West County Heart Alliance, LLC
OUTPATIENT CATH LAB

2335 Dougherty Ferry Road
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811

August 27, 2007

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

Re: Proposed Revisions to Payment Policies Under the Physicians Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

On behalf of the West County Heart Alliance and our twenty six individual practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the ***"Resource-Based PE RVU's"*** section of the above referenced July 2, 2007 Proposed Rule. We are specifically concerned with the 2008-2010 PE RVU's established for non-facility outpatient cardiac catheterization procedure codes and the significant negative impact that could result for our practice and our patients if these values are finalized for the 2008 Physicians Fee Schedule.

The West County Heart Alliance is a consortium of 8 independent cardiology practices located in St. Louis County. The WCHA serves a diverse population covering central Missouri and Southern Illinois caring for 2400 patients per year.

The West County Heart Alliance is a member of the Cardiovascular Outpatient Center Alliance (COCA) and as such we have actively been involved in the work that COCA has accomplished this year to collect and submit direct and indirect cost data to the AMA's Practice Expense Review Committee (PERC) of the Relative Value Scale Update Committee (RUC). Unfortunately, this process did not allow all of COCA's data to be considered and resulted in PE RVU recommendations to CMS that severely undervalued the direct and indirect costs associated with providing these procedures to our patients.

It is apparent from the July 2, 2007 Proposed Rule that CMS has accepted the RUC recommendations without considering the detailed direct cost information that COCA provided to CMS in May 2007. The PE-RVU values set out in the July 2 Proposed Rule would result in a draconian cut in reimbursement for cardiac catheterizations performed in

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practice or IDTF locations. For example, if the 2007 conversion factor is applied to the technical component of the primary three CPT codes for a Left Heart Cath (93510TC, 93555TC, and 93556TC) the reimbursement in 2008 would be cut by **32%** and when fully implemented the total reimbursement would be reduced by **49%**. While at the same time the reimbursement for cardiac catheterizations performed in the hospital setting is slated for an **11%** increase.

These reductions would undoubtedly result in the closing of the majority of non-facility outpatient cardiac catheterization labs in the country forcing all patients who now benefit from improved access and lower costs into more acute hospital settings.

We request that CMS review the additional cost data provided by COCA and establish PE RVU's for outpatient cardiac catheterization procedures that more reasonably reflect the direct and indirect costs of providing these procedures. If the proposed RVU's are allowed to stand, the outcome will inevitably that will cost the Medicare program more in direct APC payments **and** Medicare patients more in higher deductibles and co-insurance.

Thank you for this opportunity to comment on this important issue.

Sincerely,

Scott W. Hylton R.N,
Manager
County Heart Alliance

812

Dr. Anthony DiFilippo
23887 Lorain Road
N. Olmsted, OH 44070
August 30, 2007

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

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

Dear Mr. Weems:

I am a physical therapist and have been practicing for 15 years. I work in the out-patient physical therapy setting. It has become increasingly common for physicians to own and thus profit from sending their patients for rehabilitation in a facility that they own. I am happy that CMS has changed the requirement that physical therapy performed in a physician's office is to be performed by a physical therapist and not a random worker.

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.

I have two personal experiences with this type of abuse. For a short period of time, I was employed by a physician to provide physical therapy services. I left after seeing several instances that made me aware that the physician was more concerned about making money from the referral than the treatment of the patient. I overheard the physician tell a patient that he would not give him a referral for physical therapy and that the patient had to come to his office. The patient lived approximately 1 hour away and had several quality physical therapy offices close to where he lived. The physician strong armed the patient into getting a ride, as the patient was unable to drive due to her condition, and receive physical therapy from his office.

- Another instance is currently happening at my office. A physician that I have met with multiple times over the past year has referred only a few patients to my office. He is a surgeon and refers most of his patients to the local hospital therapy center. He recently has met with me upon his request and is being told by his billing company that he can make more money for himself if he owns his own therapy and imaging services. He wishes to move his office and have our company provide therapy services for him to enable the physician to bill services rendered to his patients. This brings up the question that if the physician feels that the hospital physical therapy is providing acceptable care for his patients and he typically refers to that physical therapy facility, why then would he refer all of his patients to a facility that has therapists providing care that he does not send to currently. The reason would be because he is going to gain an additional revenue stream.

Thank you for taking the time to consider my experiences in this matter.

Sincerely,

Anthony DiFilippo, PT, DPT, M Ed, CSCS
Physical Therapist

813

REHAB ASSOCIATES
OF CENTRAL VIRGINIA

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Hurt Practice
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Mr. Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
US Dept. Of Health and Human Services

Attn: CMS – 1385 – P

Dear Mr. Weems:

My name is John M. Wallman and I am a licensed Physical Therapist practicing in the State of Virginia. My wife, Mary (also a licensed Physical Therapist) and I are part of a large , private outpatient, Physical Therapy practice in central Virginia. Our company, Rehabilitation Associates of Central Virignia has been serving the members of our community for more than thirty years.

I wish to comment on the July 12 proposed physician fee schedule rule, especially the issue surrounding physician self referral and the "in–office ancillary services" exception.

The American Physical Therapy Association has been warning Congress, the CMS and Inspector General's office for more than a decade about the highly abusive nature of Physician Owned Physical Therapy Services (POPTS). Was it not alarming to Congress and the CMS when the OIG came forth with it's report stating that 91% of Physical Therapy services billed failed to meet the proper requirements, resulting in "improper" Medicare payments of 136 million dollars in the first 6 months of 2002 ? We have seen the potential for abuse for years and years! This was not alarming to us!

POPTS began in our very "conservative" medical community more than five years ago. One of the three existing Orthopedic physician groups began their "own" in-office Physical Therapy clinic. Since then, the other two groups have merged with them and are also participating in this arrangement. We have seen a definite shift in referral patterns. I would like to share with you just two of the many examples of POPTS abuse that I have experienced.

A Family Practice physician referred me a patient that had been experiencing a shoulder problem. I had been seeing this man twice a week for approximately 3-4 weeks. His progress was slow and I suspected a possible rotator cuff tear. I referred

him to one the orthopedic surgeons for consultation whom I considered a fantastic surgeon, friend, and one of my biggest referral sources! The doctor agreed with my suspicion of a rotator cuff tear, told the patient that he wanted him to have more physical therapy and referred him to his own clinic to continue. Took the man out of my clinic and "self referred" ! I called the physician immediately to let him know how I felt about the incident. He "backed up" quickly!

The second example, involved a patient that an Orthopedist had sent me for pre-surgical rehab. I had been seeing the man for 4 weeks in preparation for an anterior cruciate ligament repair. After the surgery, the physician once again self referred to his facility rather than sending the patient back to me, where he had received quality care pre-operatively! The patient complained about the referral and told the physician that he was not going to his clinic and demanded the referral be sent to me. The patient won!

Many times we have heard that some physicians do not disclose to their patients that they "own" the physical therapy practice they are referring them to and they are supposed to. Is that not abusive and fraudulent?

Now is the time to close the "loophole" in the Stark II physician self-referral law and protect Physical Therapy services, the Physical Therapy practitioner and consumer. My wife and I are calling on CMS and Congress to remove Physical Therapy from an "in-office" ancillary services exception to the physician self referral laws. This, without a doubt, creates a thriving environment for potential fraud and abuse! CMS needs to put a stop to physician practices that participate in Referral for Profit.

Thank you for your consideration in regard to this most important subject.

Sincerely,

John Wallman PT

John Wallman, PT

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

Re: File Code CMS-1385-P
Physician Self-Referral Provisions
Section II.M.3; In-Office Ancillary Services Exception

Dear Sir or Madam:

I am a Physical Therapist Assistant , working for an organization that provides rehab services, within a physician practice. Working within this model has proven to be very patient-centered. It allows for constant interdisciplinary communication concerning individualized treatment plans, case management, and development of clinical protocol with physician involvement that is diagnosis specific to the Physical Therapy program to facilitate a patients timely return to activities of daily living.

As a rehab service provider, I ask for your continued support of this model. The partnership between the physicians and the therapists sustains a positive stress, to provide quality care in a cost efficient manner.

Sincerely,

Linda Hargrove PTA

Linda A. Hargrove, PTA

815

Ostert, Aprille

From: Mora, Peggy
Sent: Tuesday, August 28, 2007 3:48 PM
To: Ostert, Aprille
Subject: Centers for Medicare

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

Re: File Code CMS-1385-P
Physician Self-Referral Provisions
Section II.M.3; In-Office Ancillary Services Exception

Dear Sir or Madam:

I am a Physical Therapist Assistant, working for an organization that provides rehab services, within a physician practice. Working within this model has proven to be very patient-centered. Located within the same physical space as the physicians enables me to have frequent contact with them concerning individualized treatment plans, case management to facilitate timely return to activities of daily living. The accessibility to physicians, nurses, medical records and financial records enables me to provide more comprehensive care to my patients and to provide it with cost-containment as a priority. This accessibility allows immediate attention of contraindication and immediate revision of the Physical Therapy plan of care if the patient's condition changes.

Patient satisfaction is high as patients appreciate the convenience of not having to go to a separate facility for their therapy services.

The in-house PT model holds both partners accountable to best practice principles concerning patient care and cost-containment. As a rehab provider, I ask for your continued support of this model.

Sincerely,

Peggy B. Mora, PTA

Peggy B. Mora, PTA

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PHYSICAL THERAPY SERVICES

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NPTS – Grant
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NPTS – Sparta
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NPTS – Wayland
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Wayland, MI 49348
ph: 269.792.4440
fx: 269.792.4475

Kerry N. Weems
Administrator-Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P

Re: Physician Self-Referral Issues

Dear Mr. Weems,

This letter is to comment on the physician fee schedule rule proposed for July 12, 2008. My specific concerns surround the issue of physician self-referral and "in-office ancillary services."

I am a physical therapist and have practiced in Michigan for 18 years.

The Medicare beneficiaries with their mindset of never questioning their doctor become a vulnerable populous to financially interested physicians who apparently do not have rigid enough laws to protect our system from abuse. I am therefore reinforcing the APTA in strongly urging the CMS to remove physical therapy as a designated health services permissible under the in-office ancillary exception of the federal physician self-referral laws.

Thank you for your attention to this important matter.

Sincerely,

Val Pullen MSPT

Val Pullen, M.S.P.T.

817

CLAUSEN CHIROPRACTIC

Anna M. Clausen, D.C.

217 Gilman St
P.O. Box 520
Sheffield, IA 50475
#641-892-4008

08-27-07

Dear Dallas,

I am writing to you because you have benefits under Medicare, Medicaid, or both. I have just received notification from the Iowa Chiropractic Society that the Centers for Medicare and Medicaid Services are attempting to adopt a new ruling that will exclude some x-ray benefits. Currently, Medicare and Medicaid will pay for x-rays taken at a hospital or clinic when ordered by a Doctor of Chiropractic. The new ruling states that they will no longer pay for these services. If you need x-rays, you would need to be referred to another provider (orthopedist, rheumatologist, etc) for another or duplicate examination before being referred to a radiologist for x-rays or you would pay for them out of your own pocket.

In an attempt to override this new ruling that will eliminate current x-ray benefits, I urge you to read, sign, and mail the enclosed letter in the stamped, addressed envelope I have included. **The letter must reach Medicare and Medicaid no later than Friday Aug. 31st.**

If you have any questions, please call us at the office at #641-892-4008. Thank you for your time.

Sincerely,

Anna M. Clausen, DC

August 21, 2007

Santa Barbara County Fire Department
4410 Cathedral Oaks Road
Santa Barbara, CA 93110

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

RE: "BENEFICIARY SIGNATURE, Proposed change Section 424.36

The Santa Barbara County Fire Department operates an emergency ambulance service within it's jurisdiction. The Department compliments CMS for attempting to improve the authorization process by which providers are allowed to bill for emergency services. However, we believe the present proposal adds additional complications to an already burdensome process. Therefore the Department recommends against adoption of the proposed change for the following reasons.

1) The proposed change is presented as a sympathetic effort to provide ambulance providers with an additional option for obtaining authorization in the absence of a beneficiarity signature. However, the proposed change does not remove previous requirements but only adds the additional requirement of obtaining a signature from a receiving facility. This adds an additional requirement to an already burdensome process performed during delivery of emergency medical care to an injured or ill patient.
2) The proposed change implies that the emergency treatment process stops when the patient is delivered to the treatment facility. The real circumstances of emergency medical care is that when a patient is delivered to a treatment facility, the personnel of that facility take over the patient's emergency care. The projected 5 minute time period for obtaining a signature is not realistic since the treatment facility personnel are usually committed to providing continuing care to the patient. Assisting with ambulance provider authorization becomes a low priority.
3) Upon delivery of the patient to the treatment facility, the priority of the ambulance provider is to return the ambulance to its service area, which is often quite distant. A requirement to stay at a treatment facility, waiting for a signature, will slow down a return to it's service area.
4) The proposed change requires the ambulance provider to obtain a signature from the treatment facility contemporaneous to delivery of the patient. The proposed change does not require the treatment facility to provide such a signature. As indicated above, provision of such a signature will not be a priority of the treatment facility and will likely have the unintended consequence of degrading the timely recovery of the ambulance response capability.

In closing, the Santa Barbara County Fire Department recommends not adopting the recommended change to Section 424.36. If you have questions concerning the Department's position and understanding of this issue, please contact Bill Turpin of the Department's ambulance billing section at the above address or by telephone at 805-681-5520 or by email at bill.turpin@sbcfire.com.

Sincerely, Bill Turpin,Departmental Assistant

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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

Dear Mr. Weems:

Patients should have the ability to make a choice on who provides their medical care. This being said, Physicians are highly influential in directing patient's in their health care decisions and if it is profitable for a physician to refer to his own Physical Therapy practice, why would he not direct his/her patient toward his own Physical Therapy practice.

I am writing this letter in opposition of the Stark Law loophole. This loophole has allowed physicians to benefit from referrals. It has limited Physical Therapist in some cases to practice independently from physicians.

In this states, the physician's lobbyist have made it difficult for Physical Therapist to pass rules that would limit the relationship between physicians and Physical Therapist. I think the only way to limit this abuse is if the CMS would limit funding for this type of relationship. Shutting down the loophole would benefit the patients by creating more choices from which the patient could receive care and it would improve competition between Therapist's trying to gain that patient's business.

Thank you for listening to our concerns.

Sincerely,

Matthew Mills, PT

820

REHAB ASSOCIATES
OF CENTRAL VIRGINIA

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

RE: Physician Self Referral Issues

Dear Dr. Weems,

I am writing this letter to you concerning the changes that will be discussed in the CMS regarding the proposed policies under the Physician Fee Schedule, specifically the issues surrounding physician self-referral and the "in-office ancillary services" exception. My name is Heather Walling. I am a Doctor of physical therapy and a Certified Strength and Conditioning Specialist who has been practicing since 2005. As a practicing clinician in a private orthopedic physical therapy setting, I witness the abuse of the STARK II "in office ancillary services" exception on a regular basis. This exception which allows for the self referral of physical therapy patients by the physician to his/her own physical therapy clinic is not only unethical for the field of physical therapy and the physical therapist, but most importantly, it is unethical for the patients who need such services.

First and foremost, the exception allowing for self referral infringes on the right of every patient. According to the laws written in the Coalition for Patient's Rights, it is the patient's right to choose where they would like to receive their health care services, specifically physical therapy in this case. Unfortunately, with the current STARK II laws, this right to choose is often biased by the referring physician if they are associated with a physician owned physical therapy clinic. On several occasions, patients have told

me that even after stating where they would like to go to therapy, the physician will still try to direct them to their own physical therapy clinic. It is only when the patient is adamant that they can receive PT care where they have requested.

On another occasion, I have even seen former patients out in public with another injury and in passing conversation they inform me that they tried to come to physical therapy with me again but their doctor thought it would be better to go to the physical therapy clinic in his own building. They reported that the doctor said he would be able to keep a "better eye" on the patient's therapy if she went to therapy in his own office; however, the physician does not state that they will not be attending or actually see the patient individually in any of the therapy sessions. This type of advertising gives the patient a misperception of getting better care and often persuades them to go easily to the clinic being suggested by the referring physician.

I have also had incidents where I have been providing physical therapy services for a patient up until their surgery and then, following the surgery, the patient will be sent to the physician's own clinic. When a phone call was made to check on the patient following surgery, the patient informed me that his doctor wanted him to receive therapy at his own physical therapy clinic since it would be easier for the doctor. When asked about the physician's satisfaction with progress prior to the surgery, the patient replied that he was very satisfied but, just wanted him to change places in order to keep up with his progress better after surgery since the therapy office was in his building. These occurrences are absolutely unethical and definitely unacceptable. These are just a few of the abusive situations I have encountered in my two years practicing as a physical therapist. I feel that it is my responsibility to take up for my patients and make these incidents known to those that have the power to make the changes that will decrease the incidence of biased and abusive healthcare.

In general, the patient looks to his/her doctor as a person to give them unbiased advice regarding the best and most appropriate healthcare intervention and choices. Nine times out of ten, the patient puts their trust in the doctor's recommendations and wants to please the doctor. They often want to do what the doctor deems best. This becomes a problem when the doctor decision is biased by possible individual financial gains versus being a decision based entirely on what is best for patient care. With a financial incentive involved, it can be easy for a physician to fall into the habit of referring in house even when better services and care can be provided to the patient by another clinic. The law not only requires the physician to give the patient a choice of where to receive physical therapy care but also requires them to inform the patient that by sending them to their in house clinic they will be receiving financial gains, which has been rarely revealed to the patient according to patient report.

With the current need for a physician referral to provide physical therapy services, private clinics are at the discretion of the physician for referrals. With the incidence of POPTS quickly escalating and resulting in the quick rise in the incidence of self-referral, the referring of patients to physical therapy becomes grossly biased whether it be unconscious or intentional. What does that do for the field of physical therapy? It impedes the growth of physical therapy as an autonomous profession and infringes on the rights of those that needs such services, the patient.

Research has shown that physician owned clinics tend to over bill and over utilize physical therapy services, which can be attested to the financial gains that are associated with physician self referral. With such over utilization of physical therapy services the

patient is affected, the insurance company is affected, and the field of physical therapy as an autonomous profession is affected. If a physician sends a patient to their own physical therapy clinic first instead to the necessary specialty clinic and the patient ends up coming to the specialty clinic weeks later, then the plan of care for the patient will be significantly longer leading to unnecessary physical, emotional, and financial costs to the patient. These unnecessary costs could have been avoided if the appropriate referral was initially made to the clinic that would provide the patient with the best quality of care. If fraudulent behavior continues to occur with over billing and over utilization of physical therapy services, then insurance companies will continue to pay less and the patient will suffer with higher co-pays and out of pocket pay for health care services.

I urge you to please help protect the patient's right to choose where they believe they can get the best healthcare and limit the abuse and fraud brought about by the STARK II "in-office ancillary services" exception. Those patients who have a passive personality suffer the most. They do not take up for their rights and most are not even aware of them, therefore it is up to the rules and regulations to make sure that those rights are not being abused by others. It is my hope, with your help we can make these incidents known to those in power to make the appropriate changes in order to protect the patient, decrease the incidence of abuse and fraud, and offer the most unbiased healthcare services possible to all patients in need of physical therapy services.

Thanks you so very much for your time, reflection, and consideration in this important matter.

Sincerely,

Heather M Walling PT, DPT, CSCS

Heather M Walling PT, DPT, CSCS

821

REHAB ASSOCIATES
OF CENTRAL VIRGINIA

Patricia M. Strain P.T.A
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Mr. Kerry N. Weems
Adminster- Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

RE: Physician Self Referral Issues

Dear Mr. Weems,

My name is Patricia Strain and I am a physical therapist assistant. I have worked in a privately owned specialty physical therapy clinic for over a year and have treated patients of all ages and diagnosis. I am writing you today regarding the potential changes going to be discussed in the CMS on the subject of proposed policies under the Physician Fee Schedule. Specifically, the issue surrounding physician self referral and the "in office ancillary services" that currently creates an abusive referral arrangement.

