult for me to provide ultrasound services as well as the pathology services for the determination of bladder tumors or prostate biopsies. Not being able to provide this service, will result in significant delays and difficulties for this elderly group of patients to obtain transportation and referral to another location and will result in delayed medical care at best.

The proposed "under arrangement "rule, will prohibit the provision of green light laser services since, that are provided to a hospital through a joint-venture, including green

light laser as well as cryosurgical ablation of prostate cancer. These services are not easily obtained for this Medicare population and again would at best delay them and possibly prevent them from occurring in patients who need to arrange transportation and time off from work of loved ones. Both green light laser photo ablation of benign prostate tissue and cryosurgical ablation of prostate cancer, require significant investments that hospitals do not have the resources to bring in new technology like this. The thought of using an outdated technology like transurethral resection or in many cases radiation therapy, will result in higher expenditures for Medicare and needless morbidity in terms of bleeding, transfusion of blood, a hospital stay and subsequent injury to the bladder and rectum of radiated tissues. Without such a joint venture, these services would not be available to the Medicare patients that I serve.

The prohibition of per-click payments for space and equipment rentals will prohibit those ultrasound and pathology Services for our patient population. Prohibiting these arrangements would at best delay their availability and cause significant dislocation to family members who must reschedule work time.

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

Thank you for the opportunity to comment on these federal legislations.

Sincerely,

Gene Rosenberg, MD, FACS

Submitter:

Dr. Michael Migden

Date: 09/02/2007

Organization:

University of Texas - M.D. Anderson Cancer Center

Category:

Physician

Issue Areas/Comments

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Dcar Acting Administrator Kuhn.

I am a fellow-ship-trained Mohs surgeon at the University of Texas M.D. Anderson Cancer Center. As Assistant Professor of Dermatology, my comments are made as a strictly salaried state employee who has no direct financial consequence from the proposed change.

Currently, many of the multiple tumor patients have wait times for their surgical appointment. Please consider that the benefits of effective treatment provided by Mohs surgery also come with the costs of maintaining a surgical unit (including frozen section lab) and staffing it. If reimbursement for the second site does not cover the costs for its treatment, our center will be forced to limit each patient to treatment of one site only. Having an only one site per patient per visit policy forced on us and therefore our patients will produce multiple and significant negative consequences; especially on Medicare patients. I am particularly worried about the following:

- 1) The Medicare patient population is more likely to have logistical transportation difficulty and many already are paying for special trip costs, such as cab fare (locally) or air fare (regionally). If multiple site patients have to make 2 trips for every single trip currently made, the logistics/ costs for many will become be prohibitive.
- 2) These patients wait times will significantly increase. As a result, tumors will grow and reconstruction of larger defects will become more morbid and costly.
- 3) Patient wait times are could become unconscionably long and could as a result, lead to greater incidence of metastatic squamous cell carcinoma. I would be sad to see greater mortality resulting from more skin cancers not treated in a timely fashion.
- 4) If attempting to reduce health care costs is a must, why pursue a policy change that will certainly increase costs? If this change takes place, most Mohs surgical practices will not perform the second procedure the same day at break even or lower reimbursement. With disproportionately more Medicare Mohs patients having greater than one tumor, this means there will be nearly twice as many office visits for those patients to treat the same number of tumors. No savings from the multiple procedure reduction will occur and it should be obvious that facility fees and increased costs related to items two and three above will occur.
- 5) What will solid organ transplant and chronic lymphocytic leukemia patients do if this change is made? It will be place a hardship of epic proportion on these patients to make individual trips to receive treatment of individual tumors. As both populations tend to be Medicare patients, they will be tragically and unfairly singled out and punished for having these underlying conditions.

I am concerned about the future of Mohs surgery. At a time when there had been great effort made to work with CMS to develop new Mohs codes, my colleagues and our residents see two separate actions made on this issue without consulting any of the organizations in our specialty. The mood is that Mohs surgery is under attack. As a result, the idea of pursuing a fellowship is being seen by many of our best residents as potentially a dead end; one that may not have much of a future. Mohs surgery provides skin cancer patients with the highest cure rate and least disfiguring method of treating skin cancer, but without the best and the brightest what future level of care will be provided.

Might you please consider working with the Mohs College, Mohs Society, ASDS, and AAD on issues that impact our patients and our field? The best way to ensure appropriate care and billing of Medicare patients is by working with these organizations to make sure that only adequately trained Mohs surgeons processing tissue in CLIA certified laboratories perform this procedure when indicated.

Michael Migden, MD Assistant Professor of Dermatology UT - MD Anderson Cancer Center

Submitter:

Mr. Todd Rodriguez

Organization:

Fox Rothschild LLP

Category:

Attorney/Law Firm

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See Attached Letter

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

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

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

Submitter:

Mr. Todd Rodriguez

Organization:

Fox Rothschild LLP

Category:

Attorney/Law Firm

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See attached letter.

CMS-1385-P-15640-Attach-1.TXT

CMS-1385-P-15640-Attach-2.TXT

Page 20 of 71

September 07 2007 11:29 AM



Eagleview Corporate Center 760 Constitution Drive, Suite 104 P.O. Box 673 Exton, PA 19341-0673 Tel 610.458.7500 Fax 610.458.7337 www.foxrethschild.com

Todd A. Rodriguez

Direct Dial: (610) 458-4978

Email Address: trodriguez@foxrothschild.com

August 30, 2007

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

Re: CMS-1385-P-Request for Comments/Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies - Revisions to Payment Policies for Ambulance Services for CY 2008

Dear Mr. Kuhn:

I am a licensed attorney. In my practice, I represent physicians in virtually all specialties and practice settings. On behalf of those physicians, I would like to submit these comments on the proposed changes to the Medicare Physician Fee Schedule Rules published in the Federal Register on July 12, 2007. In particular, these comments relate to (1) the request for comments on revisions to the Stark in-office ancillary services exception; and (2) the proposed revision to the definition of the term "entity" under the Stark rule.

A. <u>In-Office Ancillary Services Exception</u>.

At page 38181 of the Federal Register, CMS discusses potentially abusive arrangements and requests comments on, among other things, the following:

(1) Whether non-specialist physicians should be able to use the in-office ancillary services exception to refer patients for specialized services involving the use of equipment owned by the non-specialist; and

EX1 167720v1 09/03/07

A Pennsylvania Limited Liability Partnership

(2) Whether and, if so, how CMS should make changes to the definitions of "same building" and "centralized building."

Allow me initially to address the comment first made by CMS in the CY 2007 PFS Proposed Rule (71 FR 48982) and then reiterated in the July 12, 2007 proposed rule relating to referrals by group practice physicians to specialist physicians. Specifically, at page 38181 of the proposed rule, CMS states the following:

"... we stated our intent to address certain types of potentially abusive arrangements in which group practice physicians make a referral for a DHS to a specialist who is an independent contractor of the group practice. The specialist then performs the service for the group practice in a centralized building and reassigns his or her right to Medicare payment to the group (which then bills Medicare at a profit)."

I do not believe that any change to the in-office ancillary services exception with regard to such arrangements is warranted since adequate protections against abuse are already present. To modify the in-office ancillary services exception to address these "perceived" abusive arrangements would potentially implicate perfectly legitimate multi-specialty group practices.

It is beyond question that multi-specialty group practices have the potential to significantly increase patient convenience, enhance quality of care through the sharing of clinical information and the development of clinical protocols among physicians in differing specialties, decrease utilization and potentially reduce overall costs of patient care since care can be provided in a much more controlled environment. Physicians in a multi-specialty practice have the ability to oversee and direct DHS provided within the group practice, including the ability to select the type of equipment purchased and ultimately used and the technical staff used in performing the services.

The above comment by CMS suggests that referrals by a group practice physician to a specialist who is an independent contractor of the group practice are somehow more likely to be abusive than referrals by the same group practice physician to a specialist who is an employee of the group practice. I would submit to you, however, that the referring physician would be no more or less likely to refer to the specialist physician whether that physician is an independent contractor or an employee of the group practice. Moreover, I believe there are already sufficient controls in place to ensure against abuse in connection with the independent contractor relationship. Specifically, (1) the Medicare program will be aware of the relationship between the independent contractor and the group practice by virtue of the properly filed reassignment, and (2) the independent contractor relationship must still conform to the personal services exception under the Stark regulations. With these controls in place, the scenario described by CMS in the proposed rule is no different from referrals by a group practice physician to

another group practice physician of a different specialty within a multi-specialty clinic. If you were to revise the in-office ancillary services exception to preclude physicians of one specialty (which might include primary care physicians) from referring to a physician of another specialty within the same practice (whether a W-2 employee or an independent contractor who meets the personal services exception), you would create no further protections against abuse than already exist but would likely eliminate many of the quality-enhancing and cost-saving aspects of a multi-specialty setting.

Turning now to the definitions of "same building" and "centralized building," I believe that any revision to the existing definitions will merely serve to further confuse what are already overly complex definitions and would likely result in an increase in the cost of the delivery of health care. For example, requiring a minimum number of square feet or that equipment not be mobile, as suggested in the CY 2007 proposed rule, might address CMS's specific concerns with pod laboratory arrangements but would also likely eliminate a whole spectrum of legitimate, cost effective delivery mechanisms and ultimately, patients will suffer. At a time when the cost of health care is skyrocketing, CMS should be encouraging physicians and other providers to establish arrangements which offer the best care in the most cost effective setting. To shackle physicians by imposing arbitrary technical rules on the specific space where services will be provided and the equipment used to provide those services would result in an unprecedented level of regulatory micromanagement of the practice of medicine.

B. Services Furnished "Under Arrangements" and Revision to the Definition of "Entity."

Allow me to now comment on the proposed revision to the definition of the term "entity" as well as the MedPAC proposal set forth at page 38187 of the Federal Register. I do not believe that the term "entity" should be revised as proposed or that the MedPAC proposal should be adopted, as there are adequate controls in place to prevent against the perceived abuses noted by CMS.

With regard to the MedPAC proposal, it must be noted that for any entity to provide DHS, that entity must by necessity acquire goods and services from third parties. For example, an imaging center must necessarily acquire space (by lease or purchase) in which to house the testing equipment, purchase or lease the testing equipment itself, purchase necessary clinical supplies, and in some cases, lease technical staff to provide the diagnostic services. These items and services are obtained by the third parties at a cost for which they seek to be reimbursed by the DHS entity.