Within the last year, I have witnessed various examples of how patients are being directed toward physician owned physical therapy clinics. On more than one occasion, a patient has gone back to the doctor and has been sent to the Physician Owned Physical Therapy Clinic for no apparent reason. Patients have been seen up until surgery and then referred to the physician owned physical therapy clinic, once again for no good reason. Physicians tend to persuade patients to in house therapy by claiming he/she could keep a closer watch on them. In the end the physician was never present during one therapy treatment. In fact, it is not more convenient, cheaper or more time efficient to obtain healthcare in a physician's office compared to an independently owned practice due to the repetitive nature of physical therapy.

Most patients are referred to physical therapy by their primary care physician or an orthopedic doctor. Every patient should have the right to request where they will receive physical therapy. To hinder that right is unethical and contradicts the laws written in the Coalition for Patient's Rights, which protects the rights of the patient to choose where they would like to receive health care services. Patient's right to choose where to receive physical therapy in this case should always be protected, just like any other freedom offered in this country. Under the current STARK II laws, the ability to refer is more often then not biased by physician self referral of physical therapy patients to their own physical therapy clinic.

I am asking you today to please consider these issues in order to help protect the patient's right to choose where one feels they can receive the best and most impartial healthcare available. I would like to see the most appropriate change made to help protect the patient's freedom to choose and to avoid biases in healthcare.

Thank you for your time and consideration.

Sincerely,

Patricia Strain, PTA

822

701 Southwest 71st Avenue, North Lauderdale, Florida 33068-2395
954-722-0900 Fax 954-720-2151 www.nlauderdale.org

August 30, 2007

Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
P.O. Box 8012
Baltimore, Maryland 21244-8012

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

Dear Ms. Norwalk:

The City of North Lauderdale provides emergency ambulance services to our residents. The proposed rule would have a severely negative direct impact on our operation and the high quality health care we provide to Medicare beneficiaries. In addition, we believe this proposed rule will inappropriately provide incentives to seek signatures from patients who are in need of medical care and under mental duress. Additionally, this proposed rule would have a negative impact on wait times in the emergency room impacting our operations and the operations of emergency rooms throughout the country. We therefore urgently submit comments on ills of the proposed rule.

In summary, here are the points we would like you to consider:

- Beneficiaries under duress should not be required to sign anything;
- Exceptions where beneficiary is unable to sign already exist and should not be made more stringent for EMS;
- Authorization process is no longer relevant (no more paper claims, assignment now mandatory, HIPAA authorizes disclosures);
- Signature authorizations requirement should be waived for emergency encounters.

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

Thank you for your consideration of these comments.

Sincerely,

Jack Brady

Mayor Jack Brady
City of North Lauderdale

Cc: Richard D. Sala, City Manager
Sam Goren, City Attorney
Lou Cavallo, Public Safety Director
Kevin Bowen, Fire Chief

823

FEDERATION OF ASSOCIATIONS
OF REGULATORY BOARDS
1603 Orrington Avenue
Suite 2080
Evanston, IL 60201
847-328-7909
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www.farb.org

August 31, 2007

Via E Mail only
Administrator (www.cms.hhs.gov/eRulemaking)
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-1850

Re: CMS-1385-P Therapy Standard and Requirements
Comment to Proposed Regulations

To Whom It May Concern:

On behalf of the Board of Directors of the Federation of Associations of Regulatory Boards (FARB), I am writing to comment on the above-referenced proposed rule change regarding the qualification standards for physical therapists and physical therapist assistants. We are in receipt of the Proposed Physical Therapy Rule, 72 Federal Register 38230-28831 (July 12, 2007) (hereinafter referred to as the Proposed Rule) and provide the following comment.

FARB was incorporated as a not-for-profit corporation in 1974 and has continuously operated as an association recognized as exempt by the Internal Revenue Service from federal taxation as a charitable entity under Section 501(c)(3) of the Internal Revenue Code. FARB develops and operates programs that assist its members in fulfilling their statutory responsibilities to regulate their respective professions in the interest of protecting the public. The tax status and mission statement of FARB allow it to seek and maintain members that consist of associations of regulatory boards and the state and provincial regulatory boards which operate in the interest of public protection.

By virtue of its membership and tax status, FARB, as an association of associations of regulatory boards, does not engage in lobbying or other activities that its member regulatory boards, individually, could not undertake. FARB and its membership are distinguished from professional associations whose membership consist of practicing professionals and which promote, among other things, the economics of the profession and the professionals. This distinction is essential to understanding and differentiating between professional promotion and public protection. It is this distinction and the dangerous precedent within the Proposed Rule of delegation to and reliance upon a professional association in determining eligibility of an individual professional to receive CMS benefits that prompts this correspondence.

FARB Full members consist of associations of regulatory boards. Currently, there are thirteen Full member associations of regulatory boards relating to the regulation of the professions of accountancy, architecture, veterinary medicine, optometry, social work, chiropractic, physical therapy, funeral services, long term care administrators, pharmacy, massage therapy, and nursing (including the regulatory organizations in both the United States and Canada). Many of the FARB Full members provide uniform licensing examinations used by their member regulatory boards in determining minimum competence as one criterion of licensure eligibility in furtherance of public protection.

FARB Associate members consist of the individual state, provincial or jurisdictional regulatory boards statutorily empowered to regulate the profession through a licensure process. These regulatory boards are statutorily created and empowered to enforce the practice acts in the interest of public protection.

The FARB Mission is to promote excellence in regulation for public protection by providing expertise and innovation from a multi-professional perspective. It is with this perspective that FARB submits the following comments on the Proposed Rule that would change the definition of "physical therapist" in Section 484, Title 42 of the Code of Federal Regulations. The Proposed Rules is part of the 2008 Proposed Revisions to Payment Policies under the Physician Fee Schedule and Other Part B Payment Policies for Calendar Year 2008, found in Volume 72 of the Federal Register, published on July 12, 2007.

Under subsection (i)(B) and (ii)(B) of the proposed definition of "physical therapist," an applicant, to be eligible for CMS benefits/reimbursement for physical therapy services provided to a patient, is required to have "[p]assed the National Examination approved by the American Physical Therapy Association." The American Physical Therapy Association (APTA) is a professional association whose membership consists of individuals duly licensed by each respective state. Indeed, the APTA bylaws require its members that wish to be in good standing to not be under suspension or revocation by any licensing jurisdiction. The primary purpose of the APTA is to represent and promote the profession of physical therapy. (See APTA Bylaws Article II, Object. See: www.apta.org). While FARB understands that ancillary public protection benefits that may result from the activities of a trade association and does not wish to underestimate or downplay such a point, our comments herein are intended to voice support for recognition of the existing state based licensure system that exists for the profession of physical therapy, and so many other professions affecting the public health and welfare.

The APTA, as an advocate for the profession as a whole and for physical therapy professionals, may make decisions that are in the best interest of the professionals, even when such may be in conflict with what would best protect the public health and welfare. In identifying eligibility criteria that must be satisfied in order to qualify for benefits, CMS reliance upon and delegation to a professional association whose membership and mission are not driven by or beholden to the public protection mandates of a state-based licensure system is the impetus behind the submission of this letter on behalf of the FARB membership. The perils of vesting such authority with the professional association, an organization comprised of competing professionals, are obvious.

In order to promote public protection, it is recommended that CMS recognize the state-based licensure system already in existence and rely upon the statutory protections contained in state law. State legislatures have exercised their authority to regulate various professions by enacting practice acts which protect the public and are drafted with an eye toward the local issues regarding the profession and the public they serve. The creation by CMS of a mechanism other than the state-based licensure system for determining eligibility for benefits and reimbursement not only undermines the licensure systems already in place, but may be fraught with legal and practical issues at both the state and federal levels. These issues are magnified with the unfettered reliance upon a professional association. Finally, such reliance upon a professional association is unprecedented in that CMS relies upon state based licensure regarding eligibility benefits in human medicine, nursing, and others. (For example, CMS regulations define a physician as a "doctor of medicine ... legally authorized to practice medicine and surgery by the State in which such function or action is performed." See 42 C.F.R. § 484.4 (2006))

It is FARB's position that subsections (i)(B) and (ii)(B) of the definition of "physical therapist" be either deleted from the final rule or modified to rely upon the fact that an individual is currently licensed and in good standing as a prerequisite to eligibility. State licensure in any relevant profession for purposes of CMS eligibility determinations provides both CMS and the public with effective assurances of minimum competency and an unbiased commitment to public protection. Furthermore, state licensure provides a mechanism to hold the relevant professional accountable for maintaining appropriate competencies and following all applicable laws related to the practice of their profession.

The states, without exception, have enacted laws which promote uniformity in addressing the essential public protection elements upon which all regulatory schemes rely. FARB supports the use of the national qualifying exam for physical therapists, the National Physical Therapy Examination ("NPTE"), which is currently used in the licensure process of all United States jurisdictions. Under recognized examination development principles to ensure defensibility and reliability, the Federation of State Boards of Physical Therapy ("FSBPT") develops and administers the NPTE in close collaboration with its member state boards of physical therapy. The NPTE is provided to member boards as a minimum competence indicator to be used as part of the licensure process. Successful completion of the examination is a prerequisite to licensure and the government granted authority to practice the profession.

The licensure of the various professions has traditionally been a role reserved for the states. As evidenced in other sections of CMS regulations, CMS respects states' rights and defers to the state licensure process with regard to other health care professionals. The Proposed Rule fails to explain why recognition and deferral to the regulatory systems currently in place in the several states is acceptable for other professions but not for physical therapy. The attempt to federalize a state function seems inconsistent in the treatment of physical therapists as opposed to other health care professionals.

As stated in the preamble to the Proposed Rule, CMS is committed to uniformity in the application of its rules and regulations. FARB supports such a commitment. Such uniformity and consistency in the licensure process is in place to a great degree across the United States in the professions represented by the FARB Full members. State licensing requirements apply regardless of the location of practice. Not only do the state regulatory boards rely on national licensing examination programs, but they rely on accrediting bodies regarding recognition of educational criteria for both United States and foreign educated applicants. These examination and accreditation programs currently assist the regulatory boards in achieving an effective level of uniformity while at the same time respecting the rights of the states to oversee such programs to ensure that they adequately respond to and protect the health and welfare of their own citizens. The Proposed Rule has the potential to negatively impact this pursuit of uniformity. Non-recognition of a state-based licensure system, which the Proposed Rule would permit, could cause substantial confusion and potential interruption of service.

FARB strongly urges CMS to recognize state licensure as a prerequisite to eligibility for reimbursement. Most importantly, subsection (i)(B) and (ii)(B) of the definition inappropriately vest recognition authority in the professional association and potentially undermine the fundamental principle of state-based licensure. FARB suggests modifications to these subsections to recognize licensure criteria enforced by the statutorily created and empowered state boards of physical therapy. If it is not possible to undertake such changes at this time, FARB asks that CMS delay promulgation of the Proposed Rule until CMS has had an opportunity to further investigate the examination, credentialing, and licensing processes currently in place.

We appreciate the opportunity to comment on the Proposed Rule. Please feel free to contact me should you have any questions with regard to the comments provided herein. We would be happy to answer any questions or provide you with further information.

Sincerely,

Dale J. Atkinson
Executive Director

Cc: FARB Board of Directors

Texas Board of Physical Therapy Examiners

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~~CMS-~~ 1385-P
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August 24, 2007

Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-1850

Re: CMS-1385-P
Therapy Standards and Requirements

Dear Sir or Madam:

The Texas Board of Physical Therapy Examiners ("TBPTE") submits the following comments on the proposed rules changing the definition of "physical therapist" in Section 484, Title 42 of the Code of Federal Regulations. The proposed rules are part of the 2008 Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for Calendar Year 2008, found in Volume 72 of the Federal Register, published on July 12, 2007.

Specifically, under subsection (i)(B) and (ii)(B) of the proposed definition of "physical therapist" an applicant would need to have "[p]assed the National Examination approved by the American Physical Therapy Association." We strongly suggest that CMS rely on currently established state licensure procedures that are included in state statutes and that the additional examination requirements contained in subsections (i)(B) and(ii)(B) of the definition of "physical therapist" be deleted from the final rule.

We ask that the following facts be considered as support for our request.

- Recognizing the conflict of interest that the American Physical Therapy Association ("APTA") as an advocacy group for the Physical Therapy profession would have if it were to have authority over the examination and credentialing processes, the APTA created the Federation of State Boards of Physical Therapy ("FSBPT") two decades ago to eliminate, protect against and prevent this inherent conflict of interest.
- The FSBPT develops and administers the National Physical Therapy Examination ("NPTE") for both physical therapists and physical therapist assistants in close collaboration with the state boards.
- The FSBPT has received both Stage One and Stage Two Accreditation from the Buros Institute for Assessment Consultation and Outreach ("BIACO") following a rigorous evaluation of NPTE test development, administration, and security practices.
- Uniformity and consistency across the nation and across provider settings already exists since all state licensing authorities have adopted the NPTE to assess the basic entry-level competence for first time licensure or registration as a PT or PTA, and have adopted the FSBPT's criterion-reference passing point so that the minimum passing score is the same in all jurisdictions.
- Through the NPTE, we are able to ensure that only qualified individuals who successfully demonstrate the minimal knowledge, judgment, technical skills, and interpersonal skills that are required for the provision of safe and effective patient care are licensed within our state.

- If the APTA were to approve a different exam than the NPTE, the possible creation of a two-tiered examination system (one exam for state licensure, one to qualify for Medicare reimbursement) would create an unwarranted administrative burden on the jurisdictions, substantial confusion for our licensees, and potential interruption of service to the consumer public as they become Medicare or Medicaid eligible.

The licensing and credentialing of physical therapists and physical therapist assistants are within the domain of the states. CMS currently respects these states' rights and recognizes state licensure as the standard for other health care professions, and it should continue to do so with respect to the physical therapy profession. For example, CMS' regulations define a physician as a "doctor of medicine ... legally authorized to practice medicine and surgery by the State in which such function or action is performed." 42 C.F.R.§ 484.4 (2006). Likewise, a registered nurse is defined as "[a] graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing." 42 C.F.R. § 484.4. Establishing requirements that are different than the stringent standards that the states already require for licensing PTs would be inconsistent with not only the rights of the states, but also CMS' own standards.

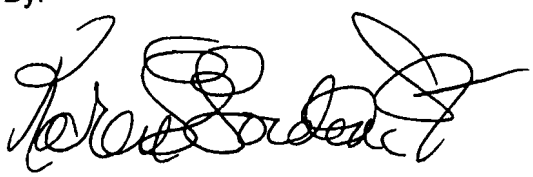
The Texas Board of Physical Therapy Examiners strongly urges CMS to require only state licensure as the criterion. Most importantly, CMS should remove the additional examination requirements contained in subsections (i)(B) and (ii)(B) of the definition of "physical therapist." At a minimum, CMS should delay promulgation of the proposed rule until CMS has had an opportunity to review and to understand the examination, credentialing, and licensing processes that are currently in place in all of the states.

We appreciate the opportunity to comment on the proposed rules regarding physical therapist and physical therapy assistant qualification requirements.

Respectfully yours,

The Texas Board of Physical Therapy Examiners

By:



Karen L. Gordon, PT
Chair, TBPTE

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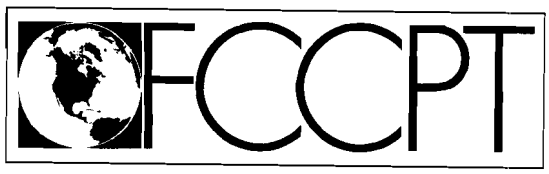

August 31, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-1850

Re: CMS-1385-P
THERAPY STANDARDS AND REQUIREMENTS

Dear Sir or Madam:

I write on behalf of the Foreign Credentialing Commission on Physical Therapy ("FCCPT"). The FCCPT is a non-profit organization created to assist the U.S. Citizenship and Immigration Services ("USCIS") and U.S. jurisdiction licensing authorities by evaluating the credentials of foreign-trained physical therapists ("PTs") who wish to work in the United States. The USCIS under 8 C.F.R. § 212.15(e) specifically identifies the FCCPT as one of two bodies responsible for credentialing foreign-trained PTs who want to immigrate. Our mission is to protect the public through the proper evaluation and authentication of foreign credentials.

We submit the following comments regarding the rules proposed by the Centers for Medicare and Medicaid Services ("CMS") to amend 42 C.F.R. § 484.4 with regard to the definition of "physical therapist" and "physical therapist assistant." The proposed rules were published by CMS in 72 Federal Register 38230-38231 (July 12, 2007). These comments are submitted on a timely basis.

According to the proposed rules, besides meeting state licensure requirements, foreign-trained PTs and physical therapist assistants ("PTAs") beginning their practice on or after January 1, 2008, would be required to undergo a credentialing process approved by the American Physical Therapy Association ("APTA").[1] We disagree with the proposed rules.

The USCIS has authorized only two entities to perform credentialing for PTs, the FCCPT and the Commission on Graduates of Foreign Nursing Schools ("CGFNS"). The states, under their licensing authority, then utilize the information for their decision-making. Therefore, we strongly urge CMS to defer to existing federal process and also respect the choice the states have made by removing the foreign credentialing requirements contained in subsection (1)(ii)(A) for PTs of the proposed regulations. CMS should instead defer to the states in deciding health care professional credentialing, as it traditionally has, and permit reimbursement of PT and PTA services to those qualified under the applicable state's credentialing requirements.

[1] Section (1)(ii)(A) of the definition of "physical therapist" under the proposed rules.

FOREIGN CREDENTIALING COMMISSION ON PHYSICAL THERAPY, Inc.
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If finalized, the proposed rules would therefore impose a second credentialing process for foreign-trained PTs. According to current federal regulations, the Department of Homeland Security ("DHS") has not included the APTA in the list of credentialing organizations.[2] Consequently, under CMS' proposed regulations, applicants would have to undergo FCCPT or CGFNS credentialing to qualify for entry into the United States *and* APTA credentialing to be eligible for Medicare reimbursement. We strongly urge CMS to consider the ill effects that the inconsistency between the USCIS and the CMS rules would create. There is no reason or justification for a dual and duplicative system.

For foreign-trained PTAs, CMS should leave the current regulations unchanged and take the issue under advisement. There are no foreign PTA programs; it is a U.S. concept. PTAs do not qualify for entry into and employment in the U.S. under existing H1-B work visa standards.

At a minimum, CMS should study the issue of foreign credentialing more closely. If CMS is not prepared to act on the FCCPT's recommendations at this time, the proposed rules regarding professional qualifications should be removed from the fee schedule regulations and delayed until CMS has an opportunity to fully understand the credentialing processes currently available and in use.

The States, and not the Federal Government, Should Decide the Qualification Standards for Admitting Foreign-Trained PTs and PTAs.

The proposal by CMS that foreign-trained PTs undergo a credentials evaluation process approved by the APTA improperly replaces the judgment of the state licensing boards with that of the APTA. The proposed rule's usurpation of state authority over this aspect of the licensure of foreign-trained PTs and PTAs is inappropriate. Licensure of health care professionals is a classically state function, and CMS should continue to respect the rights of the states. CMS has not cited any evidence indicating that the states have failed in their duty to properly screen foreign-trained PT and PTA applicants. CMS should therefore continue to defer to the states in setting the standards required for the practice of physical therapy, as it does with respect to other health care professions. CMS should not, on an issue traditionally reserved for the states, summarily supplant the authority of the states without sufficient justification.

APTA Oversight of Foreign Credentialing Conflicts with Existing Federal Immigration Laws.

The attempt to vest the APTA with authority and responsibility over foreign credentialing ignores the existing credentialing process available to foreign-trained PTs and established by another cabinet-level Department of the United States government. The APTA does not evaluate the credentials of foreign-trained PTs. In fact, the USCIS has authorized only the FCCPT and the CGFNS to perform this credentials review for PTs and to issue certifications to those who are qualified for entry into the United States.[3] This authority is derived from DHS regulations requiring that any alien seeking admission as an immigrant or nonimmigrant for the primary purpose of working in certain health care occupations present a certificate from a credentialing organization found in the DHS' approved list.[4] With respect to PTs, the approved credentialing organizations consist only of the FCCPT and the CGFNS.[5] The DHS has not included the APTA in its approved list. Because this credentialing process has been established and

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[2] See 8 C.F.R. § 212.15(e).