The MedPAC comment would appear to want to prevent a referring physician from supplying the necessary items and services to a DHS entity on the theory that "arrangements so structured are particularly problematic because referrals by physician-owners of leasing, staffing, and similar entities to a contracting DHS entity can significantly increase the physician-owned entity's profits and investor returns, creating incentives for over-utilization and corrupting medical decision-making." (72 FR 38122

at 38187, 7/12/07) This, however, is only the case where the payment by the DHS entity back to the physician or physician-owned entity is based on the volume or value of the physician's referrals to the DHS entity. Where per-click/per-unit of service payments are eliminated as proposed in the Fee Schedule, payments by the DHS entity to the physician-owned entity supplying items and services will have to be fixed in advance and could not vary, regardless of how many referrals the physician-owner makes to the DHS entity. Even if the proposal to eliminate per-click compensation arrangements is not adopted, payments to the physician-owned entity by the DHS entity are limited by both Stark and the anti-kickback statute to fair market value, which means that in any case the most the physician-owned entity could make in return for providing items and services to the DHS entity would be a return of its costs plus a reasonable rate of return on its investment in providing those items and services. Accordingly, the lease and personal services exceptions in their current form provide adequate protections against the likelihood of the abuses raised by CMS and MedPAC in the proposed rule.

The above analysis would also apply to CMS's proposal to revise the definition of the term "entity." Any profit a referring physician could make through his ownership of the entity that provides the DHS to an entity that bills for the DHS would be limited to fair market value under the current exceptions, as well as the anti-kickback statute.

In addition, your proposal to revise the definition of "entity" would eliminate what is currently a brightline test – that is – the DHS entity is the entity that submits the claim. Your proposal will require physicians to evaluate whether an entity other than the billing entity is actually "providing" the DHS. What if the entity is merely providing a component of the DHS, such as the technical staff, equipment, or even real estate on or in which the DHS is performed? In light of the existing protections against abuse which are more than adequate, I see no need to sacrifice the existing brightline test.

* * * *

Thank you for considering these comments and if I can provide any further clarification please feel free to contact me directly.

Sincerely yours,

Todd A. Rodriguez

TAR:jlh

Submitter:

Dr. Douglas Diehl

Organization:

Dr. Douglas Diehl

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslic 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. Alan Farrow-Gillespie

Organization:

Anesthesiologists for Children

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. As a practicing ancesthesiologist and an academic physician engaged in teaching our future doctors, 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.

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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. Susan Wilcox

Organization:

Albermarle Anesthesia PLC

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

Thankyou for your attention to this important subject

Submitter:

Dr. Richard Liniger

Organization:

Palo Alto Medical Foundation

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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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.

Richard Liniger, MD

Submitter:

Dr. Gerard Dang

Date: 09/03/2007

Organization:

Medical Anesthesia Consultants Medical Group, 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:

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Thank you for your consideration of this serious matter.

Submitter:

Dr. Rana Latif

Organization: Univer-

University of Louisville, KY

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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Submitter:

Dr. ELIOT HUDES

Organization:

Dr. ELIOT HUDES

Category:

Chiropractor

Issue Areas/Comments

GENERAL

GENERAL

REIMBURSEMENT FOR RADIOLOGY SERVICES ORDERED BY A CHIROPRACTOR SHOULD NOT BE ABOLISHED AS IT WOULD DRIVE UP THE COST OF HEALTHCARE. IN AN AGE OF COST CONTAINMENT THIS WOULD BE COUNTERPRODUCTIVE TO THAT MEANS AND WOULD ALSO BE DISCRIMINATORY IN NOT ALLOWING A CHIROPRACTOR TO ORDER THE SERVICE BUT WOULD ALLOW THE MD TO DETERMINE THE NECESSITY OF THE SERVICE AND YET PLACE THE LIABILITY ON THE CHIROPRACTOR IF TREATMENT IS RENDERED.

Submitter:

Mr. Michael Douglas

Organization:

National Basketball Assosciation

Category:

Health Care Provider/Association

Issue Areas/Comments

Background

Background

Dear Sir or Madam:

My name is Mike Douglas 1 am a Certified Athletic Trainer by the National Athletic Trainers Association. I am the Head athletic Trainer for the Houston Comets of the WNBA

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 cducation, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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

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

Sincerely,

Michael T, Douglas M.S., ATC NASM PES

CMS_1385_P_15649

Submitter:

Mr. Eric Taylor

Date: 09/03/2007

Organization:

Joint School District No.2 Meridian, ID

Category:

Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am an Idaho State Licensed Athletic Trainer and certified to provide athletic training services through the National Athletic Trainers' Association Board of Certification. I received my baccalaureate degree in education from the University of Idaho in 1992. I received both my master's degree in exercise and sport studies and health occupations specialist certificate in profession technical education, in 2000, from Boise State University and University of Idaho, respectively. I have practiced as an athletic trainer at Centennial High School, in the State of Idaho, since 1992. I have served on multiple state athletic training committees, as well as local school district committees over the past 15 years.

1 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.

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Sincerely,

Eric A. Taylor, MS, LAT, ATC
Teacher/Head Licensed Athletic Trainer
Centennial High School
12400 W McMillan
Boisc, ID 83713-1444
(208)855-4250 Ext 1540
taylor.cric@meridianschools.org

Submitter:

Dr. Paul Hejja

Organization:

Anesthesiologist

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.

Respectfully submitted

Paul Hejja MD FRCPC

Submitter:

Mr. Lee Miller

Organization:

Mr. Lee Miller

Category:

Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions September 1, 2007

Re: Physician self referral issues

Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule

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

I urge you to eliminate physical therapy from those in-office ancillary services that physicians are able to own and bill CMS. I have been a practicing physical therapist for 29 years, including working for a physician for a brief period, and left there when I found the practice promoted over utilization.

The chief reason that physician owned physical therapy services cost CMS millions dollars of unnecessary services. Unlike other in-office ancillary services, physical therapists are able to provide their service without any oversight or supervision of the referring physician. Therefore, the profit that physicians obtain from owing the service is an unearned fee, which essentially amounts to fee splitting. Conceptually, it is universally accepted that fee splitting results in over utilization of a service and therefore fee splitting statues exist in both federal regulation and virtually every state law that prohibit such behaviors. Proof that physician owned physical therapy resulting in 66% higher utilization was revealed in a 1988 study on Blue Cross and Blue Shield data.

It s time to close this loophole in CMS regulations so CMS dollars can be spent more wisely!

Lee Miller, PT, OCS 20 Crossroads Drive Suite 13 Owings Mills, MD 21117

Submitter:

Mr. Jon Davison

Organization:

Mr. Jon Davison

Category:

Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

Please include Physical Therapy to the restricted areas of Physician Self Referral. In Arizona, we have seen an influx of physician owned physical therapy clinics. It is an assault to autonomous practice and to the patient/client. The patient client should always have the right to choose where to recieve therapy services. Let the autonomous clinics compete amongst each other in the free market and not against a clinic that pads the pocket of the referring physician.

Jon

Submitter:

Mr. Matt Larson

Date: 09/04/2007

Organization:

St. Mary's Duluth Clinic

Category:

Health Care Professional or Association

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Athletic Trainers have been working with CMS for the last few years to ensure that Athletic Trainers are able to work with physicians as they deam appropriate. If a physician feels a patient is best suited to see an athletic trainer, occupational therapist, or physical therapist to receive physical medicine. We request that the government allows the MD to make that decision as he/she is the best individual to make that recommendation for that individual patient. Thank you,

Matt Larson ATC, CSCS, CSHE St. Mary's Duluth Clinic Duluth, MN (218) 786-8372

Submitter:

Dr. Alan Lewis

Organization:

Dr. Alan Lewis

Category:

Physician

Issue Areas/Comments

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

This correspondence is prompted by the proposed reversal of an existing policy by the Centers for Medicare and Medicaid Services (CMS). The current policy holds that multiple procedures performed as part of a skin cancer removal procedure known as Mohs' Surgery are paid at CMS determined rates without reduction in the reimbursement for the subsequent parts of the removal and the requisite repair of the cancer site. CMS is considering rescinding this policy and decreasing the payment for the reconstruction of cancer sites. We, as the Mohs' surgeons in the state of Louisiana, request that you consider opposing this unwarranted policy change by CMS.

Mohs' surgery is a procedure which has been shown to be cost effective versus other methods in the treatment of skin malignancy. It is performed by specialized physicians, who receive one to two years of additional training to master this procedure. Mohs is performed with the same physician acting as surgeon and pathologist, which streamlines the overall process, compared to other methods. It has been shown to provide unparalleled cure rates of over 99%, while being cost effective versus other methods available. It has also been shown to markedly reduce the incidence of recurrent cancers, which can prove to be dramatically more expensive and dangerous for the patient. It also reduces the overall size of skin cancer removal, resulting in less complex and costly repairs. A typical Mohs surgery case will involve removal of a malignancy and reconstruction in one convenient visit for the patient. Mohs' surgery is done under local anesthesia, thus avoiding the increased risk and cost associated with hospitalization and general anesthesia.

The inappropriate change proposed would impact the quality of skin cancer treatment in Louisiana in a number of ways. First, this policy change is expected to reduce the availability of this cost effective procedure. It would discourage the spread of this procedure in areas that are already medically underserved. Second, the change would alter utilization patterns for this procedure and in effect may increase overall expenditures for removal of a given skin cancer. It would encourage the de-streamlining of this procedure, which is the appeal of the Mohs process. It would lead to increases in pathology charges and increase the amount spent on multiple facility fees, thereby raising the overall cost of treating an individual skin cancer. In other terms, CMS proposes to reduce payment for the second part of the procedure, but this would ultimately lead to increased cost. Third, the inconvenience of multiple visits and requiring the involvement of multiple physicians is unnecessary for our aging population. As we all know, inconvenience leads to delays which would adversely affect overall health outcomes, which eventually leads to increased expenditures. Since skin cancer is dangerous, disfiguring and possibly fatal, the proposed policy change by CMS has the potential to increase the death rate from skin cancer.

As mentioned, Mohs' surgery involves the preparation and interpretation of microscopic slides which has been reimbursed in full since CMS evaluated this procedure many years ago. The procedure STILL involves this pathologic study, yet the radical changes proposed by CMS will now devalue these vital codes and the superior work performed by Mohs' surgeons. We feel CMS is targeting these codes due to their increased utilization. However, they are failing to account for the reduction in overall utilization of other services and the ultimate cost savings that these procedures are responsible for.