[3] A foreign credentialing process has not been established for PTAs. We assume this is due to the lack of any PTA training programs outside the United States. Should a need arise, however, the process currently used for PTs can be adapted to PTAs. Certainly, a simple adaptation would be easier, faster, and less expensive than having to create an entirely new process, such as what the APTA would have to do.

[4] 8 C.F.R. § 212.15.

[5] *Id.*

relied on not only by the states, but also by federal authority and regulation, there is clearly no need for CMS to create a rule requiring another credentialing procedure.

The Proposed Rules Add a Duplicative Credentialing Requirement, Thus Creating Waste and Undue and Unnecessary Burdens.

Since the proposed rules do not consider the currently available and currently used foreign credentialing process, the proposed rules in effect require applicants to satisfy two credentialing processes to qualify for Medicare reimbursement. They would require states to utilize two credentialing organizations, and defer to one that does not even exist. This would place an extraordinary burden on the states to examine, understand, comment on and interpret a second process that would only duplicate the process currently in place – as required by DHS. For years, the state boards have effectively relied on the credentialing process provided by the FCCPT. There is no need to invent a new credentialing process for foreign-trained PTs. Requiring the devotion of precious resources, expense, and effort to a task and a goal that have already been and continue to be achieved by the FCCPT would simply be wasteful, would not serve the public's interest, and would create undue and unnecessary burdens upon the states and PTs.

The proposed rule will worsen the shortage of available PTs with no benefit to public health.[6] Having to undergo credentialing twice could effectively deter foreign-trained PTs from practicing in the United States or at least from seeing Medicare or Medicaid patients. Any regulation that could inhibit the entry of high quality PTs into the United States would likely aggravate the shortage and impose unnecessary obstacles to the treatment of patients.

CMS has not expressed or demonstrated any reasons for concern over the credentials of foreign-trained PTs. Instead, CMS' goals are to update the regulations and make them uniform across the nation. The state PT licensing boards have already achieved these goals for CMS. Thus, CMS should defer to the states. Although CMS could promulgate rules that mirror the USCIS regulations (and the FCCPT would accept and welcome that approach), there does not appear to be a regulatory need.

The Proposed Approval by the APTA of Foreign Credentialing Would Create an Inappropriate Conflict of Interest and Undermine Federal Antitrust Laws.

CMS' proposed approval by the APTA of credentialing of foreign-trained PTs places the APTA in the inappropriate position of being an advocate for its members and simultaneously a gatekeeper to the profession. As a professional organization, the APTA advocates for PTs. Its goals are to promote the profession and to protect the professional, economic and other interests of its members, licensed PTs. Given that APTA's charge is to advocate for its members, it would have an incentive to establish or approve a credentials review process that is designed to limit or control the number of competitors entering the marketplace to compete with, and thereby commercially harm, its members. The effect of this could easily be to limit the supply of licensed PTs and concomitantly to increase the costs to the Medicare and Medicaid programs as well as other patients seeking PT services.

The antitrust risks associated with the erection of such anticompetitive barriers to entry are very real and have long been recognized by the federal courts.[7] CMS should be vigilant to prevent such risks and avoid placing any organization in an antitrust and conflicted predicament.

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[6] *See Study Sees Dearth of Doctors for Elders*, THE BOSTON GLOBE, Nov. 24, 2002, *available at http://nl.newsbank.com/nl-search/we/Archives?p_action=print* (last visited Aug. 16, 2007).

[7] *See, e.g., Welch v. American Psychoanalytic Ass'n.*, No. 85 Civ. 1651, 1986 U.S. Dist. LEXIS 27182 (S.D.N.Y. 1986) (recognizing antitrust risks presented where a professional association in control of professional accreditation and admissions standards has a commercial motive).

In fact, the federal immigration regulations governing credentials review require that uncertified foreign health care workers be certified by an "***independent*** credentialing organization..."[8] To qualify as a credentialing organization under federal regulations, certifying organizations must be "***independent of any organization that functions as a representative of the occupation or profession in question*** or serves as or is related to a recruitment/placement organization."[9] Moreover, these regulations preclude DHS from approving an organization "that is unable to render impartial advice regarding an individual's qualifications regarding training, experience, and licensure." This standard of independence is critical for the sanctity of the process and protection of the public. CMS should adopt and utilize the same requirement.

The APTA itself has recognized that as a professional organization whose mission is to protect the interests of its members, its oversight of the licensing process constituted an inherent conflict of interest. Two decades ago, the APTA had responsibility for administering the national licensing examination for PTs. But the APTA formally transferred that function to the Federation of State Boards of Physical Therapy ("FSBPT") in October 1989. At the time of this transfer, it was envisioned that the FSBPT, in contrast to the APTA, would function as a stand-alone entity whose ultimate responsibility was to protect the public and to ensure that candidates for licensure meet standards of competency. The APTA, on the other hand, would be free to continue to advocate for its members. Thus, vesting the APTA with authority over the credentialing process of foreign-trained PTs would place the APTA in the same conflict-of-interest position it was in twenty years ago and which it ensured in 1989 it would avoid. CMS should not put the APTA in this conflicted situation.

Conclusion and Recommendations.

CMS needs to better understand that a well-established credentialing process currently exists for foreign-trained PTs that has been approved by the USCIS and managed well by the states. We strongly recommend that CMS remove those aspects of the proposed rules that vest authority in the APTA to approve the foreign credentialing process for PTs and PTAs. CMS should instead defer to the states for licensure. Credentialing of health care professionals is a classically state function, and CMS has not demonstrated any failure by the states in this regard that would warrant imposition of federal guidelines.

Under long-established regulations of USCIS, the FCCPT and CGFNS are the credentialing organizations for foreign-trained PTs. CMS should ensure that the Medicare and Medicaid regulations do not contradict other law and do not create redundant, but resource-intensive, requirements. CMS should not impose unnecessary rules that could create harm by exacerbating the shortage of PTs. Additionally, the proposed rule would not enhance the health and welfare of the public at large or Medicare or Medicaid patients since credentialing of foreign-educated PTs is performed by nationally recognized and widely accepted organizations.

If CMS is not prepared to act on the FCCPT's recommendations at this time, the proposed rules regarding professional qualifications should be removed from the fee schedule regulations and delayed until CMS has adequately examined the credentialing processes currently available and in use. There is no reason to rush to regulate.

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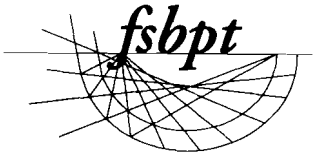
[8] *See* 8 U.S.C. § 1182(a)(5)(C).
[9] See 8 C.F.R. §212.15 (k)(1)(ii) (A) -(D).

Thank you for the opportunity to comment on the proposed PT and PTA qualifications. We look forward to your kind consideration.

Respectfully yours,

Eileen C. Bach
Chair



August 31, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-1850

Re: CMS-1385-P
THERAPY STANDARDS AND REQUIREMENTS

Dear Sir or Madam:

I write on behalf of the Federation of State Boards of Physical Therapy ("FSBPT") to submit the following comments regarding the rules proposed by the Centers for Medicare and Medicaid Services ("CMS") to amend 42 C.F.R. § 484.4 – specifically, the definition of "Physical therapist" and "Physical therapist assistant." The proposed rules were published by CMS in 72 Federal Register 38230-38231 (July 12, 2007), and these comments are submitted on a timely basis.

The FSBPT develops and administers the national licensing exam for physical therapists and physical therapist assistants. Our licensing exam, the National Physical Therapy Exam ("NPTE"), is recognized and used by our 53 member jurisdictions – the 50 U.S. states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands – to assess candidates for licensure and to ensure that licensed physical therapists ("PTs") and physical therapist assistants ("PTAs") satisfy basic standards of entry-level competence. Our primary mission is to assist these licensing jurisdictions to protect the health, safety and welfare of the public by identifying and promoting desirable and reasonable uniformity in physical therapy regulatory standards and practices. I am the President of the FSBPT. I am also a member of the American Physical Therapy Association ("APTA").

We are troubled by three aspects of the proposed regulations: the APTA approval of a licensing examination; APTA approval of foreign credentialing; and limitation of curriculum approval to only the Commission on Accreditation in Physical Therapy Education ("CAPTE"). While we join CMS in the desire to ensure quality health care, the proposed rule unnecessarily and improperly supplants the autonomy and authority of the state licensing boards and places unnecessary burdens on the states, the profession and patients, as well as undermining existing federal immigration and antitrust laws and proposing to create a monopoly for curriculum approval.

FEDERATION OF STATE BOARDS OF PHYSICAL THERAPY
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http://www.fsbpt.org

I. APTA Approval of the National Licensing Exam, Foreign Credentialing, and Educational Accreditation is Inappropriate and Unnecessary.

The proposed rules are problematic to the extent they attempt to vest authority over the national licensing exam, credentialing for foreign-educated PTs, and educational accreditation with the APTA, the professional trade association of PTs and PTAs. Because APTA is an advocacy group dedicated to benefit its members, it should not be vested with such approval to govern professional qualifications or the state government determinations. It is inappropriate to transfer the authority of the states over these issues to a professional advocacy organization. In fact, it is our understanding that the APTA itself recognizes that its approval of at least the national exam is inappropriate and intends to submit comments to CMS to this effect.

The most troubling aspects of the proposed rules relating to physical therapy are that:

1. PTs beginning their practice on or after January 1, 2008, would have to pass a national exam *approved by the APTA*. (Sections (1)(i)(B) and (1)(ii)(B)). This proposed requirement is in addition to the existing requirement that PTs meet the practice requirements of the state in which the physical therapy services are furnished, which already includes a national exam with national passing score standards.

2. Foreign-trained PTs and PTAs beginning their practice on or after January 1, 2008, would be required to undergo a credentialing process *approved by the APTA*. (Section (1)(ii)(A) of the definition of "physical therapist" and Section (1)(ii) of the definition of "physical therapist assistant"). Again, for PTs, this requirement is in addition to the existing obligation to satisfy state practice requirements. There are no foreign training programs for PTAs; so the requirement does not make sense.

3. U.S.-trained PTs beginning their practice on or after January 1, 2008, would be required to graduate from a physical therapy or physical therapist assistant curriculum *approved by the Commission on Accreditation in Physical Therapy Education ("CAPTE"), a division of the APTA*. (Section (1)(i)(A) of the definition of "physical therapist" and Section (1)(i) of the definition of "physical therapist assistant"). This proposal is too limiting.

For the reasons set forth in more detail below, we strongly suggest that, with respect to each of these issues, CMS defer to state licensure requirements. In our view, the examination requirements contained in subsections (1)(i)(B) and (1)(ii)(B), the foreign credentialing requirements contained in subsection (1)(ii)(A), and the educational accreditation requirement contained in Section (1)(i)(A) under the definition of "physical therapist" should be deleted from the final rule. Similarly, the foreign credentialing and educational accreditation requirements contained in subsections (1)(i) and (ii) under the definition of "physical therapist assistant" should be deleted. Instead, and as is the case for most other health care professions, CMS should defer to the states' authority over such issues, permitting Medicare and Medicaid reimbursement to PTs and PTAs who satisfy the respective states' licensure and certification requirements.

At a minimum, CMS should study the issues of professional licensing and qualification standards more closely. If CMS is not prepared to act on the FSBPT's recommendations at this time, the proposed rules regarding professional qualifications should be removed from the fee schedule regulations and delayed until CMS has an opportunity to study and understand the examination and credentialing processes currently available and that represent the state-of-the-art for PTs and other health care professionals.

II. The States, and not the Federal Government, Should Decide the Qualification Standards for PTs and PTAs.

The proposed rule would usurp the states' authority over the requirements of health care professionals practicing within their jurisdiction. Licensure of the health care professions is a classically state function, and CMS should continue to respect the rights of the states. Determinations of qualifications for licensure have been, and are rightly, the domain of the states. CMS has proffered no evidence to indicate that the states have failed in the execution of their licensure duties with regard to PTs or PTAs. No grounds have been offered for the United States government to usurp this classically state function from the states. There is no justification for delegating that authority to a private, professional advocacy organization. CMS should therefore rely on the states to determine the standards required for the practice of physical therapy.

A. CMS defers to the states with respect to other health care professions and should do the same with respect to PTs and PTAs.

CMS should treat physical therapist qualifications the same way it treats the qualifications for other health care professions, such as physicians and nurses. Regulatory consistency demands it. In the same section of regulations in which CMS proposes to change the definition of physical therapist (*i.e.*, 42 C.F.R. § 484.4), CMS demurs to the states' licensure requirements for other health care professions. For example, a physician is defined as a "doctor of medicine . . . legally authorized to practice medicine and surgery by the State in which such function or action is performed."[1] Likewise, a registered nurse is defined as "[a] graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing."[2] Establishing requirements that are different than what the states require for licensing or certifying PTs would be inconsistent not only with the principles of federalism but also CMS's own standards.

B. The proposed regulation adds a duplicative examination requirement, thus creating undue hardship on the states, wasteful duplication, and confusion and unnecessary burdens for patients and the profession.

The states are responsible for determining qualifications for licensure. Every state in the nation requires candidates for licensure as PTs to take and pass the NPTE. Despite this fact, the proposed rule proposes a national exam approved by the APTA. Thus, it would be logical to

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[1] 42 C.F.R. § 484.4 (2006).
[2] *Id.*

interpret the proposed rule as requiring or authorizing development of a second Medicare-qualifying exam. Undoubtedly, this is not the result CMS intended, and it would be disaster for the Medicare program and its beneficiaries needing physical therapy services.

The states have already determined that examination is necessary, and for decades they have selected the NPTE as the exam of choice. Because the proposed regulation does not consider the currently available, currently used, state-of-the-art examination and credentialing processes, the proposed rule could lead to substantial confusion and duplication of effort. Given the current realities, the proposed rule can easily be read to require or allow requirement of a second examination to qualify for Medicare reimbursement. The proposed rule change could require the states to defer to an examination that does not exist. The proposed rule would or could effectively require the states to accept an examination that they have not analyzed or had an opportunity to consider adequately. This would place an extraordinary burden on the states to compare the existing exam with another exam, evaluate consistency and continuity, determine passing scores, and devote extraordinary resources annually that they may well not have in order to meet these and the many other challenges created by the proposed regulation.

For years, the state boards have effectively relied on the NPTE as developed and administered by the FSBPT. There is no need to invent a new qualifying exam for PTs and PTAs, and no need for the APTA or any other private organization to be allowed to force its will on the state governments. Requiring the devotion of precious resources, expense, and effort to a task and a goal that have already been and continue to be achieved by the NPTE simply would be wasteful, would not serve the public's interest, and would create undue and unnecessary burdens upon the states and PTs.

Moreover, having to qualify twice could deter PTs from entering the field of physical therapy or at least from seeing Medicare or Medicaid patients. That there is a shortage of PTs is a well-recognized concern within the industry. The U.S. is facing a shortage of health care professionals, including PTs, who specialize in serving the aging population.[3] The *Boston Globe*, for one, has observed that the problem is likely to worsen as the baby boomers age. Any rule that could inhibit the development of high quality physical therapy and places extra burdens on candidates without benefit to the public or the quality of healthcare services, such as the proposed examination and credentialing rules discussed above, would likely aggravate the shortage.

III. APTA Approval of Foreign Credentialing not only Usurps State Authority, but also Conflicts with Existing Federal Immigration Laws.

For all of the reasons set forth above, CMS' proposal that foreign-educated PTs and PTAs undergo a "credentials evaluation process approved by the American Physical Therapy Association" improperly replaces the judgment of the state licensing boards with that of the APTA. The proposed rule's usurpation of state authority over this aspect of the licensure of foreign-education PTs is inappropriate.

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[3] *See Study Sees Dearth of Doctors for Elders*, THE BOSTON GLOBE, Nov. 24, 2002, *available at http://nl.newsbank.com/nl-search/we/Archives?p_action=print* (last visited Aug. 16, 2007).

In addition, the proposal to vest the APTA with authority over foreign credentialing is misguided and overlooks the existing credentialing process available to PTs educated outside of the United States. Evaluating the credentials of foreign-trained PTs and PTAs is not a function that the APTA performs. There are only two entities, the Foreign Credentialing Commission on Physical Therapy ("FCCPT") and the Commission on Graduates of Foreign Nursing Schools ("CGFNS"), that are authorized by federal law to perform this credentials review for PTs.

The U.S. Bureau of Citizenship and Immigration Services has authorized only the FCCPT and CGFNS to review the credentials of foreign-trained PTs and to issue certifications to those who are qualified for entry into the United States. This authority is derived from Department of Homeland Security ("DHS") regulations requiring that any alien seeking admission as an immigrant or nonimmigrant for the primary purpose of working in certain health care occupations present a certificate from a credentialing organization found in the DHS' approved list.[4] With respect to the physical therapy profession, the approved credentialing organizations consist of the FCCPT and the CGFNS.[5]

Because this credentialing process has been established and relied on not only by the states but also by federal authority and regulation, there is clearly no need for CMS to create a rule requiring another credentialing procedure. Imposing the requirement for an APTA-approved credentialing process not only usurps state authority over the issue, but also creates unnecessary duplication and confusion. The potential that foreign-educated professionals would have to satisfy one credentialing standard for purposes of satisfying the federal immigration laws and state licensure and a second standard in order to treat Medicare or Medicaid patients imposes unnecessary obstacles to the treatment of such patients and does not improve public health and welfare. As a result, we urge CMS to remove this requirement and defer to the states with respect to licensure requirements for foreign-educated PTs.[6]

Importantly, the federal immigration regulations governing credentials review require that uncertified foreign health care workers be certified by an "independent credentialing organization..."[7] To qualify as a credentialing organization under DHS' federal regulations, certifying organizations must be "independent of any organization that functions as a representative of the occupation or profession in question or serves as or is related to a recruitment/placement organization."[8] Moreover, these regulations preclude DHS from approving an organization "that is unable to render impartial advice regarding an individual's qualifications regarding training, experience, and licensure." This standard of independence is

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[4] 8 C.F.R. § 212.15 (2007).

[5] *Id.*

[6] With respect to credentialing of foreign-educated PTAs, no credentialing function currently is performed by any entity. This is because, as a practical matter, there are no overseas PTA educational programs, nor do PTAs typically qualify for entry into and employment in the United States under existing H1-B work visa standards. Thus, CMS should consider carefully any effort to artificially construct such a credentials review process.

[7] *See* 8 U.S.C. § 1182(a)(5)(C).

[8] *See* 8 C.F.R. §212.15 (k)(1)(ii) (A) -(D).

critical for the sanctity of the process and protection of the public. CMS should adopt or at least utilize the same requirement.

We also believe CMS' proposal to require credentialing of foreign-trained PTAs is inappropriate. Training programs for PTAs exist only in the United States. There are not any outside the U.S. Even if there were PTA education programs outside the U.S., the individuals who would attend those programs would not be eligible for immigration to this country. USCIS regulations would prohibit them from qualifying. (If those regulations were to ever change, it would also make more sense for FCCPT and CGFNS to be appointed as the credentialing agencies, since they are already doing it and since they are public health and not professional trade or advocacy organizations.) CMS should reconsider any effort to artificially construct such a credentials review process.

IV. APTA Approval with Respect to Physical Therapist Qualifications Creates a Conflict of Interest and Undermines Federal Antitrust Laws.

The proposed rule would re-establish conflicts of interest eliminated two decades ago, which is an untenable result. As previously noted, the APTA is a professional association that advocates for previously qualified PTs and PTAs. Its goals are to promote the profession and to protect the professional, economic and other interests of its member PTs and PTAs, and it does a good job in that regard. Decades ago, prior to the formation of the FSBPT, the APTA did have responsibility for the NPTE, but the APTA formally transferred that function to the FSBPT in October 1989. This transfer was motivated in large part by the APTA's recognition that, as a professional association whose mission is to protect the interests of its members, its continued oversight of the licensing exam constituted an inherent conflict of interest. At the time of this transfer, it was envisioned that the FSBPT, in contrast to the APTA, would function as a stand-alone entity whose ultimate responsibility was to protect the public and to ensure that candidates for licensure meet standards of competency. The APTA, on the other hand, would be free to continue to advocate for its members. Thus, the FSBPT has developed and administered the NPTE since the full transition of this responsibility was completed in January 1993. Although the APTA maintains minimal involvement in certain administrative aspects of the exam through the year 2014, under the contract that transferred the exam to the FSBPT, it is the FSBPT that has ultimate responsibility for, oversight of, and control of the NPTE.

The FSBPT and APTA are quite separate and distinct entities. In fact, the FSBPT and the APTA only recently concluded contentious litigation regarding the nearly 20-year old contract that transferred ownership of the NPTE, including an allegation by the APTA that it was entitled to take back authority over the exam. The settlement agreement approved by the Virginia Circuit Court makes it irrefutable that ultimate authority over the NPTE rests solely with the FSBPT. Thus, CMS should be very careful before it appoints the APTA or any other organization to have approval authority over the NPTE or any other national licensing exam for PTs. Principles of separation of the branches of government demand that CMS be deferential to the judicial resolution.

Any attempt to return authority over the national licensing exam to the APTA re-creates the untenable conflict of interest that motivated the APTA itself to transfer the exam to the FSBPT.

For the same reason, APTA oversight of other qualifications – including credentials review for foreign-educated therapists and accreditation of educational programs – places the APTA in the inappropriate position of being both an advocate for its members and a gatekeeper to the profession.

In fact, the conflict of interest that would exist in the event that the APTA were inappropriately granted approval authority over licensing, credentialing and accreditation would present potential antitrust issues. The APTA, given that its charge is to advocate for its members, would have an incentive to establish testing, credentials review and accreditation standards in a manner designed to reduce the number of competitors entering the marketplace to compete with, and thereby commercially harm, its members. The effect of this would be to reduce the supply of licensed PTs and concomitantly to increase the costs to patients seeking services from such licensed professionals. The antitrust risks associated with the erection of such anticompetitive barriers to entry are very real and have long been recognized by the federal courts. *See, e.g., Welch v. American Psychoanalytic Ass'n.*, No. 85 Civ. 1651, 1986 U.S. Dist. LEXIS 27182 (S.D.N.Y. 1986) (recognizing antitrust risks presented where a professional association in control of professional accreditation and admissions standards has a commercial motive).[9]

V. The Scope of the Proposed Rules Greatly Exceeds the Goals Enunciated by CMS.

The proposed rules exceed the concerns that CMS intended to address as expressed in the Preamble. In the Preamble, CMS noted the following:

- "[a]lthough all States license PTs, some States have no licensing provisions for PTAs...."[10]
- "[I]t is our intention to assure that Medicare payment is made only for physical therapy...services provided by personnel who meet qualifications, including consistent and appropriate education and training relevant to the discipline, so that they are adequately prepared to safely and effectively treat Medicare beneficiaries."
- Personnel qualifications for therapists and assistants should apply equally to all settings in which Medicare pays for their services.[11]
- For foreign-trained applicants, CMS wants to consider developing standards comparable to those applied to PTs and PTAs trained in the U.S.

All four of these concerns can be adequately addressed without the sweeping language found in the proposed rules. Most importantly, none of these concerns require the federal government to impose a new national examination requirement or, importantly, to require APTA approval of a national examination, credentials evaluation or educational accreditation. As expressed previously, the states already approve a national licensing exam, credentials review processes for foreign-educated candidates, and educational accreditation, and there is no basis for concluding that the states have failed in the execution of these duties. APTA oversight of these issues is not necessary to effect a goal of consistency across settings.

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[9] We note with interest the timing of the 1986 case and the 1989 spin-out of the FSBPT from and by the APTA.
[10] 72 Fed. Reg. 38,191 (July 12, 2007).
[11] 72 Fed. Reg. 38,193 (July 12, 2007).

VI. CMS' Proposal to Recognize CAPTE as the Only Organization Qualified to Accredit PT and PTA Education Programs Would Create an Inappropriate Monopoly and Eliminate the Authority of the States to Identify and Approve Acceptable Education Levels.

States identify and select accrediting organizations across the many professions and occupations, they license, certify and register. They are well-equipped to evaluate the quality of accrediting organizations and to select the ones that set the best standards. CMS should defer to the states with regard to all accreditation decisions, including those that address the curriculum for training of PTs and PTAs.

Under the proposed regulation, CMS would create a monopoly for CAPTE, which would also effectively eliminate state discretion. We encourage CMS to revise the proposed regulation to state that PTs and PTAs shall have "graduated after successful completion of a college or university physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE) or another accrediting body that is accepted in the state."

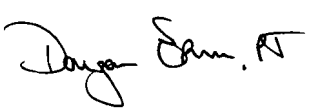
VII. Closing.

The proposed regulations discussed in the preceding paragraphs demonstrate that CMS needs to better understand how PTs and PTAs are qualified to practice their respective professions. We strongly recommend that CMS remove those aspects of the proposed rule that vest authority in the APTA to approve the national examination, foreign credentialing, and accreditation. CMS should, instead, defer to the states with respect to each of these issues, particularly in light of the fact that well-functioning processes with respect to each of these issues already exist.

There is no reason to rush to regulate. Thus, if CMS is not prepared to act on the FSBPT's recommendations at this time, the proposed rule regarding professional qualifications should be removed from the proposed rulemaking and delayed until CMS has an opportunity to study and understand the examination and credentialing processes currently available and that represent the state-of-the-art for PTs and PTAs.

Thank you for the opportunity to comment on the proposed PT and PTA qualifications. We appreciate your kind consideration.

Respectfully yours,



E. Dargan Ervin, Jr., PT
President

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LUMENIS.

Enhancing Life. Advancing Technology.

August 29, 2007

Kerry N. Weems
Administrator Nominee
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: Comments to Proposed Rule CMS-1385-P

Ladies and Gentlemen:

On behalf of the entire Lumenis corporation I thank you for the opportunity to comment on the Notice of Proposed Rulemaking regarding the Medicare Physician Fee Schedule for Calendar Year 2008 published in the Federal Register on July 12, 2007 ("NPRM"). These comments focus solely on several of the significant proposed changes to the regulations promulgated under the Ethics in Patient Referrals Act (frequently referred to as the "Stark Law") – Section II.M. of the NPRM.

Lumenis is one of the pioneers in the use of lasers and light-based technology for medical purposes. For over 40 years, our company has been involved in the research and development of laser technology. Lumenis technology is found in more than 100 countries world-wide.

We write not as a party directly affected by the proposed changes in the Stark Law regulations, but rather as a long-term member of the health care industry that has had direct experience with the financial struggles of hospitals, ambulatory surgery centers, physician practices and other providers and suppliers to continually make new and improved technology available to patients. Our concern is that while the proposed rules may aim to address some perceived problems, these changes have the potential to eliminate a number of business models that permit facilities and physician practices to acquire new technology without having to outlay the capital to purchase the technology.

I. Impact of the Stark Law and Regulations

A believed correlation between physicians' financial ties to the delivery of certain medical and health care services and measurable increases in utilization and price was the impetus for Congress to enact the Ethics in Patient Referrals Act eighteen years ago. Since that time, the Stark Law has been expanded to further restrict and/or eliminate certain physician business

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arrangements, often common in the industry, that Medicare has become convinced could be abusive to the Medicare program and beneficiaries.

Physician investment in services for which they recommend also has significant benefit. Physician-driven investments often involve the acquisition and early adoption of the newest technology or the development of alternative, more efficient sites of services (i.e., establishment of ambulatory surgery centers). Thus, these arrangements contribute to quicker and broader access to state-of-the-art services than if our health care system relied solely on facilities, such as hospitals, to have the financial and decision-making elasticity to acquire new technology quickly.

CMS has acknowledged this benefit to some extent in its ongoing attempts to carve out certain regulatory exceptions from the all-encompassing grasp of the Stark Law. But, the latest proposed changes to Stark Law seem to dismiss this balancing of the potential positives of physicians' financial relationships with entities that provide health care services they order without any definitive data cited in the preamble that these changes are necessary. Nor does the preamble contain any explicit discussion regarding the types of services about which CMS has the most concern. Rather, the proposed changes, if finalized, would institute sweeping prohibitions against arrangements that are perfectly legitimate under current regulation and in existence across the country.

The ability for physicians to participate in many of these arrangements is a primary reason certain services are available in particular areas and without the physician financial involvement these services may not have been available to Medicare beneficiaries. As such, we are very concerned about the potential unintended consequences these proposed changes to the Stark Law may have on patient access to services. This is particularly true for procedures and services that are dependent on an investment in expensive capital equipment.

II. Services Furnished "Under Arrangements"

CMS proposes to expand the definition of an "entity" to include both the entity that performs a designated health service ("DHS") as well as the entity that bills Medicare for the DHS.[1] CMS explains that this proposal is intended to reduce the number of "under arrangements" ventures, *e.g.*, where a physician-owned entity provides certain services that were previously provided by a hospital directly. According to CMS, the net effect of these arrangements is to allow physicians to make money on referrals for separately payable services that could continue to be furnished directly by the hospital.

While CMS discusses anecdotal reports related to under arrangements ventures that presumably are abusive, there is no suggestion that these concerns are equally applicable to all types of services. Yet, the proposed change would eliminate completely this significant

[1] 42 CFR § 411.351 as proposed in the Proposed Rule.

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option utilized by hospitals, particularly those without significant financial resources, to bring certain services (like new technology) to their community. Before CMS implements any changes to the Stark regulations that will restrict or eliminate under arrangements ventures with entities that are owned in whole or in part by physician referral sources, it is imperative that CMS assess the potentially significant impact such a change will have on the quality and scope of care offered by many institutions.

Most hospitals have a finite pool of dollars to spend on new technology every fiscal year. Like any business, these purchasers must understand their potential return on investment before agreeing to any outlay for new capital equipment. The natural outcome of this process is that hospitals simply decide not to offer certain services. The losing technologies often are those with the highest price tag and/or the smallest financial return. This outcome may be offset by the seriousness of the medical condition that a technology is designed to treat or the political clout of the physician pushing the hospital to purchase certain equipment. Nevertheless, some technologies simply will not be made available if the only option a hospital has is to purchase it.

Under arrangements contracts, therefore, give hospitals an important means to offer new services, particularly those that are expensive and/or used to treat smaller patient populations, without tying up scarce capital dollars. CMS itself cites the proliferation of under arrangements deals. This is not a surprise given that physician investment in technologies offered through under arrangements ventures is a vital source of funding to open access to new services. Moreover, physician driven investments may assist hospitals maintain quality since the physicians likely will be drawn to technologies they trust and believe will be important in the management of their patients. Independent third-parties cannot be relied upon to choose their investment strategy according to subtleties in clinical data.

We believe such an all-encompassing change is a critical mistake, and should not be finalized. If, however, CMS feels that these under arrangements must be limited we urge the agency to provide some exceptions that would permit physician-investors in a DHS entity to refer patients to a hospital for the service in certain situations. First, CMS should permit all arrangements existing at the time the proposed rule was published to stand without change, even if the agreement between the parties calls for annual renewal. There simply would be no way for some hospitals to fund the direct purchase of the technologies they currently offer through under arrangement deals. Consequently, the services related to these technologies would become extinct, and patients would be faced with a critical access problem. Moreover, parties to these lawful deals have invested significant resources into obtaining technology, negotiating relationships, and implementing the related services. It would be unfair to apply the changes retroactively and a challengeable use of administrative authority.

Second, CMS should craft an exception that does not prohibit physician referrals for under arrangements services at issue when the DHS involves a technology that requires a

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considerable capital investment and where the risk of overutilization is minimal because the number of patients to be treated with the technology is small (as compared, for example, to technology such as imaging equipment) or misuse would be patients at significant risk. We, at Lumenis, find it difficult to comprehend that there is a systemic problem with physicians ordering unnecessary surgical procedures or invasive tests simply to generate additional fees. We have to believe that the vast majority of physicians take seriously their ethical responsibilities.

B. Unit-of-service (Per-Click) Payments in Space and Equipment Leases

CMS is proposing to prohibit unit-of-service (per click) payments to a physician-lessor for services provided by a designated health services ("DHS") entity lessee to patients who were referred by the physician lessor.[2] If finalized the proposal would require that "per click" fees paid to the physician-lessor exclude amounts associated with the use of the equipment for patients referred by the physician. According to CMS, it is concerned that a physician-lessor has a financial incentive to refer a higher volume of patients to the lessee when the physician receives a per-click payment.

CMS's proposal will affect all space and equipment leases where a physician lessor currently receives a "per click or "per use" rental payment from a DHS entity. We assume that a physician lessor could receive another type of payment for space/equipment used in connection with patients that the physician refers, but we ask CMS to clarify this point. For example, we ask CMS to make clear that time-based rental payments, such as "block time" leases (*e.g.*, $1,000 per month), would be acceptable.

The above said, Lumenis urges CMS to reconsider its decision to eliminate all unit of service based arrangements. As with "under arrangements" ventures, unit of service leases give hospitals and other entities, which might not otherwise have the financial resources to purchase equipment outright or lease it for extended periods, the opportunity to make technology dependent services available to the community. This option is particularly important when technologies are new or very costly and entities are apprehensive about investing in a technology.

Thus, so long as a per click lease fee is fair market value for the use of the equipment then we believe the potential benefits of assuring technology is available outweighs the concern that a rogue physician will act inappropriately. If there is a prevalence of overutilization in a particular areathen the changes should be aimed at addressing real rather than theoretical concerns.

Consequently, we appeal to CMS to withdraw its proposal to eliminate click-fees.

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[2] 42 CFR § 411.357(a)(5) and § 411.357(b)(4) as proposed in the Proposed Rule.

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C. In-Office Ancillary Services Exception

CMS requested input regarding whether the in-office ancillary services (IOAS) exception should be modified to limit the types of services that qualify for the exception or restrict the circumstances to which the exception would apply. While CMS has not put forth any particular proposed changes it appears from the preamble that CMS is in favor of narrowing the IOAS exception in order to limit physician ability to profit referral for ancillary services that are not closely connected to the physician/group. CMS also clearly suspects that the exception also has contributed to the (presumably undesirable) migration of sophisticated and expensive equipment to the physician office.

While we can understand CMS's desire to ensure that IOAS offered to patients are services closely related to the physicians practice and expertise, such changes if not made carefully could result in limitations of the sites of service where certain health may be delivered. Taken together the proposed changes to the Stark regulations will eliminate most sound business opportunities that would make a physician's decision to invest in new technology a rationale choice. Consequently, it leaves all patients, including Medicare beneficiaries, at the whim of hospitals and other third-party entities to invest in new technology. Such an outcome is inconsistent with the push to move care out into the community, to build efficiency in health care delivery through the development of large multi-specialty full-service groups, and to create a level playing field across sites of service.

Accordingly, as we have articulated above, we ask CMS to reconsider such broad sweeping prohibitions. Instead, there should be a clearer articulation of the types of arrangements and related services that are leading CMS to believe these proposals are necessary and design changes to the regulations to address these specific problem areas. Physician investment in technology is an important aspect to the deployment of state-of-the-art health care. If we shut down all the incentives for physicians to make these investments, we fear that our delivery system will suffer immeasurably from decreased access and diminished quality or care. This is too high a price for all patients to pay.

* * *

Again, we thank you for the opportunity to provide these comments on the current proposals. We are hopeful that you will weigh our concerns against other competing issues.

Respectfully submitted,

Dov Ofer,
CEO

Zvi Nelis
COO

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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: Proposed Revisions to Payment Policies Under the
Physician Fee Schedule – Recalls and Replacement Devices

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments regarding the Proposed Revisions to Payment Policies Under the Physician Fee Schedule published in the *Federal Register* on July 12, 2007 (72 Fed. Reg. 38122) and, in particular, with respect to issues related to Medicare reimbursement for costs associated with recalls of and replacements for medical devices.

AHIP is the national association representing nearly 1,300 health insurance plans providing coverage to more than 200 million Americans. Our members offer a broad range of products in the commercial marketplace including health, long-term care, dental, vision, disability, and supplemental coverage. AHIP's member health insurance plans also have a strong track record of participation in Medicare, Medicaid, and other public programs.

As noted in the Proposed Revisions, recent recalls of implantable cardioverter-defibrillators (ICDs) have resulted in significant costs for public and private payers including, for example, hospitalization, surgery or other medical procedures to repair or replace the recalled device, physician consultation and follow-up visits, and lab tests. AHIP believes the manufacturers of these devices should be responsible for medical expenses associated with such recalls, in addition to the cost of any replacement device. We have enclosed prior correspondence with the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration regarding this issue.

AHIP supports efforts by CMS to identify expenditures by the Medicare program in connection with the recall of medical devices, such as ICDs, and actions to recover any expenses from the manufacturers of the devices. We do not believe the costs should be the responsibility of federal programs, such as Medicare, private payers or the general public.

Please feel free to contact me at (202) 778-3255 if you have any questions regarding this important issue.

Sincerely,

Thomas J. Wilder

Thomas J. Wilder
Senior Regulatory Counsel

Enclosures

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America's Health
Insurance Plans

August 17, 2005

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

We write today to call to your attention our concerns regarding the recent recalls of certain implantable defibrillators and pacemakers by Guidant Corporation and the impact of these recalls on the Medicare and Medicaid programs and our member health insurance plans. In our view, these recalls highlight several important public policy issues that should be addressed by CMS, and we are anxious to work closely with the agency as it addresses these issues.

As the result of advances in medical knowledge and improvements in the delivery of care, CMS and health insurance plans are providing coverage for more new technology than ever before. In particular, CMS' decision to expand its coverage of implantable devices will likely increase their use in the Medicare program. Recent information about internal defibrillators raises new and important questions about safety, effectiveness and costs for both private and public purchasers of medical devices.

As you explore these questions, we have two recommendations. The first is to urge a broader policy discussion about ultimate responsibility for medical expenses involved with device recalls. The second relates to the urgent need for better data sharing between medical device manufacturers and public and private payers and consumers, including steps to enable collection of medical device information by payers.

Responsibility for Medical Costs:

AHIP suggests that CMS consider developing a reasonable and equitable means to allocate responsibility to medical device manufacturers for the medical expenses associated with device recalls. We believe that a manufacturer should bear not just the replacement cost of a recalled device, but also the associated medical expenses. Those expenses may include hospitalization, surgery or other medical procedures to repair or replace the recalled device, physician consultation, and necessary lab tests. At present, it appears that medical device manufacturers have assumed that Medicare and private payers will bear the considerable medical expenses associated with defective device recalls.

For example, Guidant Corporation has offered to reimburse only patients themselves who receive certain replacement devices up to $2,500 for out-of-pocket medical expenses remaining after Medicare and health insurance coverage. Strikingly, it has not offered to reimburse Medicare or private health insurers for medical expenses surrounding its recalled devices. It also appears that Guidant's policy

guidelines would result in hospitals being paid by Medicare for a device that Guidant Corporation is replacing at no charge. Thus, Guidant has published a list of appropriate CPT and ICD-9 codes associated with recall-related medical expenses which specifically advises providers that: "When billed, Medicare is expected to pay providers the full Diagnosis Related Group (DRG) or Ambulatory Payment Classification (APC) rate for the replacement procedure *without discounting that amount by the value of the replaced device.*"[1]

It is troubling if manufacturers of recalled devices are pursuing policies that result in shifting of costs associated with their recalled devices to working families who pay for health insurance through forgone wages and taxpayers who fund public programs. Such expenses only compound the health care financing burdens already faced by employers, consumers, and public programs. AHIP stands ready to work with CMS and others in the health policy community to develop a fair policy for allocation of these costs.

Facilitating the Flow of Device Information:

Unfortunately, today neither public nor private payers are able to efficiently collect critical information about devices at the time of implantation, resulting in an information vacuum where payers are left in the dark about when and whether additional medical costs are attributable to a replacement of a defective device. Manufacturers, however, routinely track this information and voluntarily share it with providers at the time of a recall, but it is not currently provided to public and private payers. At present, there is no simple way for both health insurance plans and public programs like Medicare and Medicaid to identify consumers who have received a recalled device for purposes of allocating medical costs.