CMS-I385-P-15654-Attach-I.PDF

Mohs micrographic surgery: A cost analysis

Joel Cook, MD,^a and John A. Zitelli, MD^b Charleston, South Carolina, and Pittsburgh, Pennsylvania

Background: The incidence of skin cancer is increasing significantly, and many people have declared the increase an epidemic. It was estimated that 900,000 to 1.2 million cases of nonmelanoma skin cancer occurred in the United States in 1994. With increasing pressure to deliver cost-effective medical care, physicians must understand the cost and value of the various methods to treat skin cancer.

Objective: Our purpose was to define the true cost of treating a series of skin cancers with the Mohs micrographic technique and compare our costs with calculated estimates of the costs to treat the same cancers with traditional methods of surgical excision.

Methods: A group of 400 consecutive tumors was selected. The cost of treatment in the reference group included diagnosis, Mohs micrographic surgery, reconstruction (if applicable), follow-up, and the cost to treat disease recurrence. These costs were then compared with traditional methods of surgical excision: excision with permanent section margin control, excision with frozen section margin control, and excision with frozen section margin control in an ambulatory surgical facility. For cost comparisons, it was assumed that all tumors in the comparison groups would be excised with standard surgical margins and the resultant surgical defects would be reconstructed with the simplest method possible. The costs of diagnosis, excision, pathology, reconstruction, and the cost to treat disease recurrence were then calculated and compared with the costs of treating the lesions with Mohs micrographic surgery.

Results: Our calculation of costs documents that Mohs micrographic surgery is similar in cost to office-based traditional surgical excision and less expensive than ambulatory surgical facility-based surgical excision. The average cost of Mohs micrographic surgery was \$1243 versus \$1167 for excision with permanent section margin control, \$1400 for excision in the office with frozen section margin control, and \$1973 for excision with frozen section margin control in an ambulatory surgical facility. Analysis based on anatomic location yielded similar results.

Conclusion: Mohs micrographic surgery is a method of surgical excision with high intrinsic value that is cost-effective in comparison to traditional surgical excision. (J Am Acad Dermatol 1998;39:698-703.)

It was estimated that 900,000 to 1.2 million cases of nonmelanoma skin cancer occurred in the United States in 1994.1 The average annual increase in the incidence of basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) is 3% to 8%, and this increase has led many to declare this problem an epidemic.^{2,3} Cost-effective treatment of skin cancers is an important issue. With increasing pressure to deliver medical care with great attention to cost, physicians are now forced to balance therapeutic efficacy with treatment expenditures. Skin cancers can be treated by many methods such as electrodesiccation and curettage, cryotherapy, surgical excision, Mohs micrographic surgery, radiation therapy, and photodynamic therapy. In some medical settings in which cost has little influence on the choice of treatment, up to one third of cutaneous cancers are treated with Mohs micrographic surgery.4 Regardless of the therapeutic modality selected, the common goal is to provide appropriate treatment with high cure rates, good functional and cosmetic results, and minimal morbidity in a cost-effective manner.

Mohs micrographic surgery has been recognized to provide the highest cure rates for both primary and recurrent cutaneous malignancies of various types.⁵⁻¹² In addition, the more narrow

From the Department of Dermatology, Medical University of South Carolina,a and the University of Pittsburgh Medical Center.b Accepted for publication July 20, 1998.

Reprint requests: Joel Cook, MD, Department of Dermatology, Medical University of South Carolina, 171 Ashley Ave, Charleston, SC 29425. E-mail: cookjw@musc.cdu

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0190-9622/98/\$5.00 + 0 16/1/93162

Table I. Patient characteristics

•400 tumors

•311 patients: 175 male, 136 female •Average age: 64.95 y (range, 28-91 y)

excisional margins of Mohs micrographic surgery have the advantage of tissue conservation. Despite these advantages, many investigators have questioned the use of the Mohs technique by suggesting that the expense of Mohs micrographic surgery limits its utility. 1,13-16 We believe that Mohs micrographic surgery is a cost-effective treatment modality; therefore we sought to design a method by which to compare the costs of treating skin cancers by different methods of surgical excision.

METHODS

Four hundred consecutive patients referred for treatment of skin cancer to the office of one of us (J. A. Z.) were included in the study (Table I). No patients referred during the time of the study were excluded. All tumors had histologic conformation before any procedure (Table II). A routine history and directed physical examination were completed before the procedure. The clinically apparent margins of all tumors were then outlined. Initially, we planned the procedure as if traditional (non-Mohs) surgical excision with standard surgical margins* were performed. A reconstructive plan based on the envisioned surgical defect was then recorded. In the comparison groups, it was assumed that all surgical defects would be reconstructed. The simplest method of reconstruction that would provide predictably good aesthetic and functional results was selected (Table III). After a presumed non-Mohs excision was planned, the tumor was then excised by means of the Mohs technique and repaired, if appropriate (Table III). The number of surgical stages and any subsequent repair were recorded (Table IV).

We examined costs for traditional surgical excision in various settings: (1) excision in the office with permanent section margin control, (2) excision in the office with frozen section control, and (3) excision in an ambulatory surgical facility (ASF) with frozen section control. Costs were then calculated for the comparison groups and compared with the actual costs involved in treating the tumors with Mohs micrographic surgery (Fig 1).

Table II. Tumor characteristics, anatomic locations, and size

Tumor characteristics (No.) Primary (337); recurrent (63) Basal cell carcinoma (306) Squamous cell carcinoma (64) Malignant melanoma (21) Extramammary Paget's disease (2) Atypical fibroxanthoma (1) Malignant granular cell tumor (1) Sebaceous epithelioma (1) Leiomyosarcoma (1) Eccrine carcinoma (1) Dermatofibrosarcoma protuberans (1) Undifferentiated carcinoma (1) Anatomic locations and size Head and neck (346); range, 0.4-5.1 cm Torso (32); range, 0.6-5.3 cm Extremities and external genitalia (22); range, 0.6-12.0 cm

Costs calculated for each patient included the following: initial evaluation (99203), a skin biopsy (11100), permanent section pathology for diagnosis (88305), the cost of 5 years of follow-up that are not included in the global postoperative period (99213), and the cost of treating projected tumor recurrences. In the non-Mohs or traditional surgery group, cost analysis also included surgical excision (when not bundled with reconstruction) (11600-11646) and the appropriate repair (12000, 13000, 14000, and 15000 series). For tumors treated by office excision and permanent section control of the margins, we predicted that 11% would have positive surgical margins based on a study of the frequency of positive margins in excised specimens.²¹ We then assumed that all margin-positive excisions would require re-excision. Re-excision would include the entire scar or graft with a similar, albeit larger, repair. The cost of re-excision and reconstruction including pathology charges was factored into the cost calculations. However, tumors that would require flap closure, pedicled flaps, or multiply staged reconstructions were excluded from this group because we thought that few physicians would attempt complicated or staged reconstructions without prior confirmation of negative surgical margins. The calculated cost of office excision with frozen section control or ASF excision with frozen section control assumed that 21% of patients would have at least one positive margin requiring a limited re-excision before repair. This is based on Cataldo's study that demonstrated that the average skin cancer excisional case using frozen section control required 1.21 stages during the same operative session to obtain negative surgical margins.¹⁷ When using

^{*}Standard surgical margins are defined as follows: 4 mm for BCC, 4 to 6 mm for SCC, 2.0 cm for dermatofibrosarcoma protuberans, 0.5 to 2.0 cm for malignant melanoma, and 6 mm for other tumor typcs.17-20

Other* (3) (0.75%)

Table III. Proposed repairs after traditional excision and actual repairs after Mohs micrographic surgery

Proposed repairs after traditional excision (No.)
Second-intention healing (0)
Primary closure (143) (35.75%)
Local flap (119) (29.75%)
Full- or partial-thickness skin graft (128) (32.0%)
Two-staged pedicle flap (5) (1.25%)
Other* (5) (1.25%)
Actual repairs after Mohs micrographic surgery (No.)

Actual repairs after Mohs micrographic surgery (No.) Second-intention healing (157) (39.25%) Primary closure (149) (37.25%) Local flap (40) (10.0%) Full- or partial-thickness skin graft (51) (12.75%) Two-staged pedicle flap (0)

frozen section margin control we assumed that the margins would be confirmed by permanent sections and that the permanent sections would always show clear margins.

An allowance for tumor recurrence is also important in the calculation of the costs involved in treating skin cancers. In the group of traditional surgical excision, we presumed a 10.1% tumor recurrence rate based on a previously published work.⁵ The recurrent tumors would be treated with Mohs micrographic surgery and the cost to treat the recurrent tumors would equal the actual average cost of the Mohs cases in this study. We predicted a recurrence rate of 1.0% in the cases treated with Mohs micrographic surgery.⁵ We calculated that these recurrent tumors would be treated with Mohs micrographic surgery. The cost to treat the recurrences after Mohs surgery would equal the average cost of the Mohs procedures presented in this series.

The calculated costs of the procedure in the ASF were identical to the office costs with the addition of costs for facility charges based on the procedures performed, adjustments of reimbursement for site of service, differential of practice expense costs, and costs of admission laboratory work and radiographs (prothrombin time/partial thromboplastin time, complete blood cell count, sequential multiple analysis—8, chest roentgenography, electrocardiography).

The costs of Mohs micrographic surgery were calculated from the actual costs of the procedure for each patient in this series in an office setting. We did not include infrequently incurred costs of additional consultation, anesthesia charges, or immunopathology for any procedures. All reimbursement rates were based on 1996 RBRVS values for Western Pennsylvania.

Table IV. Number of Mohs micrographic surgery stages to reach a tumor-free plane*

Stage	No. of patients (N = 400) (%)
1	268 (67.0)
2	90 (22.5)
. 3	16 (4.0)
4	14 (3.5)
≥5	12 (3.0)

^{*}Average number of stages, 1.55; range, 1-7 stages.

RESULTS

Our calculation of costs documents that Mohs micrographic surgery is similar in cost to officebased surgery and less expensive than ASF-based excision of skin cancer (Table V). Mohs micrographic surgery was 7% more expensive than office excision with permanent sections but 11% less expensive than office excision using frozen sections. Mohs surgery is significantly less expensive than ASF-based surgical excision. In addition, our results show that by anatomic location, Mohs surgery is cost effective as well (Table VI). On the head and neck, Mohs micrographic surgery is 6% more expensive than office excision with permanent sections and 12% and 27% less expensive, respectively, than office excision with frozen sections and ASF excision. On the trunk, the cost of Mohs surgery also falls between office surgery with permanent section control and office surgery with frozen section control. However, on the extremities and genitalia Mohs micrographic surgery is the least expensive choice of excision.