Until such time that there can be a broader policy resolution concerning the allocation of responsibility for medical costs associated with recalled devices, AHIP asks CMS to work with AHIP's members, the FDA, and device manufacturers to consider ways to facilitate the flow of key information about recalled devices (*e.g.*, model number, serial number, identifying patient information) from medical device manufacturers to public and private payers. We also understand that CMS will be collecting registry information on internal defibrillators in connection with the expanded coverage of these devices. We urge CMS to work with AHIP and others to facilitate the collection of this important information so that costs can be properly allocated.

AHIP appreciates the significant role CMS plays in working with AHIP's members and assuring coverage for medical devices for Medicare and Medicaid beneficiaries. We look forward to a continuing dialogue with you on an issue critical to both public and private payers.

Sincerely,

Karen Ignagni

Karen Ignagni

c: Lester M. Crawford, Ph.D., DVM
Leslie Norwalk, Esq.

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[1] *See* http://www.guidant.com/reimbursement/guidelines.pdf; *see also* Ch 16§40.4 – Items Covered Under Warranty, Medicare Benefit Policy Manual, http://www.cms.hhs.gov/manuals/102_policy/bp102c16.pdf; Medicare transmittal http://www.cms.hhs.gov/manuals/pm_trans/R599CP.pdf

America's Health Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org

March 14, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
United States Food and Drug Administration
Office of the Commissioner
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: The Medical Device User Fee Modernization Act of 2002 – Docket No. 02N-05341

Dear Dr. von Eschenbach:

I am writing on behalf of America's Health Insurance Plans (AHIP) representing 1,300 member companies providing health insurance coverage to more than 200 million Americans to provide comments on the Medical Device User Fee Modernization Act and to follow-up on previous discussions with your staff about collaborative initiatives to improve the safety and efficacy of pharmaceutical products and medical devices.

Our comments are designed to urge you to consider analyzing the long-term safety and effectiveness of prescription drugs, biological products, and medical devices as part of FDA's enforcement activity and to set aside funding for ongoing effectiveness analysis and comparisons across available treatments. We believe the agency has an important role to play in facilitating the transition to a more evidence-based, safe, and effective health care system and we are making five recommendations to help achieve these goals.

1. Require and Adequately Fund Post-Market Studies of Prescription Drugs, Biological Products, and Medical Devices

The FDA has committed significant resources to pre-market testing of prescription drugs, biological products, and medical devices through funding available under the Prescription Drug User Fee Act and the Medical Device User Fee Act. As the population ages and the number of individuals with multiple chronic diseases increases, it is critical that FDA expand its activities to include post-marketing surveillance that focuses on the long-term effects of drugs, biologics, and devices.

We believe that FDA should require manufacturers to conduct selected post-market studies of their products, including situations where safety concerns have not been raised, to determine if the drug, biologic, or device is safe, effective, and fulfilling its intended purpose. In addition, FDA should seek adequate support for its post-market surveillance activities through user fee funding. The Prescription Drug User Fee Act and the Medical Device User Fee Act provide critical resources to conduct cost-effective and efficient review of new prescription drugs, biological products, and medical devices. We support reauthorization of these two important laws, which are scheduled to expire next year, and urge the earmarking of specific user fee funds for both pre- and post-market studies of prescription drugs, biological products, and medical devices.

2. Develop Public-Private Partnerships to Conduct Post-Marketing Studies of Drugs and Devices

An overwhelming majority of Americans have their health care financed through or administered by health insurance plans. As a result, health insurance plans have comprehensive data sets that could be used in evaluating safety and effectiveness. We recommend that FDA work with health plans and other key stakeholders to design post-marketing studies that will draw upon these de-identified data. We would be delighted to bring together representatives of health plans and FDA staff to discuss this issue.

The Centers for Medicare & Medicaid Services (CMS) also can provide important information about drug, biologic, and device usage for older Americans and for the disabled. These data, coupled with information available from health insurance plans, could provide an expanded view of how prescription drugs, biological products, and devices impact patient outcomes.

We recommend that FDA work with CMS to establish appropriate protocols to utilize Medicare data in the development of post-marketing studies. We are available to participate in this dialogue to ensure that data sets available from health insurance plans can be integrated into data available from CMS.

3. Provider Early Warning Monitoring Through Linkages to the National Health Information Infrastructure

Health plans have taken a leading role in using information technology to improve health quality and care outcomes through activities such as electronic prescribing, creation of personal health records, and development of decision support tools for consumers and caregivers. These initiatives are part of a larger effort by the health care community to create an electronic "health information highway" to link physicians, hospitals, health plans, state and federal governments, and consumers.

We recommend that FDA consider ways to monitor drug and device safety through linkages with public and private health data systems. Such linkages will provide the tools to obtain early indications of potential problems with prescription drugs, biologics, and medical devices that impact patient safety.

4. Establish Procedures to Track Implanted Medical Devices

FDA's Center for Devices and Radiological Health (CDRH) recently published a report (*Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program*) discussing its process for post-market surveillance of medical devices. One important issue raised in the report is the lack of complete documentation in health care records at the time devices are implanted which results in an inability to monitor device performance. Unlike prescription drugs, which have a National Drug Code identifier, there is no currently reliable system to track medical devices.

We recommend FDA work with health plans, health care providers, standards organizations, and other stakeholders to establish procedures to track medical devices. This process should include the development of unique identifiers for medical devices that can be used for health reporting purposes and in the claims and payment process (such as the UB 04, HCFA 1500, and HIPAA 837 claim forms). In

addition, a process should be developed to identify medical procedures that are performed as a result of device failures.

5. Encourage Accountability for Device Failures

Recent recalls of implantable defibrillators and pacemakers highlight the impact of device failures on patient safety and the cost of medical care. If device manufacturers are not held accountable for medical expenses associated with voluntary and involuntary device recalls, these costs are shifted to the public at large. We believe that manufacturers are responsible for all expenses related to a recall, including replacement costs, hospitalization, surgery, and other medical procedures to replace or repair the device. We recommend FDA use its existing authority to establish a process for medical device manufacturers to assume the cost of voluntary and involuntary device recalls. We have previously shared with FDA's General Counsel an analysis of this authority and would be happy to discuss this issue with you.

We believe the Food and Drug Administration plays an essential role in protecting patient safety and promoting quality health care for all Americans and we look forward to continuing our dialogue on how health plans can assist the FDA in this critical endeavor.

Sincerely,

Karen Ignagni

Karen Ignagni

America's Health
Insurance Plans

August 17, 2005

Lester M. Crawford, PhD, DVM
Commissioner of Food and Drugs
U.S. Food and Drug Administration
Department of Health and Human Services
Rockville, MD 20857

Dear Commissioner Crawford:

We write today to call to your attention our concerns regarding the recent well-publicized voluntary recalls of certain implantable defibrillators and pacemakers and the impact of these recalls on our member health insurance plans. These recent recalls of implantable medical devices highlight important public policy issues that should be addressed by the Food and Drug Administration concerning safety and efficacy, postmarket surveillance, and the responsibilities of manufacturers of recalled devices.

America's Health Insurance Plans (AHIP) is the national association representing health insurance plans. Our nearly 1,300 members provide coverage to over 200 million Americans, including coverage for or administration of public and private programs that cover implantable medical devices. These coverage decisions are based on the scientific evidence validating the effectiveness of such devices.

As the result of advances in medical knowledge and improvements in the delivery of care, our health insurance plans are providing coverage for more implantable medical devices. In addition, the recent decision by the Centers for Medicare and Medicaid Services (CMS) to expand its coverage of these devices in certain cases will likely increase their use in the Medicare program. The recent information surfacing about recalled devices raises new and important questions for both private and public purchasers.

As the FDA formulates a response to the recent surge of recalls, AHIP has three recommendations:

- **Safety and Efficacy.** While we recognize that implantable devices can save lives and improve health outcomes, we ask the FDA to carefully consider appropriate initiatives to ensure the safety and long term effectiveness of implantable medical devices through postmarket surveillance programs. The FDA, by January 2007, is required to report to Congress on the effects of the medical device user fee program on postmarket surveillance, including compliance with requirements by device companies and the need for programmatic improvements and additional funding. Given the recent recalls of internal defibrillators and pacemakers, we recommend that a report be made to Congress and the public on an expedited timetable.

- **Responsibility for Medical Costs.** AHIP suggests that FDA, working with other appropriate policymakers, consider the responsibility that medical device manufacturers should bear for medical expenses associated with both voluntary and involuntary device recalls. These costs are separate from the replacement cost of the device itself. We believe that – in addition to taking responsibility for the replacement cost of a recalled device – a manufacturer should take responsibility for associated medical expenses. Medical expenses may include, for example, hospitalization, surgery or other medical procedures to repair or replace the recalled device, physician consultation, and necessary lab tests. If manufacturers of recalled medical devices do not voluntarily assume these medical costs, the costs will be shifted to working families who pay for health insurance through forgone wages and taxpayers who fund public programs. Such expenses only compound the health care financing burdens already faced by employers, consumers, and public programs. At present, if a device manufacturer does not voluntarily opt to pay for medical costs associated with recalled devices, the only recourse to recover payment is through litigation, which is an inefficient and costly process. We urge the FDA to lend its significant expertise to the health care community to fashion a better solution to this problem and to work with CMS as it considers whether Medicare beneficiaries and taxpayers should bear the burden of these costs.

- **Facilitating the Flow of Recall Information.** Until such time that there has been a broader policy resolution concerning the allocation of responsibility for medical costs associated with recalled devices, AHIP asks FDA to consider ways to facilitate the flow of key information about recalled devices (*e.g.*, model number, serial number, identifying patient information) from medical device manufacturers to public and private payers. Although this information is already tracked by the manufacturers and voluntarily shared with providers, it is not currently provided to public and private payers. At present, there is no simple way for both health insurance plans and public programs, such as Medicare and Medicaid, to identify consumers who have received a recalled device for purposes of allocating medical costs.

AHIP appreciates the significant role FDA plays in maintaining patient safety and promoting quality health care, and looks forward to a continuing dialogue with you on these important issues. We will call your office to schedule an appointment to discuss AHIP's concerns and ways we can move forward to address these critical cost, quality, and safety issues.

Sincerely,

Karen Ignagni

Karen Ignagni

c: Mark McClellan, M.D., Ph.D.
Janet Woodcock, M.D.

Matt Blunt
Governor
State of Missouri

DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
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and Professional Registration
Douglas M. Ommen, Director

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David T. Broeker
Division Director

http://www.pr.mo.gov

August 22, 2007

Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-1850

Re: CMS-1385-P
THERAPY STANDARDS AND REQUIREMENTS

Dear Sir or Madam:

The Missouri State Board of Healing Arts' Advisory Commission for Physical Therapists submits the following comments on the proposed rules changing the definition of "physical therapist" in Section 484, Title 42 of the Code of Federal Regulations. The proposed rules are part of the 2008 Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for Calendar Year 2008, found in Volume 72 of the Federal Register, published on July 12, 2007.

Under subsection (i)(B) and (ii)(B) of the proposed definition of "physical therapist" an applicant would need to have "[p]assed the National Examination approved by the American Physical Therapy Association." We strongly suggest that CMS rely on state licensure and that the additional examination requirements contained in subsections (i)(B) and (ii)(B) of the definition of "physical therapist" be deleted from the final rule. At the very least, the Centers for Medicare and Medicaid Services ("CMS") should delay promulgation of the proposed rule until CMS has had an opportunity to understand the examination, credentialing, and licensing processes currently in place.

We, along with all of the other state boards of physical therapy examiners, have already adopted a national qualifying exam for physical therapists, the National Physical Therapy Examination ("NPTE"). The Federation of State Boards of Physical Therapy ("FSBPT") develops and administers the NPTE in close collaboration with the state boards. Working together, we have

developed a national passing score. The FSBPT has done an outstanding job of meeting our needs. Likewise, the NPTE has been a valuable tool in screening physical therapist applicants. Through the NPTE, we have been able to successfully filter applicants. In turn, we, as a policing body, have been able to protect the public by ensuring that only qualified therapists are licensed care for our citizens.

CMS should not usurp the states' function of licensing physical therapists and other professionals. Health care professional credentialing and licensing is a classically state function. Licensing and credentialing are the domain of the states. CMS' proposal would inappropriately transform a state function into a federal function. There is no justification for this action, and CMS should prevent it by removing the proposed rule.

CMS respects states' rights and state licensure for other health care professions, and it should continue to do so with respect to physical therapists. For example, CMS' regulations define a physician as a "doctor of medicine ... legally authorized to practice medicine and surgery by the State in which such function or action is performed." 42 C.F.R. § 484.4 (2006). Likewise, a registered nurse is defined as "[a] graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing." 42 C.F.R. § 484.4. Establishing requirements that are different than what the states require for licensing PTs would be inconsistent with not only the rights of the states, but also CMS' own standards.

Moreover, the federal government should not impose an additional burden on the states, particularly since its stated desire for a national examination already satisfied and its other stated goals would not be better met by the burden it proposes to impose. The proposed unfunded mandate could result in the development of a second exam, which would create confusion and more work for the states, without benefit. Our resources are already limited and stretched.

In the preamble to the proposed regulations, CMS says that it is seeking uniformity. The fact of the matter is that uniformity and consistency across the nation and across provider settings already exists. State licensing requirements apply to physical therapists without regard to where they practice. All states accept CAPTE accreditation. All states accept the NPTE and have adopted the same passing score. No federal regulation is required.

In fact, the proposed regulations would likely defeat CMS' own goal of uniformity. If, for example, the APTA were to approve a different exam than the NPTE, which the regulations would permit it to do, physical therapists, patients, including Medicare and Medicaid beneficiaries and recipients, and others could face substantial confusion and interruption of service. As a state board of physical therapy examiners, we would continue to have authority to select an exam of our choice for licensing purposes. However, under the proposed rule, a physical therapist would have to pass a second exam approved by the APTA to qualify for Medicare reimbursement. Thus, patients might be forced to change physical therapists as they become Medicare or Medicaid eligible, and the current uniformity and continuity of standards across the country would be lost. Thus, the proposed rules undermine CMS' ambition for uniformity of standards.

CMS and the federal government should not empower an advocacy group, like the APTA, to establish an examination or any qualifications for professionals to provide healthcare services to

patients. The APTA's mission is to advocate and promote the profession. As a licensing body, our mission is to ensure that physical therapists are qualified to provide physical therapy services and are authorized to do the work for which they are trained. The FSBPT, the organization to which we look for the national licensing exam, was created to eliminate, protect against and prevent the inherent conflict of interest that the APTA would have if it were to have authority over the examination and credentialing processes. Even the APTA recognized this conflict of interest problem two decades ago when it created the Federation of State Boards of Physical Therapy. CMS must not allow this conflict of interest to become a rule.

The Missouri State Board of Healing Arts' Advisory Commission for Physical Therapists strongly urges CMS to require only state licensure. Most importantly, CMS should remove the additional examination requirements contained in subsections (i)(B) and (ii)(B) of the definition of "physical therapist." At a minimum , CMS should delay promulgation of the proposed rule until CMS has had an opportunity to understand the examination, credentialing, and licensing processes currently in place.

We appreciate the opportunity to comment on the proposed rules regarding physical therapist and physical therapy assistant qualification requirements.

Respectfully yours,

Melinda Christianson, P.T.
Advisory Commission Chair

Department of Health
Three Capitol Hill
Providence, RI 02908-5097
TTY: 711
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830

August 29, 2007

Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-1850

Re: CMS-1385-P
THERAPY STANDARDS AND REQUIREMENTS

Dear Sir or Madam:

As members of the Rhode Island Board of Physical Therapy, we are writing to express our concern regarding the proposed rules changing the definition of "physical therapist" in Section 484, Title 42 of the Code of Federal Regulations.

The proposed rules (subsections (i)(B) and (ii)(B)) would change the definition of "physical therapist" so as to require an applicant to have "passed the National Examination approved by the American Physical Therapy Association." Similarly, foreign-educated physical therapists would be required to undergo an education credentials evaluation process also approved by the APTA. Instead of vesting licensing and credentialing authority in the hands of APTA, a professional association and advocacy group, CMS should rely on state licensure as the sole requirement under CMS rules and regulations. At the very least, CMS should delay promulgation of the proposed rule until it has had an opportunity to understand the examination, credentialing, and licensing processes currently in place.

CMS should not usurp the states' authority to license physical therapists and other professionals. The proposed rules would inappropriately transform a state function into a federal function and should be removed. CMS respects states' rights and state licensure for other health care professions, and it should continue to do so with respect to physical therapists. For example, CMS' regulations define a physician as a "doctor of medicine . . . legally authorized to practice medicine and surgery by the State in which such function or action is performed." 42 C.F.R. § 484.4 (2006). Establishing requirements that are different than those the states require for licensing physical therapists would therefore be inconsistent with not only the rights of the states, but also CMS' own standards.

All fifty states, including our own, have already adopted a national qualifying exam for physical therapists, the National Physical Therapy Examination ("NPTE"). Our state, like the other states, also has in place requirements for the approval of the education credentials of foreign-educated licensure applicants. Through the NPTE and our existing foreign credentialing standards, our state's licensing board has been able to successfully filter applicants and protect the public by ensuring that only qualified therapists are licensed to care for our citizens. Thus, no foreign regulation is necessary.

Moreover, the proposed regulations would likely defeat CMS' stated goal of uniformity. Uniformity and consistency across the nation and across provider settings already exist. If, for example, the APTA were to approve a different exam than the NPTE, which the regulations would permit it to do, physical therapists, patients, including Medicare and Medicaid beneficiaries and recipients, and others could face substantial confusion and interruption of service. Although we as the state's board of physical therapy examiners would continue to have authority to select an exam of our choice for licensing purposes, a physical therapist would have to pass a second exam approved by the APTA to qualify for Medicare reimbursement. This could force physical therapists to forego treatment of Medicare/Medicaid patients or, at the very least, impose unnecessary obstacles to the treatment of such patients. This would have obvious negative repercussions for patients seeking treatment, and the current uniformity and continuity of standards across the country would be lost.

We are also concerned that the proposed rules will impose an additional burden on our state. This proposed unfunded mandate could result in the development of a second exam or, at the very least, would create administrative confusion and more work for our state, without benefit. This two-tiered system would further drain our already limited resources. This is particularly troubling since CMS' stated desire for a national examination is already satisfied, and the burden on the states far outweighs any of CMS's other stated goals.

Finally, the proposed rules would place APTA – a professional association and advocacy group – in a conflict of interest position, to the extent it would become a gatekeeper for entry into the profession. The APTA's mission is to advocate and promote the profession. In contrast, the Federation of State Boards of Physical Therapy (FSBPT), the national organization on which all states rely for the national licensing exam, was created to eliminate, protect against and prevent this inherent conflict of interest. Even the APTA recognized this conflict of interest two decades ago when it transferred authority over the NPTE to the FSBPT. CMS must not allow this conflict of interest to become a rule.

We, therefore, urge CMS to require only state licensure for physical therapists wishing to treat Medicare/Medicaid patients. Most importantly, CMS should remove the additional examination requirements contained in subsections (i)(B) and (ii)(B) of the definition of "physical therapist." At a minimum, CMS should delay promulgation of the proposed rule until CMS has had an opportunity to understand the examination, credentialing, and licensing processes currently in place.

Sincerely,

Rhode Island Board of Physical Therapy
Office of Health Professionals Regulation
Rhode Island Department of Health
(401) 222-2828

RICHARD G. LUGAR
INDIANA

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WASHINGTON, DC 20510
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http://lugar.senate.gov

831

COMMITTEES:
FOREIGN RELATIONS, RANKING MEMBER
AGRICULTURE, NUTRITION, AND FORESTRY

United States Senate

WASHINGTON, DC 20510-1401

August 27, 2007

Mr. Herb Kuhn
Centers for Medicare and Medicaid Services
The Administrator
Post Office Box 8000
Baltimore, Maryland 21244

Dear Mr. Kuhn:

Because of the desire of this office to be responsive to all inquiries and communications, your consideration of the attached is requested.

Your findings and views, in duplicate form, along with the return of the enclosure, will be greatly appreciated. Please direct your reply to the attention of Darlee McCollum of my Washington office.

Thank you for your thoughtful attention.

Sincerely,

Richard G. Lugar
United States Senator

RGL/cgd
Enclosure

Lugar, Senator (Lugar)

From: Lezlie Woods [woodslvw@tiptontel.com]
Sent: Monday, August 06, 2007 8:34 AM
To: Lugar, Senator (Lugar)
Subject: STOP POD LABS NOW !!! - Phase II

Lezlie Woods
5155 South 200 West
Peru, IN 46970-7786

August 6, 2007

The Honorable Richard G. Lugar
United States Senate
306 Hart Senate Office Building
Washington, DC 20510-1401

Dear Senator Lugar:

As one of your constituents and as a member of our nation's laboratory medicine team, I am requesting that you contact the Centers for Medicare & Medicaid Services (CMS) regarding its recently published proposed physician fee schedule [72 FR 38179-38181]. Specifically, I urge that you write or call CMS in support of immediate implementation of its proposal to amend the physician self-referral rules regarding reimbursement for laboratory services.

Over the past several months, many Congressional offices have called CMS to urge the agency to adopt regulations governing pod labs. The rules CMS has drafted would impose anti-markup provisions on pathology services, hopefully putting an end to abusive billing practices by so-called "pod"
or "condo" laboratories by closing a loophole inadvertently created when CMS amended its in-office ancillary exceptions rules in 2005. The loophole enabled the proliferation of pod labs which can enable health care providers to profit from the laboratory services they order.

Pod labs are scaled down laboratories, offering a limited menu of services such as analyzing biopsies. These entities in many cases might be little more than an office divided by cubicles with a microscope on a cart being wheeled from one cubicle to the next. These referring providers are engaging in unethical billing practices by pocketing taxpayer dollars from the Medicare program.

Allowing such practices, according to the CMS rule, "may lead to patient and program abuse in the form of higher utilization of services and result in higher costs to the Medicare program." The U.S. Department of Health and Human Services Office of Inspector General has stated that these types of arrangements, which may violate federal anti-kickback statutes, "can distort medical decision-making, cause overutilization, increase costs and result in unfair competition" and "can also adversely affect the quality of patient care."

The Wall Street Journal has run several articles on pod labs, including a feature on October 23, 2006 that stated "patients, in some cases, are being referred for tests…at lower-quality labs simply because the referring physician stands to get a cut of the profits from that work."
The American Medical Associations Council on Ethical and Judicial Affairs has called the practice of ordering providers marking up the cost of laboratory services "unethical."

We in the laboratory medical field need you to urge CMS to implement immediately strict anti-markup requirements on the laboratory services.
Failure to establish stringent regulations will only further hurt the practice of

laboratory medicine and ultimately the patients we seek to serve.

Thank you for your consideration of my request. I look forward to learning your position on this issue and would welcome any correspondence you send to CMS. The comment period ends on August 31st.

Respectfully

Sincerely,

Lezlie Woods

Lugar, Senator (Lugar)

From: Marsha Linville [mlinville@ameripath.com]
Sent: Monday, August 06, 2007 8:15 AM
To: Lugar, Senator (Lugar)
Subject: STOP POD LABS NOW !!! - Phase II

Marsha Linville
10201 E County Rd 650 S
Cloverdale, IN 46120-8939

August 6, 2007

The Honorable Richard G. Lugar
United States Senate
306 Hart Senate Office Building
Washington, DC 20510-1401

Dear Senator Lugar:

As one of your constituents and as a member of our nation's laboratory medicine team, I am requesting that you contact the Centers for Medicare & Medicaid Services (CMS) regarding its recently published proposed physician fee schedule [72 FR 38179-38181]. Specifically, I urge that you write or call CMS in support of immediate implementation of its proposal to amend the physician self-referral rules regarding reimbursement for laboratory services.

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We in the laboratory medical field need you to urge CMS to implement immediately strict anti-markup requirements on the laboratory services.
Failure to establish stringent regulations will only further hurt the practice of

laboratory medicine and ultimately the patients we seek to serve.

Thank you for your consideration of my request. I look forward to learning your position on this issue and would welcome any correspondence you send to CMS. The comment period ends on August 31st.

Respectfully

Sincerely,

Marsha Linville
317-275-8140

Lugar, Senator (Lugar)

From: Linda Marler [lmmarler@iupui.edu]
Sent: Saturday, August 04, 2007 4:40 PM
To: Lugar, Senator (Lugar)
Subject: STOP POD LABS NOW !!! - Phase II

Linda Marler
350 W. 11th St.
Indianapolis,, IN 46202-4108

August 4, 2007

The Honorable Richard G. Lugar
United States Senate
306 Hart Senate Office Building
Washington, DC 20510-1401

Dear Senator Lugar:

As one of your constituents and as a member of our nation's laboratory medicine team, I am requesting that you contact the Centers for Medicare & Medicaid Services (CMS) regarding its recently published proposed physician fee schedule [72 FR 38179-38181]. Specifically, I urge that you write or call CMS in support of immediate implementation of its proposal to amend the physician self-referral rules regarding reimbursement for laboratory services.

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Allowing such practices, according to the CMS rule, "may lead to patient and program abuse in the form of higher utilization of services and result in higher costs to the Medicare program." The U.S. Department of Health and Human Services Office of Inspector General has stated that these types of arrangements, which may violate federal anti-kickback statutes, "can distort medical decision-making, cause overutilization, increase costs and result in unfair competition" and "can also adversely affect the quality of patient care."

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The American Medical Associations Council on Ethical and Judicial Affairs has called the practice of ordering providers marking up the cost of laboratory services "unethical."

We in the laboratory medical field need you to urge CMS to implement immediately strict anti-markup requirements on the laboratory services.
Failure to establish stringent regulations will only further hurt the practice of

laboratory medicine and ultimately the patients we seek to serve.

Thank you for your consideration of my request. I look forward to learning your position on this issue and would welcome any correspondence you send to CMS. The comment period ends on August 31st.

Respectfully

Sincerely,

Linda M. Marler, M.S., MT(ASCP)SM

Lugar, Senator (Lugar)

From: Carolyn Blake [indblake@sbcglobal.net]
Sent: Friday, August 17, 2007 8:32 PM
To: Lugar, Senator (Lugar)
Subject: STOP POD LABS NOW !!! - Phase II

Carolyn Blake
2403 Lakewood Dr
Dyer, IN 46311-2127

August 17, 2007

The Honorable Richard G. Lugar
United States Senate
306 Hart Senate Office Building
Washington, DC 20510-1401

Dear Senator Lugar:

As one of your constituents and as a member of our nation's laboratory medicine team, I am requesting that you contact the Centers for Medicare & Medicaid Services (CMS) regarding its recently published proposed physician fee schedule [72 FR 38179-38181]. Specifically, I urge that you write or call CMS in support of immediate implementation of its proposal to amend the physician self-referral rules regarding reimbursement for laboratory services.

Over the past several months, many Congressional offices have called CMS to urge the agency to adopt regulations governing pod labs. The rules CMS has drafted would impose anti-markup provisions on pathology services, hopefully putting an end to abusive billing practices by so-called "pod"
or "condo" laboratories by closing a loophole inadvertently created when CMS amended its in-office ancillary exceptions rules in 2005. The loophole enabled the proliferation of pod labs which can enable health care providers to profit from the laboratory services they order.

Pod labs are scaled down laboratories, offering a limited menu of services such as analyzing biopsies. These entities in many cases might be little more than an office divided by cubicles with a microscope on a cart being wheeled from one cubicle to the next. These referring providers are engaging in unethical billing practices by pocketing taxpayer dollars from the Medicare program.

Allowing such practices, according to the CMS rule, "may lead to patient and program abuse in the form of higher utilization of services and result in higher costs to the Medicare program." The U.S. Department of Health and Human Services Office of Inspector General has stated that these types of arrangements, which may violate federal anti-kickback statutes, "can distort medical decision-making, cause overutilization, increase costs and result in unfair competition" and "can also adversely affect the quality of patient care."

As a certified medical technologist I am very concerned about the quality of care provided to patients. This quality can only be ensured by providing all laboratory testing in organizations that participate in all aspects of regulatory compliance. In addition, the drain of volume away from qualified facilities increases the cost of busines for healthcare organizations that are struggling to maintain services for the patients in their communities.

The Wall Street Journal has run several articles on pod labs, including a feature on October 23, 2006 that stated "patients, in some cases, are being referred for tests…at lower-quality labs simply because the referring physician stands to get a cut of the profits from that work."
The American Medical Associations Council on Ethical and Judicial Affairs has called the

practice of ordering providers marking up the cost of laboratory services "unethical."

We in the laboratory medical field need you to urge CMS to implement immediately strict anti-markup requirements on the laboratory services.
Failure to establish stringent regulations will only further hurt the practice of laboratory medicine and ultimately the patients we seek to serve.

Thank you for your consideration of my request. I look forward to learning your position on this issue and would welcome any correspondence you send to CMS. The comment period ends on August 31st.

Respectfully

Sincerely,

Carolyn Blake

August 14, 2007

The Honorable Richard G. Lugar
United States Senate
306 Hart Senate Office Building
Washington, D.C. 20510-1401

Dear Senator Lugar:

I am a pathologist who lives and works in the Bloomington area. I am writing because of my concern over so-called "pod" or "condo" labs, and ask that you contact the Centers for Medicare and Medicaid Services (CMS) about its recently published proposed physician fee schedule (72 FR 38170-38181). In particular, I would urge you to contact them in support of its proposal to amend the physician self-referral rules regarding reimbursement for laboratory services.

"Pod" labs are small anatomic pathology labs contained within physician offices, and allow these providers to take a "cut" of the pathology reimbursement from every biopsy obtained by that physician or group. Pathologists are hired to do the work, and paid a fee for interpretation of the biopsies—leaving a substantial profit for the referring physician. I regard these arrangements as unethical and abusive, since there is an incentive for the provider to overutilize biopsies and rack up pathology charges that he or she will directly profit from. The CMS is attempting to eliminate the loophole (inadvertently created in 2005) that allows these labs to exist, since their practices, in its words, "may lead to patient and program abuse in the form of higher utilization of services and result in higher costs to the Medicare program."

Opponents of these proposed changes claim that these "pod" labs enhance patient care. I disagree. One of these labs has been set up in Bloomington by a local physician group. Far from improving patient care, I believe that it has only led to a diminution and greater fragmentation of medical care in our community. For example, results of prostate biopsies are no longer available at Bloomington Hospital when a patient is scheduled for a prostatectomy, which makes it more difficult for my group to evaluate the specimens once a patient has had surgery. I am also concerned that more biopsies are being obtained simply because there is greater reimbursement for doing so. Why obtain only two sets of biopsies when Medicare will reimburse for twelve, and the obtaining physician can keep most of the difference?

I agree with the U.S. Department of Health and Human Services Office of Inspector General when it states that "pod" labs may violate federal anti-kickback statutes, "can distort medical decision-making, cause overutilization, increase costs and result in unfair competition." I believe that failure to establish stringent regulations on this matter will be detrimental to the practice of laboratory medicine and decrease the quality of patient care. I urge you to contact the CMS and ask them to immediately implement their proposed regulations.

Thank you for your consideration on this matter. The comment period for the proposed CMS rules ends on August 31st.

Sincerely,

Eric C. Stevens, M.D.
8191 E. North Shore Dr.
Unionville, IN 47468

Lugar, Senator (Lugar)

From: Henry Bockelman [henry_bockelman@deaconess.com]
Sent: Friday, August 03, 2007 3:46 PM
To: Lugar, Senator (Lugar)
Subject: STOP POD LABS NOW !!! - Phase II

Henry Bockelman
600 Mary Street
Evansville, IN 47747-0001

August 3, 2007

The Honorable Richard G. Lugar
United States Senate
306 Hart Senate Office Building
Washington, DC 20510-1401

Dear Senator Lugar:

As one of your constituents and as a member of our nation's laboratory medicine team, I am requesting that you contact the Centers for Medicare & Medicaid Services (CMS) regarding its recently published proposed physician fee schedule [72 FR 38179-38181]. Specifically, I urge that you write or call CMS in support of immediate implementation of its proposal to amend the physician self-referral rules regarding reimbursement for laboratory services.

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We in the laboratory medical field need you to urge CMS to implement immediately strict anti-markup requirements on the laboratory services.
Failure to establish stringent regulations will only further hurt the practice of

20 August, 2007

TO: Centers for Medicare & Medicaid Services, (CMS)

From: Captain Hank Hester, City of Longview Texas Fire Department

Ref: BENEFICIARY SIGNATURE

To Whom It May Concern,

In dealing with the proposed changes in Section 424.36, "BENEFICIARY SIGNATURE", the Longview Fire Department would like to express its concerns and *disapproval* of such changes in the rule as outlined in the following.

The proposal focuses on the instances of "emergency ambulance transports", and the provider's ability to obtain signatures. Emergency ambulance providers are frequently faced with the task of locating individuals authorized to sign documents in the event that the beneficiary is unable due to mental or physical status. This process is time consuming and burdensome to the provider and often results in confusion and distraction. The process will only become more burdensome by requiring an additional signature from the receiving facility. This additional signature *will* result in conflict with the receiving facilities (emergency departments) secondary to apprehensive employees signing a liable document or statement. In addition, this extra signature signifies less trust in the emergency ambulance provider's ability to declare a patient incapable of signing the claim.

In summary, the Longview Fire Department believes the proposal is not sympathetic to the emergency ambulance providers. This rule will only imply that emergency ambulance professionals cannot make sound decisions without additional documentation from emergency departments. We believe that an ambulance provider can document the inability of the beneficiary to sign, and no individual was able or willing to sign for the beneficiary, and include the date and time the beneficiary was transported, without receiving a signed statement from the receiving facility.

Thank you for your attention in this matter,

Captain Hank Hester
EMS Coordinator
Longview Fire Department

JO BONNER
1ST DISTRICT, ALABAMA

ASSISTANT REPUBLICAN WHIP

REPUBLICAN POLICY COMMITTEE

SERVING BALDWIN, CLARKE, ESCAMBIA, MOBILE, MONROE AND WASHINGTON COUNTIES

833

COMMITTEES:
AGRICULTURE
BUDGET
ETHICS
SCIENCE

ALAN C. SPENCER
CHIEF OF STAFF

Congress of the United States
House of Representatives
Washington, DC 20515

August 27, 2007

Ms. Carleen Talley
Director, Congressional Affairs
U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Room 341-H
Washington, DC 20201-0004

Dear Ms. Talley:

Enclosed please find information from Dr. Charles White of Urology Associates of Mobile, P.A. concerning proposed regulations of physician fee schedules.

I respectfully request that CMS consider the issues that Dr. White addresses in his letter. I am in strong support of Dr. White and the services provided by therapeutic joint ventures.

I would like my comments to be part of the official record of proposal and look forward to hearing from you at your earliest convenience.

With best regards, I remain

Sincerely,

Jo Bonner
Member of Congress

JB:ebr

Enclosure

It was never received.

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(202) 225-4931
FAX: (202) 225-0562
www.house.gov/bonner

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MOBILE, AL 36609
(251) 690-2811
FAX: (251) 342-0404
TOLL FREE: 1-800-288-USA1

1302 NORTH MCKENZIE STREET
FOLEY, AL 36535
(251) 943-2073
FAX: (251) 943-2093

August 30, 2007

VIA FEDERAL EXPRESS

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

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

Dear Acting Deputy Administrator Kuhn:

I am a urologist who practices in the State of Maryland as a member of Eastern Shore Urology Associates, P.A. ("Eastern Shore Urology"). Eastern Shore Urology, is comprised of 5 physicians serving 5 counties on the eastern shore of Maryland. Collectively, we care for over 15,000 Maryland patients every year. Physicians in our practice specialize in both general adult and pediatric urologic care. We also provide specialized care in advanced laparoscopy, incontinence and infertility. I personally care for over 2,500 patients a year. The physicians of Eastern Shore Urology are dedicated to furnishing the highest quality of medical and surgical urologic care in the State of Maryland, with a full range of services provided in a convenient, comfortable, supportive and patient-friendly setting.

As a Maryland urologist, I thank you for the opportunity to comment on the Proposed Rule, published by the Centers for Medicare & Medicaid Services ("CMS") on July 12, 2007. See 72 Fed. Reg. 38122 (July 12, 2007). Although I commend CMS on its continuing efforts to develop clear and comprehensive regulations that implement the Stark Law, I write to express my concerns about the changes contained in the Proposed Rule and the nature of the Preamble discussion with respect to the in-office ancillary services exception (the "Exception"). 42 U.S.C. § 1395nn(b)(2)(A). Let me begin by saying that I do not think that changes to the Exception are necessary to protect against program or patient abuse. In fact, any narrowing of the Exception, or the

implementation of the changes to the reassignment and anti-markup provisions of the purchased diagnostic tests rule that are contained in the Proposed Rule, 72 Fed. Reg. at 38225, 38229, would have a deleterious effect on the health care community generally and on the quality and availability of patient care services offered by Eastern Shore Urology in particular.

The physicians at Eastern Shore Urology take pride in furnishing the very best in quality patient care in a manner that maximizes patient convenience. The care that we provide is enhanced by our current ability to furnish diagnostic services in our offices.

The ability of physicians to affiliate with pathologists allows practices such as ours to identify and work with highly qualified and trained specialists with whom we are familiar and whose work product we trust. This, to us, is critical to our ability to furnish the highest quality care to our Maryland patients. Because we at Eastern Shore Urology know and would personally select the pathologists with whom we would work based on their outstanding credentials, our present ability to practice with pathologists of our choosing provides for a considerably and consistently higher quality of care. They have, in essence, developed a subspecialty in prostate-related diagnoses, have a special interest in prostate pathology and have become experts at reading prostate slides. They are better able, for example, to identify true prostrate cancer from benign tissue and prostate cancer mimickers, thereby reducing "false positives" and saving our patients unnecessary anxiety and cancer treatments. As such, we know and trust the consistency and quality of their reads, which is not something we could do if we are forced by changes in the Exception or the purchased diagnostic tests rule no longer to provide pathology services in the office setting and to send our prostate slides to large hospital-based or commercial labs. Under such circumstances, we would have no idea who is reading the slide; what that person's credentials are; the nature of the person's expertise or training; or whether that person has read one prostate slide or 1,000 prostate slides.

Because we would work together with our pathologists on a daily basis, the means by which we communicate and discuss test results and prepare written reports have become standardized, thereby increasing the efficiency of our practice and our ability rapidly to deliver diagnoses to our anxiously waiting patients. In fact, whereas the national average for turning around test results is five to seven days, our pathologists return test results in three to four days. Moreover, better and more proximate communication with our pathologists, particularly in difficult cases, results in improved clinical diagnoses and outcomes for our patients.

Eastern Shore Urology physicians always have immediate, often face-to-face access to our pathologists to discuss nuances in results and diagnoses, and to engage

the pathologist in the development of an appropriate plan of care for a particular patient. Because our pathologists would be part of our practice, they have access to the patient's complete medical record, previous biopsies and clinical history, and they even can review the slides with the treating physician in person. The treating physician and the pathologist then can – and do – track the effectiveness of the treatment plan and are able quickly to compare test results over a period of time, something that cannot easily be done, if at all, if a member of our practice is forced to rely on community or large commercial labs. Finally, our pathologists clearly are exercising their prerogative to affiliate with Eastern Shore Urology in an arrangement of their choosing, something that might be prohibited by changes to the purchased diagnostic tests rule or a narrowing of the Exception.