DISCUSSION

This study calculating the actual costs of excising 400 skin cancers documents that Mohs micrographic surgery is cost effective on all body locations compared with other methods of surgical excision. At first this may seem surprising because the codes for Mohs surgery (17304-17310) are reimbursed significantly higher than the codes for routine excision (11600-11646). However, there are many reasons that the calculated costs are reasonable. First, the code for Mohs surgery includes reimbursement both for excision and pathology (microscopic evaluation of the surgical margins). For routine excision, these fees are unbundled and paid separately. When the costs of excision and pathology are rebundled, the total costs of treating

^{*}Multiple staged procedures or single-staged complex reconstructions (eg, multiple flaps, cartilage grafting).

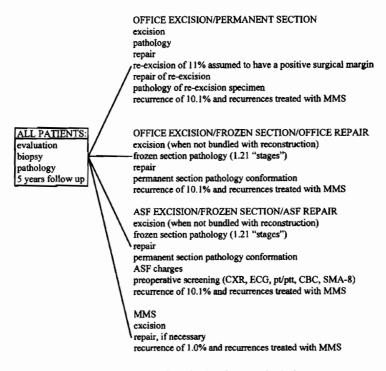


Fig 1. Summary of methods of cost calculations.

Table V. Calculated costs of treating skin cancers

Method	Cost (\$)	Range (\$)
Destruction*	652	NA
Office excision/permanent sections	1167	809-1599
Mohs micrographic surgery	1243	836-2940
Office excision/frozen sections	1400	864-3384
Ambulatory surgical facility excision/frozen sections	1973	1367-5169
Radiation therapy*	4558	NA

NA, Not available.

skin cancers with the Mohs technique is comparable to other forms of office-based excision.

The more narrow surgical margins of Mohs micrographic surgery (when compared with traditional surgical excision) often result in smaller surgical defects. With these smaller wounds, more simple and economical reconstructions may be possible. Moreover, important anatomic structures may be preserved. Previously published studies have demonstrated the presence of larger surgical defects after conventional surgical excision when compared with Mohs micrographic surgery. Bumstead and Ceilley²² found that conventional

surgery removed 180% more tissue than Mohs surgery in primary skin cancers and 347% more tissue than Mohs surgery in recurrent tumors. Dowes et al found that Mohs surgery frequently preserved important anatomic structures and subsequent reconstructions were often less complicated or less extensive than the reconstructions envisioned before Mohs surgery.²³ We found a similar result in our group; many tumors that we predicted to require complex flap or skin graft reconstruction after traditional excision were able to be closed in a more simple manner or allowed to heal by second intention after Mohs surgery. This obvi-

^{*}Calculated cost to treat a 1.5-cm facial tumor.

Table VI. Calculated cost of excision of skin cancer by location

Method	Head/neck (\$)	Trunk (\$)	Extremities/genitalia (\$)
Office excision/permanent sections	1201	905	1125
Mohs micrographic surgery .	1278	964	993
Office excision/frozen sections	1438	1117	1136
Ambulatory surgical facility excision/frozen sections	2012	1694	1620

ously has positive economic implications. Flaps or grafts were almost 3 times more likely after routine excision than after Mohs surgery. A significant portion (39%) of our wounds were allowed to heal by second intention, thereby avoiding the entire expense of reconstruction. This ability to conserve tissue and prevent recurrence is not apparent when examining the reimbursement of one code but is a factor in the true cost of treating skin cancer. The higher cure rates of Mohs surgery reduce the overall 5-year cost of treating skin cancer because only 1% of cases require retreatment compared with approximately 10% of cases treated by routine surgical excision.⁵

Although this study calculated costs to compare the cost-effectiveness of various excisional techniques, other factors are also important when comparing value. Value of medical services is an interaction of quality and cost. Quality of a medical procedure is determined by measuring many variables, for instance, the morbidity of the surgical procedure and tumor recurrence rates.²⁴ Mohs micrographic surgery has many advantages that add to its value. When compared with other forms of excision, the smaller wounds noted above not only decrease costs but often provide better cosmetic and functional results. The higher cure rates provide a sense of patient and physician security and obviate the inconvenience and morbidity of repeated surgical procedures. The frozen section laboratory of the Mohs surgery unit allows the diagnostic biopsy and the Mohs surgery to be performed on the same day, thereby reducing the inconvenience of multiple visits, care of a biopsy wound, and the occasional difficulty of finding a healed biopsy site or determining clinical margins in an inflamed biopsy site. Although the operating time of Mohs micrographic surgery is often considered a disadvantage, the average time in the office for the patients in the study was less than 5 hours. These factors are additional important considerations of value.

We recognize that this study has relied on many assumptions to derive the cost calculations. These assumptions were based on current surgical standards across the United States. We believe this represents a fair analysis of the true cost of treating skin cancers with Mohs micrographic surgery versus conventional surgical excision. In some hands, the actual costs of Mohs surgery may vary according to the skill of the surgeon and the laboratory, the decision to repair or use second-intention healing, and the complexity of tumors in the patients referred for treatment.

We did not calculate the costs of destruction or radiation therapy in this study because these techniques were not applicable to the cases referred for Mohs surgery. However, estimates of these treatment costs similar to the methods in this study for a 1.5-cm facial cancer are included in Tables V and VI. Destructive techniques are usually the least expensive treatment option, and radiation therapy is generally the most expensive method to treat cutaneous cancers. Destructive therapy is commonly used in the treatment of smaller skin cancers. Many features limit its use, such as location, histologic type of tumor, presence of scarring or recurrence, ability to detect clinical margins, and predicted cosmetic and functional results. Radiation therapy is not only expensive, but also inconvenient because of the need for multiple visits (often 10 to 20 treatment sessions). Although it obviously eliminates the need for surgery, the cure rate is no better than traditional excisional surgery.

The decision to use any method for treating skin cancer is usually based on a variety of factors including cure rate, predicted functional and cosmetic results, cost, convenience, and availability. This study provides a factual basis to consider cost and value in the decision-making process. Mohs micrographic surgery is not a costly procedure, nor should its use be limited to high-risk tumors on the central portion of the face. It should be considered a cost-effective treatment with high intrinsic value

that compares favorably with traditional surgical excision. Patients, referring physicians, third-party payors, and managed care organizations responsible for decision making regarding the surgical management of skin cancers should understand these cost and value comparisons.

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Bound volumes of the Journal of the American Academy of Dermatology are available to subscribers (only) for the 1998 issues from the Publisher at a cost of \$112.00 for domestic, \$139.10 for Canadian, and \$130.00 for international for volume 38 (January-June) and volume 39 (July-December). Shipping charges are included. Each bound volume contains a subject and author index and all advertising is removed. Copies are shipped within 60 days after publication of the last issue in the volume. The binding is durable buckram with the journal name, volume number, and year stamped in gold on the spine. Payment must accompany all orders. Contact Mosby, Inc., Periodical Subscription Services, 11830 Westline Industrial Dr., St. Louis, MO 63146-3318. USA: phone (800) 453-4351; (314) 453-4351.

Subscriptions must be in force to qualify. Bound volumes are not available in place of a regular journal subscription.

Submitter:

Mr. James E. Everett

Organization: Wake County Public Schools

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am an Athletic Trainer at Green Hope High School in Cary NC.

l 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,

James E. Everctt, LAT, ATC

Submitter:

Organization:

Dr. Kabel Morgan

Anesthesia Consultants of Knoxville

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dcar Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Submitter:

Mr. Robert Kilpatrick

Organization:

Blue Ridge Healthcare System

Category:

Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I do not think that physicians should have the right to refer patients to their own physical therapy practice as it is a monopoly to other PT practices in the area who do not have their own Physicians. Just as MDs do not own their own pharmacies, they should not control their own PT practice. They should be at least telling their patients now that they don't have to use their PT practice, but that rarely happens. The physicians may argue that they train their employee PTs to treat the patients the way they want, but so could the Pts in other clinics be so instructed. Basically, this is a money making monopoly for orthopedic and neurologic physicians who use physical therapy services a lot for treatment of their patients.

Submitter:

Dr. Chris Thu

Date: 09/04/2007

Organization:

Capitol Anesthesiology Association

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

A change on Medicare reimbursement not only makes things more fair and equitable, but also insures that anesthesia groups like ours remain competitive in a tightening market. This will insure that all Medicare patients have access to quality anesthesia care in the future.

Submitter:

Mr. Jason Moyns

Organization:

Mr. Jason Moyns

Category:

Other Health Care Professional

Issue Areas/Comments

Background

Background

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,

Jason Moyns, SRNA 1524 Scott Ave, #441 Charlotte, NC 28203

Submitter:

Mr. Don Marcus

San Benito County

Organization:
Category:

Local Government

Issue Areas/Comments

GENERAL

GENERAL

Subject: Department of Health Services 42 CFR Parts 409, 410 et al Proposed Revisions to Payment Policies under the Physician Fee Schedule.

San Benito County California is a regional neighbor and shares jurisdictional boarders with the counties of Monterey and Santa Cruz. As such, we share many regional health care physicians and practices. Medicare physician fees in our geographic region are in dire need of adjustment to recognize the high cost of providing services here. It is our belief that Option 3-revision to payment localities of the proposed rule is the most equitable and best option for California, but its calculation is faulty. If properly computed San Benito would qualify to be moved into the same locality as Monterey. The data that should be used to correctly calculate adjustments is the information unearthed by the General Accounting Office in its June Report. Please review this data and it will be apparent that our needs in San Benito County are equally significant to our neighbor counties.

Sincerely,

Don Marcus

San Benito County Board of Supervisor, District 1

Submitter : Organization : Ms. Anthony DAngelo

Professional Orthopedic and Sports PT

Category:

Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

If an athletic trainer is qualified to administer rehabilitation in school setting and perform life saving aide on field why are they not qualified to assist in a clinical setting?