With respect to diagnostic imaging, any narrowing of the Exception might impose limits on patient access to the very types of diagnostic imaging services that have become the standard of care in Maryland and throughout the United States by restricting or prohibiting non-radiologists from providing CT services to patients in the office setting. The rapid advance in CT technology, followed by a reduction in acquisition and installation costs, makes it possible for patients to avoid the inconvenience of having to see multiple doctors to have CT services performed outside of their own doctor's offices. This technology, once considered expensive, cumbersome and difficult to use, has advanced into available, affordable and indeed indispensable patient diagnostic tools. As a result, we have incorporated CT technology into our practice to provide more effective and cost efficient diagnosis and treatment to our patients. It is important to note that no matter where a Maryland patient goes for his or her MRI or CT scan, the actual images will be taken by trained technicians who are licensed by the Maryland Board of Physicians using the appropriate imaging technology, and a radiologist will read and interpret the images. There is, therefore, no clinical, quality of care reason to restrict the definition of in-office ancillary services so as to eliminate our ability to furnish state-of-the-art diagnostic imaging services in a setting that is most convenient for our patients and is most efficient with respect to our ability to make a diagnosis.

The changes suggested by the Proposed Rule, and the nature of the comments solicited with respect to the Exception, go far beyond what is necessary to protect the Medicare program from fraud and abuse and to ensure patient care. The Exception as currently interpreted and applied recognizes that certain employment and contractual relationships among physicians are beneficial to patients and strike the appropriate public policy balance between the prophylactic prohibition on self-referrals and the recognition that certain arrangements not only are appropriate, but also are necessary to enhance the efficient provision of quality health care.

Consequently, if the Exception is narrowed in any meaningful way, particularly in a manner that limits the types of ancillary services that can be provided pursuant to the Exception or that restricts the ability of physicians or groups to furnish services in the "same building," 42 U.S.C. § 1395nn(b)(2)(A)(ii)(I), the manner in which the physicians of Eastern Shore Urology practice medicine will be severely impacted, and the quality and convenience of care that we provide to our patients will be significantly compromised. The practical effect would be to restrict access for our patients to routine medical procedures that have become the standard of care throughout the country. Implementation of the proposed changes to the purchased diagnostic test rules would have a similar effect by limiting our ability to provide such services with anything but full-time employees. Both potential changes would create an unjustified monopoly for particular physician specialties to the detriment of patient access and care.

Thank you again for the opportunity to submit these comments on the Proposed Rule.

Sincerely,

John P Foley, M.D.

August 30, 2007

VIA FEDERAL EXPRESS

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

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

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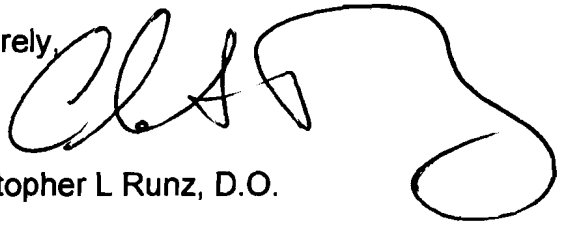

Christopher L Runz, D.O.

836

PENNSYLVANIA ORTHOPAEDIC SOCIETY

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August 30, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
PO Box 8011
Baltimore, MD 21244-1850

RE: CMS-1385-P [PAYMENT CHANGES FOR PHYSICIAN SERVICES IN 2008]

Dear Ms. Norwalk:

The Pennsylvania Orthopaedic Society (POS) appreciates the opportunity to review some of CMS' decision-making process as it contemplates changes to the "Stark" self-referral regulations. While CMS does not make specific proposals with regard to some of the self-referral provisions, we would like to submit comments and clarifications.

ANTI-MARKUP PROVISION

The fiscal and ethical integrity of the Medicare program is a goal shared by all those who participate in it. The POS believes, however, that the proposed "anti-markup" provision is inherently unfair and unreasonably interferes with existing business relationships. We believe orthopaedic practices should have the freedom to either hire in-house professionals or contract with other practices to perform services without fear of financial penalty. We further believe there is little substantive distinction between the two business relationships, and therefore, there should be no reimbursement differential.

IN-OFFICE ANCILLARY EXCEPTION

The POS strongly believes that since physicians have plenary licenses and the authority to supervise and control physical therapy (PT), they should have the right to provide physical therapy services in their offices by employing PTs. Our member orthopaedic surgeons report demonstrable patient care advantages to in-office PT and other services, such as improved communication because patients, PTs and surgeons can all gather in same room to discuss diagnosis and treatment options. Surveys show patients, particularly the elderly or infirmed, prefer the convenience of one-stop orthopaedic and PT care.

In addition, we strongly challenge some of the characterizations articulated in this section of the proposed rule. CMS refers to "hundreds of letters from physical therapists and occupational therapists that the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices." CMS does not elaborate any further on the propriety or harm of this activity. The advantages of physician owned physical and occupational therapy practices to physicians, therapists and, most importantly, patients are well understood. These practices give patients more places to choose from to get physical therapy services. In some cases, it may be more convenient for patients to obtain therapy at their physicians' offices than have to travel somewhere else to get them. In addition, some patients may feel more comfortable knowing that their therapists and physicians are working together at the same location.

Finally, POS submits the limitation of physical therapy services in orthopedic surgeon practices unnecessarily advances the interests of physical therapists and improperly limits orthopaedic surgeons' ability to compete with PTs. Every year, OIG inquires about new potential safe harbor regulations, focusing on arrangements that do not negatively affect a number of issues including, cost, competition, quality and utilization. Eliminating or restricting PT in orthopaedic surgeon practices limits competition and is directly contrary to OIG's longstanding principles.

Further, the benefits of market competition were also acknowledged more recently in a joint report issued by the Federal Trade Commission (FTC) and the Department of Justice (DOJ) entitled "Improving Health Care: A Dose of Competition". This report, based on a two-year study of the role of competition in the health care marketplace, concludes that "vigorous competition promotes the delivery of high quality, cost-effective health care" by lowering prices and promoting quality and innovation resulting in, among other things, "treatments offered in a manner and location consumers desire." With respect to ASCs in particular, the FTC and DOJ concluded that ASCs "had a number of beneficial consequences for consumers," such as improved technology, a non-institutional, friendly environment and "more convenient locations, shorter wait times, and lower coinsurance than a hospital department." In commenting on the effect competition has on hospitals ability to provide certain services, the report stated:

> Competition has a number of effects on hospitals, including the potential to improve quality and lower costs. Competition will also undermine the ability of hospitals to engage in cross-subsidization, however. To address this issue, Congress and state legislatures should consider whether direct subsidies for desired conduct are advisable.

The POS opposes any rule change that would inhibit our members' abilities to provide in-office ancillary services.

ALTERNATIVE CRITERIA FOR SATISFYING CERTAIN EXCEPTIONS

The POS commends CMS on its attempt to bring rationality to the strict enforcement of inadvertent form violations of the self-referral regulations. We do, however, believe that CMS should amend the proposal so as not to be so unilateral on the part of CMS. We believe that CMS can preserve its authority, while simultaneously ensuring that those that are subjected to this rule and exception are able to access the benefits of it.

The Pennsylvania Orthopaedic Society again thanks you for the opportunity to review and comment on the CMS' decision-making process as it contemplates changes to the "Stark" self-referral regulations.

Sincerely,

Chip Hummer

Charles D. Hummer III, MD
President

August 30, 2007

VIA FEDERAL EXPRESS

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

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

Dear Acting Deputy Administrator Kuhn:

I am a urologist who practices in the State of Maryland as a member of Eastern Shore Urology Associates, P.A. ("Eastern Shore Urology"). Eastern Shore Urology, is comprised of 5 physicians serving 5 counties on the eastern shore of Maryland. Collectively, we care for over 15,000 Maryland patients every year. Physicians in our practice specialize in both general adult and pediatric urologic care. We also provide specialized care in advanced laparoscopy, incontinence and infertility. I personally care for over 2,500 patients a year. The physicians of Eastern Shore Urology are dedicated to furnishing the highest quality of medical and surgical urologic care in the State of Maryland, with a full range of services provided in a convenient, comfortable, supportive and patient-friendly setting.

As a Maryland urologist, I thank you for the opportunity to comment on the Proposed Rule, published by the Centers for Medicare & Medicaid Services ("CMS") on July 12, 2007. See 72 Fed. Reg. 38122 (July 12, 2007). Although I commend CMS on its continuing efforts to develop clear and comprehensive regulations that implement the Stark Law, I write to express my concerns about the changes contained in the Proposed Rule and the nature of the Preamble discussion with respect to the in-office ancillary services exception (the "Exception"). 42 U.S.C. § 1395nn(b)(2)(A). Let me begin by saying that I do not think that changes to the Exception are necessary to protect against program or patient abuse. In fact, any narrowing of the Exception, or the

implementation of the changes to the reassignment and anti-markup provisions of the purchased diagnostic tests rule that are contained in the Proposed Rule, 72 Fed. Reg. at 38225, 38229, would have a deleterious effect on the health care community generally and on the quality and availability of patient care services offered by Eastern Shore Urology in particular.

The physicians at Eastern Shore Urology take pride in furnishing the very best in quality patient care in a manner that maximizes patient convenience. The care that we provide is enhanced by our current ability to furnish diagnostic services in our offices.

The ability of physicians to affiliate with pathologists allows practices such as ours to identify and work with highly qualified and trained specialists with whom we are familiar and whose work product we trust. This, to us, is critical to our ability to furnish the highest quality care to our Maryland patients. Because we at Eastern Shore Urology know and would personally select the pathologists with whom we would work based on their outstanding credentials, our present ability to practice with pathologists of our choosing provides for a considerably and consistently higher quality of care. They have, in essence, developed a subspecialty in prostate-related diagnoses, have a special interest in prostate pathology and have become experts at reading prostate slides. They are better able, for example, to identify true prostrate cancer from benign tissue and prostate cancer mimickers, thereby reducing "false positives" and saving our patients unnecessary anxiety and cancer treatments. As such, we know and trust the consistency and quality of their reads, which is not something we could do if we are forced by changes in the Exception or the purchased diagnostic tests rule no longer to provide pathology services in the office setting and to send our prostate slides to large hospital-based or commercial labs. Under such circumstances, we would have no idea who is reading the slide; what that person's credentials are; the nature of the person's expertise or training; or whether that person has read one prostate slide or 1,000 prostate slides.

Because we would work together with our pathologists on a daily basis, the means by which we communicate and discuss test results and prepare written reports have become standardized, thereby increasing the efficiency of our practice and our ability rapidly to deliver diagnoses to our anxiously waiting patients. In fact, whereas the national average for turning around test results is five to seven days, our pathologists return test results in three to four days. Moreover, better and more proximate communication with our pathologists, particularly in difficult cases, results in improved clinical diagnoses and outcomes for our patients.

Eastern Shore Urology physicians always have immediate, often face-to-face access to our pathologists to discuss nuances in results and diagnoses, and to engage

the pathologist in the development of an appropriate plan of care for a particular patient. Because our pathologists would be part of our practice, they have access to the patient's complete medical record, previous biopsies and clinical history, and they even can review the slides with the treating physician in person. The treating physician and the pathologist then can – and do – track the effectiveness of the treatment plan and are able quickly to compare test results over a period of time, something that cannot easily be done, if at all, if a member of our practice is forced to rely on community or large commercial labs. Finally, our pathologists clearly are exercising their prerogative to affiliate with Eastern Shore Urology in an arrangement of their choosing, something that might be prohibited by changes to the purchased diagnostic tests rule or a narrowing of the Exception.

With respect to diagnostic imaging, any narrowing of the Exception might impose limits on patient access to the very types of diagnostic imaging services that have become the standard of care in Maryland and throughout the United States by restricting or prohibiting non-radiologists from providing CT services to patients in the office setting. The rapid advance in CT technology, followed by a reduction in acquisition and installation costs, makes it possible for patients to avoid the inconvenience of having to see multiple doctors to have CT services performed outside of their own doctor's offices. This technology, once considered expensive, cumbersome and difficult to use, has advanced into available, affordable and indeed indispensable patient diagnostic tools. As a result, we have incorporated CT technology into our practice to provide more effective and cost efficient diagnosis and treatment to our patients. It is important to note that no matter where a Maryland patient goes for his or her MRI or CT scan, the actual images will be taken by trained technicians who are licensed by the Maryland Board of Physicians using the appropriate imaging technology, and a radiologist will read and interpret the images. There is, therefore, no clinical, quality of care reason to restrict the definition of in-office ancillary services so as to eliminate our ability to furnish state-of-the-art diagnostic imaging services in a setting that is most convenient for our patients and is most efficient with respect to our ability to make a diagnosis.

The changes suggested by the Proposed Rule, and the nature of the comments solicited with respect to the Exception, go far beyond what is necessary to protect the Medicare program from fraud and abuse and to ensure patient care. The Exception as currently interpreted and applied recognizes that certain employment and contractual relationships among physicians are beneficial to patients and strike the appropriate public policy balance between the prophylactic prohibition on self-referrals and the recognition that certain arrangements not only are appropriate, but also are necessary to enhance the efficient provision of quality health care.

Consequently, if the Exception is narrowed in any meaningful way, particularly in a manner that limits the types of ancillary services that can be provided pursuant to the Exception or that restricts the ability of physicians or groups to furnish services in the "same building," 42 U.S.C. § 1395nn(b)(2)(A)(ii)(I), the manner in which the physicians of Eastern Shore Urology practice medicine will be severely impacted, and the quality and convenience of care that we provide to our patients will be significantly compromised. The practical effect would be to restrict access for our patients to routine medical procedures that have become the standard of care throughout the country. Implementation of the proposed changes to the purchased diagnostic test rules would have a similar effect by limiting our ability to provide such services with anything but full-time employees. Both potential changes would create an unjustified monopoly for particular physician specialties to the detriment of patient access and care.

Thank you again for the opportunity to submit these comments on the Proposed Rule.

Sincerely,

Edmond J FitzGerald, M.D.

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August 27, 2007

Kerry N. Weems
Administrator Designee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Comments to Proposed Rule [CMS-1385-P]

Dear Administrator Weems:

My name is John Adler and I am a Professor of Neurosurgery at Stanford University. I have been involved with image-guided robotic radiosurgery since the mid-1990s, and my institution is a CyberKnife Coalition member. Moreover, I have considerable experience with a range of surgical procedures as well as advanced radiation techniques. I am grateful to have this opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) on CMS-1385-P RIN 0938-AO65 Medicare Program: Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008.

To provide some background to the current discussion, it is worth noting that medical linear accelerators were developed in the 1960s, and as a point of pertinent history, the first medical accelerator was installed here at Stanford University. Regardless, this technology allowed physicians to deliver isocentric radiation treatments for a spectrum of different tumors over the course of several weeks. The need to administer this radiation over several weeks was to minimize the impact on the irradiated normal tissues. In the 1980s, there were advancements in computers and imaging which then led to three-dimensional conformal radiation (3D-CRT) and, eventually, image-guided radiation therapy. The latter technique enabled CT imaging to be more tightly coupled to LINAC irradiation and therefore more precisely register the location of the

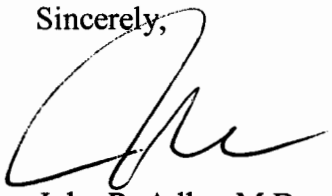
tumor with respect to the radiation field. Intensity modulated radiation therapy (IMRT) arrived in the 1990s and enabled radiation oncologists to better customize the shape of the radiation field to conform to an irregularly-shaped tumor.

In parallel with the above developments, frame-based stereotactic radiosurgery was developed, beginning in the 1960s. Stereotactic radiosurgery (SRS) gave neurosurgeons the ability to deliver radiation with exceptionally high accuracy to both the brain and the skull base. Such intracranial treatments relied on the attachment of an external head frame to the patient's skull and then manual adjustment of the patient with respect to the LINAC isocenter. The value of this measure of accuracy was that it allowed greater doses of radiation to be administered, typically in a single session. The clinical benefits of this approach in the mid-1990s inspired the development of image-guided robotic stereotactic radiosurgery (r-SRS). This new technique proved significantly different from traditional radiosurgery in two ways: (1) no head or body frame was required, and (2) the flexibility of targeting allowed non-isocentric treatments for the first time. This latter capacity made possible something we call dose painting, where one can nearly optimize the way radiation is deposited on an irregularly-shaped tumor. In doing so, one can even further minimize the amount of radiation that lands on normal tissue.

In light of the above history, I wish to comment on the pending CMS decision. In the CY 2007, PFS Final Rule, CMS revised the status indicator of Level II HCPCS codes for image-guided robotic linear accelerator-based stereotactic radiosurgery (G0339 and G0340) to indicate that they would be Carrier-priced. I wholeheartedly support CMS in maintaining these HCPCS codes for CY 2008, with the current status indicator, so that Medicare beneficiaries may continue to have access to this treatment in the free-standing center setting, and providers may continue to bill for services using the most appropriate codes.

In conclusion, I appreciate the opportunity to comment, and thank the Agency for its decision to continue the use of Carrier-priced Level II HCPCS codes for image-guided robotic stereotactic radiosurgery in CY 2008.

Sincerely,



John R. Adler, M.D.
Professor
Department of Neurosurgery

JRA:msm

ASDS
American Society for
Dermatologic Surgery

August 28, 2007

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

Re: CMS 1385-P: 2008 Medicare Fee Schedule
Coding – Multiple Procedure Reduction Rule for Mohs Surgery

Dear Acting Administrator Kuhn:

As President of the American Society for Dermatologic Surgery (ASDS), a medical specialty organization representing over 4700 dermatologic surgeons, including the vast majority of those performing Mohs micrographic surgery, I would like to thank you for the opportunity to comment on the proposed change in the exempt status of Mohs surgery codes 17311 and 17313 from the Multiple Procedure Reduction Rule (MPRR).

We are concerned that the proposed rule, which would be a significant reversal of CMS' own longstanding exemption of the Mohs codes from the MPRR, may represent a misunderstanding of the separate and unique nature of Mohs surgery relative to other procedures on the same day. The result would be an inappropriate application of the MPRR that will have a negative impact on Medicare beneficiaries' access to timely care, with a potential increase in risk and cost.

Back in 1991, CMS determined that the Mohs codes were indeed separate and distinct procedures, for which an exemption from the Multiple Procedure Reduction Rule was appropriate. CMS stated at that time that Mohs surgeries "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." We believe this determination by CMS was correct, and note that the exemption has been maintained ever since.

At the request of CMS in the 2006 five-year review of the Mohs codes, we worked with AMA CPT/AMA RUC to develop two new base codes, 17311 and 17313, to reflect Mohs surgery on different anatomic sites. The new codes differed only in the specification of anatomic site. Although new codes were created, there were and have been no changes in the "technical elements of the procedure" that should alter CMS' original determination that exemption was appropriate. The AMA CPT/AMA RUC review of the new codes and descriptors did not change the characteristics that qualified the new 17311 and 17313 codes for inclusion on the modifier -51 exemption list. While the old Mohs surgery code was deleted with the adoption of the new codes, the nature of the procedure has not changed, nor should the exempt status of the new codes change.

The basis for CMS's original exemption related to an examination of the procedure itself. Mohs surgical excision of a skin cancer includes meticulous excision of the tumor and complete histopathologic examination of the margins. The excision of tumors is completed in stages, such that each stage must be completed in entirety prior to subsequent stages or repair. Each stage consists of rooming the patient, discussing, positioning, anesthetizing, prepping, draping, excising, dressing, mapping, inking, processing, and interpreting the histopathology; stages are repeated until tumor margins are clear.

Treatment of multiple tumors at the same time requires each component be completed for each tumor. The patient waits during the processing and interpretation portions of the procedure. Repair procedures following Mohs tumor excision require that all the same steps be undertaken again (except the tissue processing and interpretation), usually with new instrumentation and often in different rooms. As such, each Mohs tumor excision is performed in a completely separate operative session from every other tumor excision and from any repair procedure. There is minimal overlap in work from one stage to the next, from excision to repair, or between Mohs excision of two separate tumors at the same time.