Submitter:

Dr. Eric Skolnick

Organization:

Dr. Eric Skolnick

Category:

Physician

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

I am writing to express my support for the proposed change to Medicare payments to anestheiologists. Anesthesiology work has long been undervalued and so I agree that it is time to upwardly adjust the payments as proposed. This will increase the availability of expert care by anesthesiologists for Medicare recipients.

Submitter:

Michelle Kania

Organization:

AthletiCo LTD

Category:

Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Michelle Kania and I work as an athletic trainer for AthletiCo LTD in River Grove, IL. My educational background includes a Bachleor's of Science degree in Kinesiology from the University of Illinois at Chicago and a Master's of Science also in Kinesiology from the University of Wisconsin-Milwaukee. After five years working as an athletic trainer in the collegiate setting, I moved to a clinic-outreach position at AthletiCo. As an employee at AthletiCo I am contracted to work at a local high school and college where I perform injury prevention, injury evaluation/assessment, injury rehabilitation, and communicate with coaches, athletes, parents, and doctors regarding medical care for the athletes I work with. In the clinic, I am only able to assist physical therapists with their patients.

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. Kania, MS, ATC

Submitter:

Dr. Steven Jacobs

Organization:

Dr. Steven Jacobs

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1385-P

I am writing to strongly support the proposed increase in payments for anesthesiology services under the 2008 Physician Fee Schedule.

As someone who's been on board since the RBRVS was instituted I have been painfully aware of how undervalued anesthesiology services have been. The result is that it is increasing difficult for Medicare patients to secure these services, given the gross disparity between reimbursement for these services compared to both other physician services and to their reimbursement in the private sector.

The work value for anesthesiology services is simply way too low.

I appreciate greatly that the RUC has recommended a \$4 increase in the conversion factor. This is not only fair to anesthesiologists, but more importantly will ensure that our patients have access to such important care.

Again, thank you.

--Steven S. Jacobs, M.D.

Submitter:

Dr. Angelina Bhandari

Organization:

Rush University Medicla Center

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-15665-Attach-1.PDF

CMS-1385-P-15665-Attach-2.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 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 Yours,
Angelina Bhandari, MD
Assistant Professor

Rush University

Deleted: ,MD

Deleted: Assisstant

Submitter:

Mrs. Toni Miller

Organization:

Baptist Sports Medicine

Category:

Other Practitioner

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am an occupational therapist in middle Tennessee and have seen a significant decline in occupational and physical therapy referrals in recent years as physicians have been allowed to own physical/occupational therapy practices and refer their patients to their own therapy clinics. I feel that allowing physicians to refer patients to their own clinics for therapy services is a conflict of interest due to the physicans ability to benefit monitarily from referring patients to themselves. This appears to have great potential for fraudelent charging practices. In addition, on many occasions, I have heard patients say that the physician's staff did not give them options for location of treatment for therapy services unless the patient requested. This can limit the patient's potential for improvement if a specialized treatment is needed but only offered at a clinic outside of the physician practice.

Submitter:

Mr. Luigi Rende

Date: 09/04/2007

Organization:

The Center for Sports Medicine

Category:

Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

BRIEF INTRO ABOUT SELF ie. Where you work, what you do, education, certification, etc.

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,

Luig F. Rende, MS, ATC Director The Center For Sports Medicine

Submitter:

Mr. WILLIAM GREENE

Organization:

ORTHOARKANSAS, P. A.

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

ORTHOARKANSAS IS A 21 PHYSICIAN ORTHOPEDIC PRACTICE WITH ALMOST 40% OF OUR REVENUE COMING FROM MEDICARE, MEDICAID AND RELATED PROGRAMS. AS ONE OF THE LARGEST PROVIDERS OF ORTHOPEDIC SERVICES IN ARKANSAS WE ARE VERY FAMILIAR WITH THE NEEDS AND REFERENCES OF THIS POPULATION. WE BELIEVE THAT SERVICES PROVIDED UNDER THE IN-OFFICE ANCILLARY SERVICES EXCEPTION SHOULD BE PERFORMED IN A BUILDING WHERE THE CORE MEMBERS OF THE GROUP PRACTICE AND THEIR STAFF ARE PRESENT AS THE CURRENT DEFINITION STATES. REGARDING THE PROVISION OF PHYSICAL THERAPY SERVICES IN A PRACTICE BASED SETTING WE BELIEVE THAT THOSE SERVICES ARE PROVIDED MORE TIMELY, MORE EFFICIENTLY AND MORE CLOSELY IN TUNE WITH THE ORDERING PHYSICIANS EXPECTATIONS THAN IN OTHER SETTINGS. AVAILABILITY OF PT SERVICES AND PATIENT COMPLIANCE WILL BOTH DECLINE IF OFFICE BASED SERVICES ARE NOT AVAILABLE RESULTING IN LESS EFFECTIVE OUTCOMES AND ULTIMATELY HIGHER PROGRAM COSTS.

SERVICES UNDER ARRANGEMENT HOLD SIGNIFICANT POTENTIAL FOR ALLIGNING PHYSICIAN AND HOSPITAL INCENTIVES AND THEREBY REDUCING COSTS IN A VARIETY OF AREAS. CMS SHOULD MOVE VERY CAUTIOUSLY IN CHANGING CURRENT RULES IN THIS AREA OR RISK LOOSING A POTENTIALLY VALUABLE TOOL TO CREATE SAVINGS IN AN OTHERWISE DISTORTED SYSTEM OF DELIVERING PRODUCTS AND SERVICES.

IN GENERAL CMS SHOULD BE AWARE OF THE OVERALL TRENDS IN PAYMENTS FOR PHYSICIAN SERVICES. THE PAYMENT FOR EACH CPT CODE HAS BEEN STEADILY RATCHED DOWNWARD DRIVING PHYSICIANS TO SEARCH FOR COST EFFECTIVE WAYS TO COMPETE FOR OTHER REVENUE SOURCES IN AN ATTEMPT TO MAINTAIN A COMPETITIVE LEVEL OF COMPENSATION. PHYSICIAN PRACTICES AND MEDICAL TRAINING CENTERS WILL NOT BE ABLE TO RECRUIT NEW PROVIDERS IF PHYSICIAN COMPENSATION IS REDUCED TO AN UNATTRACTIVE LEVEL.

Submitter:

Dr. Norman Abbott

Organization:

Dr. Norman Abbott

Category:

Physician

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Dear Ms. Bassano:

I am writing to comment on payment for MTWA test. This modality is extremely useful in triaging patients who may or may not benefit from an inplatable defibrillator. I have seen very exciting results in my practice using this very important test.

The Medicare Practice Expense formula is grossly unfair. I test several select high risk patients each week but significantly less than 50 percent of the time. The test takes about 60 minutes to complete. CMS should use the ACTUAL usage rate to pay appropriately for this modality. I would be very happy to provide you documentation of my utilization numbers. Please call me if you would like to further discuss this very exciting and lifesaving procedure

Sincercly Norman Abbott M.D.

727-787-4875

Submitter:

John Smith

Organization:

John Smith

Category:

Individual

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

Submitter:

Dr. Edward Lee

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

Rc: 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. Karl Talts

Organization:

Dr. Karl Talts

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

Rc: CMS-1385-P

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Thank you for your consideration of this serious matter.

Dr. Karl Talts

Submitter:

Dr. Paul Clark

Organization:

Dr. Paul Clark

Category:

Physician

Issue Areas/Comments

Therapy Standards and

Requirements

Therapy Standards and Requirements

CMS is proposing to amend the regulations to change the plan of treatment recertification schedule. Currently there is a 30 day recertification requirement and the proposal is to change this to a 90 day recertification requirement. I strongly support this proposal. The 30 day recertification standard currently is ineffective and burdensome to physicians particularly those of us who practice geriatrics. There are other mechanisms CMS has to monitor appropriateness of therapy and utilization.

Thank you for your consideration.

Submitter:

Dr. Richard Denovan

Organization:

United Anesthesia Services

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dcar Ms. Norwalk:

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

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

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

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

Thank you for your consideration of this serious matter.

Richard Denovan, M.D.
President, United Anesthesia Services

Submitter:

Dr. Sueny Seeney

Organization:

Riddle OB/GYN Associates

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

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

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Thank you for your consideration of this serious matter.

Sueny M. Seency MD

Submitter:

Organization:

Robert Khederian

Cambridge Heart, Inc.

Category:

Device Industry

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

We appreciate the opportunity to comment on the 2008 Physician Fee Schedule Proposed Rule. Cambridge Heart, Inc. is the manufacturer of the Microvolt T-Wave Alternans (MTWA) non-invasive diagnostic test for the assessment of the risk of sudden cardiac death. The attached letter primarily addresses the negative impact of the equipment usage percentage in the practice expense calculation on the physician payment rate for MTWA.

Please see the attached letter for a detailed discussion of these issues.

CMS-1385-P-15676-Attach-1.PDF



August 2, 2007

Amy Bassano
Director, Division of Practitioner Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, C4-01-26
Baltimore, MD 21244

Re Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 CMS-1285-P Practice Expense -- Equipment Usage Percentage

Dear Ms. Bassano:

We appreciate the opportunity to comment on the 2008 Physician Fee Schedule Proposed Rule as published in Federal Register on July 12, 2007. Cambridge Heart, Inc. is the manufacturer of the Microvolt T-Wave Alternans (MTWA) non-invasive diagnostic test for the assessment of the risk of sudden cardiac death. This letter primarily addresses the negative impact of the equipment usage percentage in the practice expense calculation on the physician payment rate for MTWA. We would like to meet with the agency during the comment period to review these issues.

Summary

The application of a standard equipment usage assumption of 50% in calculating the PE component of the PFS payment for medical equipment vastly overstates MTWA's actual utilization rate. As a result, over the next four years physicians will be subject to a reduction of more than 40% in the Medicare payment rate for MTWA. This is contrary to the purpose of the revised PFS PE methodology, and threatens to compromise patient access to this breakthrough diagnostic technology.

For the reasons set forth below, Cambridge Heart respectfully requests that CMS employ the actual equipment usage for MTWA:

- CMS's issuance of a National Coverage Determination (NCD) for MTWA testing
 reflects the agency's view that MTWA is an effective risk stratifier for patients under
 consideration for costly Implantable Cardioverter Defibrillator (ICD) placement.
- The dramatic overstatement of MTWA equipment utilization under CMS's standard utilization assumption inappropriately understates physician costs, and thereby deters physicians from using this non-invasive and inexpensive life-saving risk stratification tool

 Because Cambridge Heart is the sole supplier of the single-use disposable sensors required for MTWA testing, the company can determine with great accuracy the actual usage of MTWA equipment.

Background on MTWA

MTWA is a noninvasive diagnostic test that assesses the risk of sudden cardiac arrest and sudden cardiac death resulting from ventricular arrhythmias. Sudden cardiac death from ventricular arrhythmias claims the lives of 400,000 Americans each year, a large proportion of who are Medicare beneficiaries. Cambridge Heart developed and manufactures the only MTWA test recognized and covered by Medicare.

Cambridge Heart's MTWA test uses propriety algorithms and specialized alternans sensors to detect minute beat-to-beat fluctuations in the T-wave portion of a patient's electrocardiogram. MTWA testing has been evaluated in numerous prospective clinical trials. These trials have shown that patients, who are potentially at risk of life threatening arrhythmias due to the presence of cardiac disease, who have a normal (negative) MTWA test bear only minimal risk for a sudden cardiac event while those with an abnormal test bear a substantially higher risk. MTWA testing enables physicians to guide truly at-risk patients to life saving ICD therapy, while allowing patients who are at minimal risk and unlikely to benefit from ICD therapy to avoid an expensive and invasive procedure associated with its own risk of morbidity and mortality.

In March 2006, CMS issued a National Coverage Decision to expand coverage of MTWA for the evaluation of patients at risk of sudden cardiac death. This expansion of Medicare coverage provided physicians and beneficiaries with a non-invasive and inexpensive means of assessing the risk of sudden cardiac death in individuals who are candidates for ICD implantation.

The majority of the usage of the MTWA testing is in cardiology based physician offices. In a typical office based examination, a patient at risk for sudden cardiac death due to underlying structural heart disease would undergo MTWA testing in addition to a battery of other non-invasive tests directed towards evaluating his/her underlying heart disease. It is not common practice for a cardiologist to refer a patient to a hospital for an MTWA test.

CMS Should Use the Actual Usage Rate

In the proposed rule CMS indicated its desire to assign appropriate usage rates to different types of equipment. CMS states:

We are interested in receiving comments relating to alternative percentages and approaches that differentially classify equipment into mutually exclusive categories with category specific usage rate assumptions. We are committed to continuing our work with the physician community to examine, equipment usage rate assumptions that ensure appropriate payments and encourage appropriate utilization of equipment. Additionally, we would welcome any empirical data that would assist us in these efforts.

Cambridge Heart believes that CMS should base the PE RVU for MTWA testing on its actual usage rate. For many types of equipment, it is exceedingly difficult to determine the actual usage rate. In order to accommodate this common informational deficiency, CMS has applied an equipment usage assumption of 50%; that is, equipment required to furnish a service is assumed to be used for one-half of the maximum possible minutes per year.

While the application of a standard equipment usage assumption may be reasonable for categories of equipment for which it is difficult to determine accurately actual usage, it is inappropriate with respect to equipment for which actual usage is well documented.

In the case of MTWA testing, the standard 50% usage assumption is significantly greater than the actual utilization rate.

We understand that MedPAC has already begun to investigate the possibility of updating the PE RVU methodology by accounting for utilization rates that are substantially *higher* than the standard 50% assumption. In its June 2006 report to CMS, MedPAC noted that some categories of high priced equipment have utilization rates between 70% and 90%, and proposed that CMS could "improve the accuracy of input prices" by revisiting "the assumptions it uses to estimate the per service cost of medical equipment, particularly the assumption that equipment is operated 50 percent of the time." Additionally, Congress is considering legislation that would increase equipment usage assumption from 50% to 75% for imaging technologies.

Cambridge Heart is encouraged by these efforts to incorporate actual utilization rates, and is committed to working with CMS and others to establish a more accurate equipment usage rate for MTWA testing.

Cambridge Heart believes that in the final rule CMS should create a category for those items for which the actual utilization is accurately known and documented. Cambridge Heart is prepared to work with CMS on an ongoing basis to provide actual equipment utilization data for MTWA testing to document any future changes in utilization.

MTWA Testing Equipment Actual Utilization Rate

The actual utilization rate for MTWA testing equipment is precisely known and very well documented. MTWA tests require a single-use disposable sensor, of which Cambridge Heart is the sole supplier. Cambridge Heart has conducted a review of all fielded MTWA units to determine their actual usage.

The Table below presents the calculation of the MTWA equipment utilization based on an MTWA equipment utilization time per test of 15 minutes which is the current CMS input for this data element. The Cambridge Heart MTWA systems utilize a single-use disposable set of Micro-VTM sensors for which Cambridge Heart is the sole supplier. Cambridge Heart knows how many of its MTWA systems are fielded and the precise number of sensor sets shipped each year. Using the number of sensor sets shipped allows us to calculate an upper limit for the actual equipment utilization (actual utilization would be a bit less if some of the shipped sensor sets end up not being used).

Table: 2006 Microvolt T-Wave Alternans Equipment Utilization

Fielded MTWA Systems (US - year end)	
Micro-V Alternans Sensor TM sets shipped in US	30,900
Tests per MTWA System per Year	44.98
(30,900 Sensor Sets / 687 Fielded Systems)	
Minutes Used per MTWA System per Year	
(44.98 tests/yr x 15 min/test)	
Actual Utilization Rate	0.45%
(675 min/yr) /(150,000 min/yr max)	

Current Utilization Rate for MTWA is Low

CMS has raised questions regarding the low utilization of MTWA. The current utilization is reflective of the patient populations in which the technology is used and current limitations of reimbursement and coverage and also, as discussed below, the artificially low CMS time input for MTWA equipment utilization. Utilization is expected to increase over the next several years but the equipment utilization will always be substantially below the 50% usage assumption. We should also mention that if CMS adopts the correction to the time input for MTWA equipment usage recommended below the current utilization rate would be 1.59% instead of 0.45% - still very substantially below the 50% assumption.

The current primary target population for MTWA testing are those patients with left ventricular ejection fraction (LVEF) less than or equal to 35% with no prior history of cardiac arrest (CA). These patients are generally covered by Medicare and most private carriers for implantable cardioverter/defibrillator (ICD) therapy to prevent future CA and sudden cardiac death (SCD). MTWA identifies approximately one-third of this population as being at very low risk of SCD and unlikely to benefit from ICD therapy. ICD therapy while very effective in reducing mortality from SCD is associated with its own significant mortality and morbidity risk and is also a costly therapy. MTWA testing is used by physicians to help guide ICD therapy in this population. It is estimated that approximately 100,000 ICDs per year are implanted in the United States in this primary prevention population. In 2006, Cambridge Heart, Inc shipped 30,900 sensor sets in the United States the majority of which we believe were used in this primary prevention population. Thus even though MTWA is early in its adoption phase, the number of MTWA tests performed per year in the United States is already equal to a significant fraction of the number of primary prevention patients who receive ICD therapy each year in the United States.

MTWA was approved by the FDA in 2001. In the initial years, Medicare coverage and private payer coverage for MTWA varied by region. This patch work of coverage policies limited utilization. In 2005, Medicare expanded coverage of ICD therapy. In March 2006, CMS expanded coverage of MTWA for sudden cardiac death through a National Coverage Decision (NCD) and this has led to increased coverage by a number of the large private payers. Cambridge Heart therefore expects that there will be increased levels of MTWA testing in future years; however, Cambridge Heart also expects that there will an increased number of fielded MTWA systems. Cambridge Heart, Inc. hopes that utilization per system (currently 3.75 tests

per month per US fielded system) will increase. However, even if that rate were to double the equipment utilization would remain a very small fraction of the current 50% utilization assumption.

Despite the fact that the total number of tests performed is modest, the medical/clinical impact of the test for an individual Medicare beneficiary is enormous. If the MTWA test indicates that ICD therapy is necessary, the result of an MTWA test may quite literally be life-saving for that patient. Conversely, if the MTWA test indicates that the patient is at very low risk, that patient may avoid a costly invasive procedure which carries the risk of device-related mortality and morbidity.

Complications of ICD therapy include infection, perforation, inappropriate shocks, lead breakage and device recall. In the absence of MTWA testing, a large number of ICDs (estimated at 15-20) must be implanted in the primary prevention population in order to save one life for some period of time. MTWA testing is inexpensive, but ICD therapy is quite costly. MTWA testing has the potential of substantially reducing Medicare expenditures for un-needed ICDs while helping to ensure that ICDs are received by Medicare beneficiaries who actually will benefit from this therapy.

CMS Time and Data PE Inputs for MTWA Testing CPT Code

A realistic clinical scenario is that all the MTWA associated equipment is located in a room in a physician's office and that this room can be used at most for one patient at a time to perform MTWA testing or for stress testing. We believe therefore that it is accurate to estimate that all the MTWA associated equipment is used for at least the 53 minutes although we would argue (after consulting with MTWA clinical experts) should be 60 minutes or one hour per test and that the associated nurse time (staff type should be at least the same level as stress test but currently is not – an MTWA test requires more skill and training to perform than a standard stress test) to conduct the stress test is also at least 53 minutes or our estimate as one hour. Cambridge Heart requests that CMS make the following specific adjustments to their PE data inputs.

- Change Staff type from L037D RN/LPN/MTA to LO51A RN this is the same personnel input as for a Stress Test see CPT 93015 and CPT 93017
- Change Table Time from EF023 at 23 minutes to 53 minutes
- Change the cardiac monitor w-treadmill (12-lead PC-based ECG) EQ078 from 15 minutes to 53 minutes
- Change the cardiac monitor w-treadmill (microvolt, CH2000) from EQ079 15 minutes to 53 minutes.

At present a physician may not bill for the practice expense of an MTWA test and a stress test on the same date of service. Cambridge Heart believes the reason for this is that it was believed that the data collected during an MTWA test could also be used for purposes of stress testing. In fact this is not the case. The exercise protocols for the two tests are entirely different. If a physician wanted to perform a maximum capacity stress test at the same time as an MTWA test, typically the physician would perform the MTWA test, let the patient rest for at least 15 minutes and then perform a standard stress test protocol.

Cambridge Heart will be requesting through the CMS CCI edit contractor a change from 0 to 1 to allow for the limited and appropriate times a maximum capacity stress test would be performed on the same day as an MTWA study.

Conclusion

CMS greatly expanded Medicare coverage for, and beneficiary access to, MTWA testing through development of an NCD. Because the 50% equipment usage assumption inappropriately understates physician payments, it deters physicians from using MTWA and thus limits beneficiary access to this non-invasive and inexpensive life-saving risk stratification tool.

We are available to work with and assist CMS in implementing the most appropriate and accurate method of calculating practice expense costs for MTWA.

We appreciate your attention to this issue.

Sinceral

Robert P. Khederian

CEO, Cambridge Heart, Inc.

Submitter:

Date: 09/05/2007

Organization:

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

Rc: 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 PLIC'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.

Sincercly,

David K. Lenser, MD

Submitter:

Mr. Christopher Gebeck

Organization:

St. Mary's / Duluth Clinic

Category:

Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer working a large healthcare system in Northern Minnesota. Our healthcare system employees 6,600 people, 25 are ATC's (certified athletic trainer's). The utilization of athletic trainer's throughout our system is multi-faceted. Our athletic trainer's work in many areas of the hospital/elinic, not just in the traditional sports arena, but also in the out patient rehab areas, and especially with our physicians in the Orthopedic Dept. The skill sets that ATC's have are complimentary to our physicians in the treatment of muscluloskeletal disorders. Our administrators and physicians have put forth much time and effort for athletic trainer's to be utilized properly in our healthcare system.

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

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

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

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

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

Sincerely,

Chris Gebeck, ATC Athletic Trainer St. Mary's/ Duluth Clinic Employee Health and Rehab Services 218-786-3050

Submitter:

NATCO

Organization:

MAICO

Category:

Other Association

Issue Areas/Comments

GENERAL

GENERAL

August 31, 2007

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

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

On behalf of NATCO, the Organization for Transplant Professionals, I would like to express the organization s support for increasing access and the availability of immunosuppressive drugs. NATCO s professionals, including transplant coordinators, nurses, and social workers, collaborate with specialty transplant pharmacies and other pharmacies to ensure that patients with solid organ transplants receive access to critical immunosuppressant medication. NATCO understands that reductions in the Medicarc Part B payment for immunosuppressants makes it difficult for many pharmacies to sustain this service.

In addition to providing immunosuppressant medications, pharmacies also provide critical billing and patient management services that help to encourage proper adherence and compliance with medication regimens. This helps to ensure that patients receive access to immunosuppressants in a timely manner and makes the billing process as seamless as possible for transplant recipients. The Medicare Part B billing processes require more paperwork and staff time than other billing pharmacy systems that provide real-time, online approval of claims. CMS should take this into consideration.

NATCO urgcs you to review data submitted by specialty transplant pharmacies and other pharmacies regarding their needs in order to ensure that immunosuppressive medications are readily available to all those who require them.

Sincerely, NATCO, The Organization for Transplant Professionals P.O. Box 15384 Lencxa, KS 66285-5384

August 31, 2007

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

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

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Sincerely, NATCO, the Organization for Transplant Professionals P.O. Box 15384 Lenexa, KS 66285-5384

Submitter:

Dr. Kimberly Maziarz

Date: 09/06/2007

Organization:

Kimberly Maziarz-Carlucci DC LLC

Category:

Chiropractor

Issue Areas/Comments

GENERAL

GENERAL

The non-covering of X-rays used by chiropractors is a hazard for medicare patients. Is medicare going to pay our malpractice if a cancer is missed?

Submitter :

Date: 09/06/2007

Organization:

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

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

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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

Thank you for your consideration of this serious matter.

Romeo Wildon Laroya, MD

Submitter:

Date: 09/06/2007

Organization:

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.

Keith Green, MD

Submitter:

Date: 09/06/2007

Organization:

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)

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Thank you for your consideration of this serious matter.

Jose Menendez, MD

Submitter:

Dr. sephr tabibzadeh

Date: 09/06/2007

Organization:

Anesthesia Services Medical Group

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

I think it is a move in the right direction to increase physician reimbursements for taking care of an ever increasing number of Medicare patients.

Submitter:

Mrs. Heidi Allshouse

Date: 09/06/2007

Organization:

Cardiovascular Institute at North Colorado Medical

Category:

Other Technician

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

The proposal by The Center for Medicare Services to bundle color flow doppler in with the base code for echocardiography procedures and not providing any additional payment for this base codes does not seem legitimate. Performing color doppler studies with the echocardiogram does require more time to perform and to interpret. Also, with ICAEL standards they are requiring more images involving color doppler, and not all echo studies require that color doppler be performed.

Submitter:

Dr. Kusum Prabhakar

 ${\bf Organization:}$

Dr. Kusum Prabhakar

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

To Whom it may concern,

I am a practising anesthesiologist, in New Mexico. I am sending this comment in support of the proposed increase in the reimbursement for the anethesilogists. This increase is long overdue. I thank CMS in advance for the proposed change.

Submitter:

Dr. Lou Lorenzo

Organization:

Dr. Lou Lorenzo

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

Baltimorc, 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. 1 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 scniors 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,

Lou Lorenzo, DC

Submitter:

Nicholas Gierman

Organization:

AthletiCo LTD

Category:

Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Nicholas Gierman and I am a Certified Athletic Trainer. I work for AthletiCo LTD as well as Glenbard West High School. I am licensed in the state of Illinois and received my education at Illinois State 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.

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, Nicholas J Gierman..., ATC

Submitter:

Mr. Kevin Hendrix

Organization:

Athletico LTD.

Category:

Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

My name is Kevin Hendrix and I am a Physical Therapist and Athletic Trainer for Athletico Physical Therapy. I have been employed there for 7 years with my first 6 as an athletic trainer. I went back to get my physical therapy degree and license because I noticed some of the unfair changes that athletic trainers had to deal with. Although both professions receive different educational programs, both fields are qualified to deliver health services including physical medicine and rehabilitation.

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

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

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

Sincerely,

Kevin Hendrix PT, DPT, ATC, NASM-PES

Submitter:

ravinder bevli

Organization:

ravinder bevli

Category:

Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

physical therapy services should NOT be included in the in-office ancillary services exception.

CMS-1385-P-15690 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter: ravinder bevli Date & Time: 09/07/2007

Organization: ravinder bevli

Category: Physical Therapist

Issue Areas/Comments Physician Self-Referral Provisions

Physician Self-Referral Provisions

physical therapy services should NOT be included in the in-office ancillary services exception.

CMS-1385-P-15691 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter: Ms. Patricia Reyerson, RDCS Date & Time: 09/07/2007

Organization: Midatlantic cardiovascular

Category: Other Technician

Issue Areas/Comments
Coding-- Additional Codes
From 5-Year Review

Coding-- Additional Codes From 5-Year Review

The additional time and effort is separate from 2D pictures and color flow pictures. These are 2 separate modalities, and should be recognized as such. Much sonographer and physician time is spent obtaining and evaluating 2D views. Not all echos include color flow.

For example...wall motion abnormalities in the setting of an MI, or r/o tamponade. The codes should be kept separate, since color flow is a different procedure and evaluation, again by both the sonographer and the cardiologist.

CMS-1385-P-15692 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter: Dr. Donna Sirbasku Date & Time: 09/07/2007

Organization: Dr. Donna Sirbasku

Category: Physician

Issue Areas/Comments
Physician Self-Referral
Provisions

Physician Self-Referral Provisions

I am a pathologist of many years' experience who has found a niche in Pathology that supports my family and provides great satisfaction to me, the physicians' offices in which I work, and their patients. I travel to Urologists' offices several times a week to sign out pathology specimens. The tissue and urine Cytology specimens are sent to a specialty Urologic Pathology laboratory for processing. A technician is employed by the office to coordinate the specimen handling. Processing at a specialty lab is very important since prostate biopsies are among the most difficult to orient and process. Ribbons of extra tissue must also be cut onto an unstained slide at the same time as the original sectioning, to use if special stains are needed. In addition, the immunostains are very difficult. The slides are sent to the various offices by overnight mail and I sign them out in an office space provided for me. The cases are finalized on the computer and printed out on site. If special stains are needed they are ordered on the computer program. If consultation is needed, the slides can be sent to the Urologic Laboratory. Working within the offices provides access to charts and to the surgeons' findings in the cases; clinical consultation is always available. This satisfying process can be contrasted to that of sending a specimen to one of the large laboratories (I do have experience with this since I have worked at both AmeriPath and Quest). In these labs the sections are poorly processed and often much of the tissue is lost. Extra ribbons are not collected and immunostains often do not contain the area suspicious for carcinoma. There is no communication with the physicians' office and usually no clinical information. Any of several pathologists, from those with one or two years' experience to 30 years could be reading your cases - the physician has no choice. I recently read a set of prostate biopsies from a 45-year old with a PSA of 2.5 that had a recent biopsy diagnosed with 7 of 12 biopsies showing HGPIN, a precursor to adenocarcinoma - at a large Pathology laboratory. The set I read on re-biopsy 4 months later showed no HGPIN. Not only was the patient made to worry during this time, but the mistaken biopsy reading led to the expense of the re-biopsy and its pathology reading and processing. Mistakes cause trillions of dollars. So, please do not change the CMS rules to take away my livelihood and this very satisfactory way of handling these very important specimens. It is said that this method causes overuse of testing, but all of the studies by the OIG have found no overuse and, in fact, fewer biopsies because of better handling and more precise and correct diagnoses. Also, since I am on my own schedule I often spend 1 hour or more on one prostate; pathologists at the large labs ("the mills") are expected to look at from 110 to 150 slides each day! It seems that the impetus for these rule changes is the large laboratories and their organizations, since if this method spreads they will lose money. Medicare pays no more for this better method and does not have to pay for the fancy offices of the many administrative types in the large labs - and for their Lear jets and limousines. I work full time in this program, so I am able to give timely service and very good "turnaround times". But since my work in this program is full time, I will be out of work if the rules are changed. I spent 6 months visiting every hospital and medical center in the DFW area before I found this opportunity! If you feel there is fraud, a program to root out these cases would make more sense, rather than "throwing out the baby with the bath water". I hope the comments from some of us "little people" will be taken into account. Our income in a tight Pathology market, especially for "experienced" pathologists - is at stake. Thank you for your consideration of these thoughts. Dr. Donna Sirbasku Cell 972- 978-0323

CMS-1385-P-15693 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter: Dr. Donna M. Sirbasku Date & Time: 09/07/2007

Organization: DMS Pathology

Category: Physician

Issue Areas/Comments
Physician Self-Referral
Provisions

Physician Self-Referral Provisions

Docket Number & Title: CMS-1385-P Comment Period End Date: 09/07/07

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pathologists - is at stake. Thank you for your consideration of these thoughts. Dr. Donna Sirbasku 972-978-0323 Cell

Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter: Mr. John Madrid

Date & Time: 09/07/2007

Organization: osteoporosis diagnostic center

Category: Other Technician

Issue Areas/Comments

GENERAL

GENERAL

Kerry Weems, Acting 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, Maryland 21244-1850

RE: CMS-1385-P Proposed Revisions to payment policies under the physician fee schedule and other Part B payment policies for CY 2008

Comments:

The Physician Work RVU-CPT 77080 (DXA)

The Direct Practice Expense RVU for 77080 (DXA)

Indirect Practice Expense for DXA and VFA

Deficit Reduction Act
Dear Mr. Weems: I appreciate the opportunity to offer general comments on the proposed rule regarding changes to the Medicare physician fee schedule CMS-1385- P.
As a provider of DXA and/or VFA services, I request CMS to reevaluate the following:
a. The Physician Work RVU for 77080 (DXA) should be increased from 0.2 to 0.5, consistent with the most comprehensive survey data available;
b. The Direct Practice Expense RVU for 77080 (DXA) should reflect the following adjustments:
* the equipment type for DXA should be changed from pencil beam to fan beam with a corresponding increase in equipment cost from \$41,000 to \$85,000;
* the utilization rate for preventive health services involving equipment designed to diagnose and treat a single disease or a preventive health service should be calculated in a different manner than other utilization rates so as to reflect the actual utilization of that service. In the case of DXA and VFA, the 50% utilization rate should be changed to reflect the utilization rate for DXA to 12%.
c. The inputs used to derive Indirect Practice Expense for DXA and VFA should be made available to the general public, and
d. DXA (77080) should not be considered an imaging service within the meaning of the section 5012 (b) of the Deficit Reduction Act of 2005 because the diagnosis and treatment of osteoporosis is based on a score and not an image.
Sincerely,
John D. Madrid

6200 Dellyne Ct.

Albuquerque, NM 87120

Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter: Myra Looney Wood

Date & Time: 09/07/2007

Organization: Vital Link EMS

Category: Other Health Care Professional

Issue Areas/Comments Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

I am CEO of a small regional not for profit ambulance service in north central Arkansas and I appreciate the opportunity to make comments regarding the GPCIs used as a multiplier of the Ambulance Fee Schedule Conversion Factor.

What makes the cost of physicians offices applicable to the ambulance industry? Physicians offices in Arkansas are notorious for hiring untrained people and paying fairly low wages. Additionally most doctors offices are only open 4 to 5 days per week and take long breaks during holidays and summer during which their staff is often unpaid. Physicians offices have overhead for offices, office and billing staff, and some medical equipment but they do not have the costs of operating emergency vehicles and all the required medical equipment and disposable supplies. Their costs of operations as computed in the GPCI have absolutely nothing to do with the costs of operating an ambulance service!

Vital Link EMS like all ambulance services have considerably higher operting cost than any physicians office. Vital Link must maintain constant availability in our four county service area for emergencies 24 hours per day which means we must maintain 7 ambulances staffed with 7 paramedics and 7 EMTs 24/7. In order to meet the non-emergency medical transportation demands we must also staff 4 to 5 ambulances on an as needs basis with a paramedic and EMT. Each long distance non-emergency medical trip can take up to 5 hours which takes that ambulance out of the service area requiring replacement ambulances to be staffed. All EMTs and Paramedics are certified individuals and Vital Link must pay competitive wages and provide excellent benefits in order to recruit and retain qualified individuals. Additionally, Vital Link has to operate a 24/7 dispatch center. Since no dispatch training program is available in our area we have to spend considerable dollars on training each dispatcher for this critical and responsible job. All of these employees must be paid 24 hours per day and have built in over time as they work a minimum of 48 hours per week. OHSA and Homeland Security standards requires that all EMS personnel even our managers and office staff receive training in hazardous materials and NIMS and ICS which is not required of physicians office staff.

The fee schedule payment system results in inadequte compensation for emergency medical services and particularly for rural services that do not have high enough call volumes to cover all the cost of maintaining readiness that EMS requires. Please read the GAO Report to Congressional Committees of September 2003 entitled Ambulance Services Medicare Payments Can Be Better Targeted to Trips in Less Densely Populated Rural Areas GAO-03-986.

Once the GPCI for Arkansas is applied to the already inadequate fee schedule allowable for ambulance service the payment to Arkansas ambulance providers is below cost, even for not-for-profit efficient and low cost providers such as Vital Link.

Let me experess my sincere appreciation that the GPCI for Arkansas may be going up very slightly. Every little bit of movement toward an appropriate reimbursement rate is appreciated.

Please consider deleting the GPCI altogether and increasing the ambulance fee schedule allowables to more reasonable amounts based on actual cost figures obtained directly from ambulance providers.

If you would like specific financial data please contact me as follows:

Myra Looney Wood, RN, BSN, MBA Chief Executive Officer Vital Link EMS 1033 EMS Drive Batesville, AR 72501 870-793-3351 mlwood@vitallinkems.org

Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter:

Date & Time: 09/07/2007

Organization: BioScrip, Inc.

Category: Drug Industry

Issue Areas/Comments

CAP Issues

CAP Issues

See Attached

Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter:

Date & Time: 09/07/2007

Organization: BioScrip

Category: Drug Industry

Issue Areas/Comments

CAP Issues

CAP Issues

See attached

Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter:

Date & Time: 09/07/2007

Organization: BioScrip

Category: Drug Industry

Issue Areas/Comments

CAP Issues

CAP Issues

Alternatives to the CAP Prescription Order Number

The requirement of a prescription order number creates a barrier that prevents physicians from enrolling in the CAP because of the administrative burden associated with using a prescription order number for tracking and reporting each drug. Since the prescription order number is not required for non-CAP transactions, physicians enrolling in the CAP are faced with the additional burden of updating their systems and addressing accounting problems that result from the prescription order number requirement. Further, since April 2007, the prescription order number is no longer needed to determine the prepayment edit due to changes in CAP claims processing. While CMS relies on the prescription drug order number for the post-payment review process, we believe it can be eliminated. BioScrip verifies the administration of the drug has occurred prior to submitting a claim for payment. Further, physicians maintain records of drug administrations. The CAP vendor and physician records provide a viable alternative to meeting the requirements of the post-payment review process and would allow for the burden of the prescription order number to be eliminated.

Recommendation: CMS should eliminate the prescription order number requirement and rely upon the CAP vendor and physician records to verify the administration of the drugs

Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter:

Date & Time: 09/07/2007

Organization: BioScrip, Inc

Category: Drug Industry

Issue Areas/Comments

CAP Issues

CAP Issues

Transporting CAP Drugs

The current restriction that CAP drugs be shipped directly to the location where they will be administered creates barriers that prevent many physicians from enrolling in the program. Further, the restriction does not allow physicians to receive CAP drugs at their office and administer the drugs in an alternate setting. For example, physician practices with satellite operations that are not open every business day are not able to receive shipments of CAP drugs at another practice location and then administer the drugs in the satellite office. Under these circumstances, rural patients and practices are particularly affected. These obstacles can be eliminated through a policy that allows for flexibility in the location to which a CAP drug is shipped to a physician.

Based on BioScrip sexperience with the CAP since July 2006 implementation, we believe CMS should implement a policy that allows CAP physicians the flexibility to decide the location where the drugs will be shipped, similar to the process currently used under the buy and bill alternative. Thus, drugs would be shipped to the location chosen by the physician, including the practices central office, and then transported and prepared at the location of administration by the physician. This policy should apply to all drugs in the CAP. We believe that adherence to current applicable laws and regulations will ensure the integrity, stability and sterility of CAP drugs while being transported. Further, this would give CAP-enrolled physicians the same flexibility afforded to them under the buy and bill system.

Recommendation: Consistent with our comments above, BioScrip recommends CMS implement a policy that allows physicians to determine the location to which a CAP drug is shipped.

Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter: Date & Time: 09/07/2007

Organization: BioScrip, Inc.

Category: Drug Industry

Issue Areas/Comments

CAP Issues

CAP Issues

Prefilled Syringes

As the sole vendor under the CAP, BioScrip has a unique perspective on permitting the use of prefilled syringes under the program. BioScrip has the trained personnel and facilities for the small-scale preparation of sterile drug products in response to a specific prescription order for a specific patient. We believe it is feasible to make the option of using prefilled syringes supplied by an approved CAP vendor available to all physicians who participate in the CAP. This policy would allow CAP-enrolled physicians to rely on the CAP vendor for these drugs, rather than requiring physicians to go outside the CAP in order to obtain CAP drugs in prefilled syringes. There are three important elements that must be considered by CMS in developing a new policy allowing for prefilled syringes to be included under CAP: non-returnable products; time stability; and payment for professional time and supplies.

Non-returnable Products \Box Most drugs prepared in prefilled syringes would be non-returnable to the CAP vendor once they have been mixed and shipped to a physician because of concerns with the stability of the drug. Therefore, under the circumstance when a prefilled syringe is delivered to the CAP physician but not administered to the beneficiary, the CAP vendor must be paid for the product. BioScrip believes it can work together with CAP physicians and CMS to develop a process that secures payment to the CAP vendor for prefilled syringes that are mixed and shipped, while also giving physicians access to prefilled syringes without going outside of the CAP.

Time Stability of Mixed Drugs \square Several CAP drugs are packaged by manufactures in quantities larger than the patient-specific quantity used to fill an order for a prefilled syringe. Further, once a product is mixed, the stability is limited by time. As a result, some of the product may be wasted when a portion of the product is mixed but not dispensed before the time limit. Payment to the CAP vendor for a drug provided via prefilled syringe must account for any non-usable portion of the product associated with filling the order for a prefilled syringe.

Payment for Professional Time and Materials \square The process of filling orders for prefilled syringes requires the professional time of trained personnel and special supplies to ensure the mixing, handling and shipping is clinically appropriate for the patient. In order to cover the CAP vendor \square s additional costs for filling a prefilled syringe, CMS should adopt a dispensing fee that appropriately covers these added costs.

Recommendation: Should CMS develop a new policy allowing for prefilled syringes to be included under CAP, provisions must be made to account for non-returnable products, time stability of mixed drugs, and payment for professional time and supplies.

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