Mohs surgery includes both surgical and pathological components; the inherent requirements for both account for the minimal overlap between Mohs excision of two separate tumors at the same time and between Mohs excision and a subsequent repair. Because of these dual components of surgery and pathology, 80% of the work of Mohs code 17311 is intra-service work (78% for 17313), with little pre- or post-service work. Such valuation was examined and approved by the RUC. The large amount of intra-service work, in addition to the fact that the Mohs tumor excisions are performed at separate operative sessions from repairs, differentiate the Mohs codes from other surgical codes. Because of the large pathology component of the Mohs codes, which must be completed in its entirety for each tumor independently and before contemplating repair, the "efficiencies" referred to in the proposed rule are not realized for Mohs surgery, even for treatment of two tumors on the same date. **It is inappropriate to subject these codes to the MPRR for efficiencies which don't exist.**

Additionally, approximately half the physician work of the Mohs codes represents work related to histopathology. As with all pathology codes, work of interpreting one block or specimen is completely independent of interpretation of other specimens; as such, exemption of pathology codes is appropriate, and they traditionally have not been subject to multiple surgery reduction. **Application of the MPRR to the Mohs codes would be incongruous with the appropriate exemption of other pathology codes.**

In determining characteristics of codes appropriate for exemption from the MPRR, the AMA CPT/AMA RUC Modifier -51 Workgroup identified various criteria. In addition to CMS longstanding exemption and the large amount of intra-service work referred to above, which meet two of the criteria, Mohs surgery codes are used both as adjunct codes

and as stand-alone codes. Although usually used as adjunct codes with separate repair codes, in 10-30% of cases, depending on the surgeon, wounds created by Mohs excision
are allowed to heal by second intention, with no repair procedure performed. This is particularly true for defects in concave areas such as the alar crease, medial canthus, and conchal bowl, in addition to sites off the face and less noticeable areas, such as the posterior pinna. **Such adjunct and stand-alone use meets a third criterion for exemption.**

We are concerned that the application of the MPRR to the Mohs codes will decrease Medicare beneficiaries' access to timely care and potentially increase complications and costs. In approximately 10% of cases, more than one Mohs excision is performed on the same date. This is most likely for patients with multiple tumors, who tend to be older patients and those patients at high risk due to immunosuppression from organ transplantation, chemotherapy, medication, etc. These are also the patients at greatest risk for metastasis from squamous cell carcinoma and subsequent morbidity and mortality. Application of the MPRR will delay treatment for these high-risk patients and increase the risk of subsequent complications.

Application of the MPRR to the Mohs codes may also affect repair patterns, with potential increases in cost. Reduced reimbursement for the lower-valued code, whether Mohs tumor excision or the associated repair, will make it less cost-effective for surgeons to excise and reconstruct cancers on the same day. This will likely result in an increase in referral by Mohs surgeons to other surgeons for reconstruction. Such referrals would most often be to plastic surgeons, facial plastic surgeons, or oculoplastic surgeons, most of whom operate in the hospital or in ambulatory surgery centers, where the cost of reconstruction is greater than that of the Mohs surgeon practicing in less expensive facilities. **The increased cost of repair will offset potential cost savings of the MPRR.**

ASDS
American Society for
Dermatologic Surgery

There are many reasons for the increase in utilization of the Mohs codes, including an increasing number of skin cancers, which currently affect over one million Americans and are projected to affect one in five Americans in their lifetimes. At the same time, there is an increasing number of surgeons trained in the Mohs technique utilizing the codes. While application of the Multiple Procedure Reduction Rule could appear to be a cost-savings measure and tempting to apply to Mohs surgery, it is inappropriate by previous CMS decision and current RUC policy, as I have detailed previously. Mohs surgery is a separate and distinct procedure from other procedures performed on the same day and for which no significant gain in efficiencies exists when performed with other procedures.

Application of the reduction will negatively impact care and unnecessarily put patients at risk without generating significant cost savings. We urge CMS to amend the Proposed Rule and permanently restore the exemption from the Multiple Procedure Reduction Rule to the Mohs codes 17311 and 17313.

Thank you again for the opportunity to comment on an issue that is critically important to our members and the skin cancer patients we serve. Should you require additional information, please do not hesitate to contact Lisle Poulsen, ASDS Advocacy and Socioeconomic Affairs Manager, at lpoulsen@asds.net or (847) 956-9125. I appreciate your attention to this important matter.

Sincerely,

Alastair Carruthers, FRCPC
President

cc: Terrence Kay, Director, Hospital and Ambulatory Policy Group, Centers for Medicare and Medicaid Services
Amy Bassano, Director, Practitioner Services Division, Centers for Medicare and Medicaid Services
Diane Baker, MD, President, American Academy of Dermatology
David G. Brodland, MD, President, American College of Mohs Surgery
Sharon Tiefenbrunn, MD, President, American Society for Mohs Surgery
Katherine J. Svedman, Executive Director
Lisle Poulsen, Advocacy and Socioeconomic Affairs Manager
Ronald A. Henrichs, CAE, Executive Director and CEO, American Academy of Dermatology
Georganne Dixon, Executive Director, American College of Mohs Surgery
Novella Rodgers, Executive Director, American Society for Mohs Surgery

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August 31, 2007

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

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

In its review of the Mohs codes in 1991, CMS agreed that Mohs excisions are "separate staged procedures; they will be paid separately with no multiple surgery reductions." This rule was placed in the Federal Register at that time (Federal Register, November 25, 1991, volume 56, #227, pg 59602). In 2004, the Mohs codes were added to the CPT Appendix E list of codes exempt from the -51 modifier and the multiple surgery reduction rule, to eliminate the occasional carrier misunderstanding when the multiple surgery reduction was applied to these codes. The July 2004 CPT Assistant article reviewed the rationale: "The rationale for this policy is that for many surgical procedures some of the work of a procedure is not repeated when two or more procedures are performed. For these procedures the intraservice work is only 50% of the total work, while the other 50% represents pre- and post-service work that overlaps when multiple procedures are performed on the same patient on the same date of service. For Mohs surgery, however, greater than 80% of the work is intraservice work that does not overlap when two or more procedures are performed. The pathology portion of Mohs surgery constitutes a large portion of this total and also is not reduced with multiple procedures. The preservice and postservice work values are small because there is a zero-day global period. Together there is very little overlap or reduction in work when two or more tumors are treated on the same patient on the same day. Therefore, Mohs surgery codes are exempt from the use of modifier 51."

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

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

I am asking that you use re-consider this change that negatively impacts appropriate care for the patient and appropriate reimbursement for services provided by the physician.

Sincerely,

Camille Mason

Signature Date

Camille Mason

Name (print)

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August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: 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; and the Proposed Elimination of the E-Prescribing Exemption for Computer-generated Facsimile Transmissions.

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the proposed revisions to the 2008 Medicare Physician Fee Schedule.

IMPACT: 2008 MEDICARE PHYSICIAN PAYMENT RATE

Since 2001, physician payments have fallen more than 20 percent below the cost of providing care. Additionally, physicians face cuts of 9.9 percent in their Medicare payment update in 2008. If the current Medicare payment formula is not replaced, physicians will face cuts of greater than 40 percent over the next eight years. Since many health care programs link their payments to Medicare, cuts in other systems will compound the impact.

As a result of the flawed Sustainable Growth Rate formula, physicians are not investing in health information technology and other efforts to support quality initiatives and resource management. The SGR penalizes physicians and other health professionals for any spending over the target, even when spending is focused on preventive care services to reduce future hospitalizations.

The AOA continues to survey its members regarding the impact that current financial pressures is having on their ability to practice medicine. Many physicians have begun to alter their participation in the Medicare program creating potential access to care issues for millions of beneficiaries. If more reimbursement cuts take effect, many physicians will determine that participating in Medicare is no longer feasible. Here is a sampling of our physicians' reactions:

Family Practice physician, Lake Montezuma, AZ: *I am an osteopathic physician working in a rural practice in Northern Arizona. If my income continues to decrease, I will be forced to move to a salaried position in a larger city. Many patients in this rural community will be without care. Many of my patients are elderly and simply cannot drive on the highway to get to another physician.*

Family Practice physician, Tucson, AZ: *Our office cannot afford to take any NEW Medicare patients. We will stay loyal to the patients we already have, including those who eventually become Medicare eligible, but not any NEW ones. If Medicare cuts are implemented, we will once again have to reevaluate our cash flow. Depending upon the impact of those cuts on our cash flow, further Medicare services may need to be eliminated.*

Orthopedic Surgeon, Palm Harbor, Fla: *If these cuts take effect, I can almost certainly assure you that I and probably the rest of my 6-man group will stop accepting Medicare patients into our practice. It is very sad that on average, Medicare reimburses 26-cents on the dollar for our services. No other business would ever DREAM of accepting this amount as payment in full for their services yet physicians do. Lowering the already dismal reimbursement for physicians will do nothing but lower the availability of services for a very needy population.*

Family Physician, Indianapolis, IN: *I am an osteopathic family physician because I believe in taking time and caring for the whole patient. If reimbursement continues to decrease I will be unable to continue to give the high quality patient centered care that I can currently provide. Further pay cuts require seeing more patients just to keep the doors open. Add to that the reality that I personally have over $150,000 of medical school debt. Cuts in reimbursement means medical students will be choosing specialties with higher compensation and fewer and fewer will be choosing to be high quality primary care physicians. I loved my primary care physician growing up. He cared for the whole family. This is an American way of life that should not be lost.*

Sustainable Growth Rate (SGR)

The SGR is tied to flawed methodologies and produces negative updates based upon economic factors, not the health care needs of patients. Medicare should reimburse physicians in a manner that reflects the costs of providing care to beneficiaries. The current payment formula fails to account for changes in practice patterns, coverage determinations, and new treatment options and technologies. Steps must be taken to eliminate the year-to-year uncertainty that has plagued the Medicare physician payment formula for the past five years.

We recognize there are financial obstacles to accomplishing this goal. However, the costs of not reforming the system may be greater. Physicians cannot afford to have continued reductions in reimbursements. Ultimately, they either will stop participating in the Medicare program or limit the number of beneficiaries they accept into their practices. Either of these scenarios results in decreased access for our growing Medicare population.

The AOA believes CMS has the administrative authority to alleviate the problems related to the SGR such as removing the cost of physician-administered drugs and providing a more accurate account for the numerous policy changes and coverage decisions in the SGR targets. However, ultimately Congress must repeal the formula and replace it with a system that provides all physicians participating in the Medicare program with positive updates that reflect increases in practice costs. Until a repeal is enacted, payments should be stabilized for a minimum of two years by providing positive baseline updates to all physicians, comparable to increases in practice costs.

The AOA also believes it is imperative for Medicare to reflect fairly the increased role of physicians and outpatient services as cost savers to the Part A Trust Fund. Quality improvement programs may increase spending in Part B, but very well could result in savings in Part A or Part D. These savings should be credited to physicians through a gain-sharing program between Parts A, B, and D.

Budget Neutrality

CMS proposes to make an 11.8 percent budget-neutrality adjustment to the work relative value units to address the financial impact of the proposed changes in the 2008 Medicare Physician Fee Schedule. The AOA disagrees with this approach as it did when CMS proposed and finalized a similar adjustment for the 2007 Medicare Physician Fee Schedule. The AOA remains concerned that adjusting only the work RVUs will result in undervaluing these services relative to the remaining Medicare Fee Schedule.

We believe that budget neutrality adjustments should not alter these existing relationships. In addition, adjusting the Medicare conversion factor is preferable because it will prevent confusion and misinterpretation by other payers who utilize the MFS to determine physician payments.

The AOA believes that adjustment to the conversion factor appropriately recognizes that budget neutrality is a fiscal issue, not an issue of relativity, and will maintain the integrity of the entire MFS. We are concerned that adjusting the work RVUs will compromise the improvements made to the values of the E&M services.

Budget neutrality is mandated for monetary purposes, therefore applying the budget neutrality adjustment to the conversion factor is the proper approach. In addition, applying the adjustment to the conversion factor would be in line with CMS' goal of making the Medicare payment system transparent. Therefore, the AOA supports a budget neutrality adjustment of the conversion factor as the appropriate method and requests that CMS reconsider its present position.

TRHCA – SECTION 101 (d): PAQI

We believe CMS should use the $1.35 billion Physician Assistance and Quality Initiative Fund (PAQI) provided as part of the Tax Relief and Health Care Act of 2006 (H.R. 6111) to help stabilize the 2008 physician payment update. CMS cites "fundamental legal and operational problems" that would not make such an application possible. We disagree and we are calling on Congress to provide clear direction to CMS about the use of the PAQI fund.

GEOGRAPHIC PRACTICE COST INDEX (GPCI)

The AOA was pleased when the Tax Relief & Health Care Act of 2006 (HR 6111) extended the floor of 1.000 on the work GPCI adjustments for another year. The adjustment provided equity in how the Medicare program views and evaluates the work of physicians regardless of geographic location.

The gap between urban and rural payment rates for identical services has exacerbated the mal-distribution of physicians in urban versus rural areas. As a result of the 1.000 floor provision's expiration on December 31, 2007, many physicians, especially those in rural areas, will experience reimbursement cuts in addition to the 9.9 percent reduction in the payment update.

CMS also proposes three options for updating California's payment localities. CMS requests comments on refining localities because they may be applied more broadly in the future. Our primary concern is ensuring that the geographic adjustment factor (GAF) appropriately reflects cost of living in the various regions.

Since federal law requires changes in the Medicare program to be budget neutral, all three options would require some localities to experience additional payment cuts. Physicians already face significant payment reductions due to the flawed Medicare payment formula. The AOA does not support any of the options in their current form. Physicians should not be penalized for practicing in any particular locality.

RESOURCE-BASED PE RVUs

The AOA commends CMS for proposing to adopt all of the AMA/Specialty Society Relative Value Update Committee (RUC) recommendations provided in 2007.

Equipment Usage Percentage Assumptions - Equipment Utilization Data

The AOA also supports the RUC's position that the equipment utilization rate should be higher than the current 50 percent. A higher rate should be coupled with an opportunity for specialty societies to provide data to support lower utilization rates, if appropriate, based on clinical or geographic considerations. An increase in the utilization rate should redistribute practice expense relative values to all services within the RBRVS.

MEI

The President's budget proposal for 2008 recommends that the payment update for inpatient and outpatient hospital services, hospices and ambulance services be reduced by 0.65 percentage points each year to offset productivity increases. CMS adjusts the MEI downward to account for physicians' productivity in providing patient care. The productivity adjustment for 2007 was 1.3 percent. For 2008, CMS forecasts a 1.5 percent productivity offset based on the 10-year moving average of multifactor productivity.

The AOA questions why other providers receive a .65 percent adjustment while physicians face an adjustment of more than twice the amount? The AOA believes the 1.5% adjustment for physicians is too high. In addition, the MEI does not adequately account for the costs related to the multitude of regulations and requirements that physicians must comply with in their practices.

Without an accurate accounting, the practice cost measurement will always be too low. CMS and the physician community should work together to set an adjustment that accurately measures increases in physician productivity.

PHYSICIAN SELF-REFERRAL PROVISIONS

The complexities and confusion relating to the self-referral requirements is a chronic problem. The self-referral requirements have a history of creating obstacles for physicians to provide services to their patients. The latest proposals do not alleviate these challenges. In addition, the agency just released the final regulations (Phase III of Stark II) prohibiting physician self-referrals.

The AOA recommends that CMS withdraw its self-referral proposals. We believe the agency should place its emphasis on simplifying the regulations so that physicians are not penalized for arrangements that are not related to self-referrals and that provide better care for their patients.

PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

The AOA believes that the widespread adoption of health information technologies, such as electronic medical records and electronic prescribing, will reduce the occurrences of medical errors, enhance quality, and improve the efficiency of providing medical care. The AOA supports efforts to ensure that all patient populations, especially those in rural and underserved communities, benefit from this effort.

In the Nov. 7, 2005 final rule, CMS included an exemption for computer-generated faxes from the NCPDP Script Standard. CMS noted the concern that without the exemption, users would revert back to paper prescribing. It was also believed that users of computer generated faxes eventually would transition to fully functional e-prescribing.

CMS now believes that "eliminating the exemption for computer generated faxes would move prescribers and dispensers using this technology to upgrade to software products or to new version of the products they already use that would enable electronic transmission of SCRIPT transactions. Because the requirement would fall on prescribers that already use e-prescribing software, it would increase the number of SCRIPT transactions fairly significantly in a relatively short time period, and this could in turn create a tipping point that could create an economic incentive for independent pharmacies to adopt software to begin to exchange SCRIPT transactions with their prescriber partners."

Therefore, CMS proposes to eliminate the computer-generated facsimiles exemption to the NCPDP SCRIPT Standard for the communication of prescription or certain prescription-related information between prescribers and dispensers. The proposed deadline for eliminating the exemption for computer-generated faxes is Jan. 1, 2009.

The AOA shares the agency's goal. The AOA encourages its members to adopt e-prescribing systems because they will improve patient safety, customer service, and decrease the wait times for prescriptions. Overall, software and hardware used throughout the healthcare system must be interoperable. There is no benefit to be found in the utilization of systems unable to communicate with others. The AOA believes strongly that systems developed and implemented must not compromise the essential patient-physician relationship.

A variety of challenges remain regarding the adoption of e-prescribing, including computer-generated faxes. For example, implementing e-prescribing in a physician's office requires significant staff resources, and substantial time and effort with vendors, state regulators, and local pharmacies to implement and maintain the system. In addition, many local pharmacies are not prepared to use e-prescribing. These challenges slow the transition to a fully functional e-prescribing system. Due to these overall complexities, more opportunities are needed for businesses to comply with e-prescribing standards. The AOA recommends that CMS extend the deadline for eliminating the exemption for computer-generated faxes to Jan. 1, 2011.

PHYSICIAN SCARCITY AREAS

The AOA and the osteopathic medical profession are committed to providing care in underserved areas of the U.S. The Medicare Modernization Act provided a five percent incentive payment to physicians furnishing services in physician scarcity areas (PSAs) on or after Jan. 1, 2005 and before January 1, 2008. The AOA regrets that the PSA program is set to expire. The five percent bonus is a good program for

physicians serving in underserved areas particularly during a time when reimbursements are on the decline. The AOA hopes that Congress will extend financing for this program.

TRHCA-SECTION 101 (b): PQRI

Osteopathic physicians work to provide the highest quality care to their patients. Our members are committed to ensuring that all patients receive the appropriate health care based upon their medical condition and the latest research and technology. We support programs that aim to improve the quality of care provided within the Medicare program. Additionally, we are supportive of establishing reasonable standards that allow for the reporting and analysis of reliable quality data.

While the AOA has cooperated with CMS in providing educational material and continual updates on PQRI to our members, we remain concerned that physicians, particularly in small practices, cannot afford to participate in the program. According to comments we have received from our members, participating in PQRI would require an additional full-time employee to gather the data required to be reported. The increased reimbursement (at the 1.5% - max) would not cover the cost incurred for the additional FTE required.

At a time when physicians face decreases in their reimbursement rates, participating in PQRI is financially detrimental. Regulatory and administrative demands created by non-patient care expenses result in fewer resources being available for physician and nursing time with patients. Participating in PQRI requires physicians to assume a larger administrative task at a time when their reimbursement rates have fallen more than 20 percent below inflation.

We urge CMS to share with the physician community the results of PQRI for 2007 in terms of the level of physician participation, the challenges, and lessons learned from the program.

Consensus Organizations and Consensus-based Process for Developing Measures

CMS proposes eight policies in identifying measures that meet the MIEA-TRHCA requirements for having used a consensus-based process for development and the requirement for having been endorsed or adopted by a consensus organization such as the NQF or AQA, and that are appropriate for inclusion as 2008 measures.

According to CMS, "the basic steps for developing the physician level measures may be carried out by a variety of different organizations. We do not interpret the MIEA-TRHCA to place special restrictions on the type or make up of the organizations carrying out this basic development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the basic development of physician quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards."

All measures, used on physician performance or quality, should be developed by physicians. Physicians must take the lead in developing, updating, and implementing any initiative to improve the quality of care. Third-party influences could lead to greater loss of physician autonomy, more interference with clinical judgment, added regulatory/administrative burdens, the stifling of innovation, and the demise of individualized care.

Practicing physicians must be involved in the development of quality measures and the reporting process. Clear channels of input and feedback for physicians must be established throughout the process regarding the impact and potential flaws within the quality measures and program. All methodologies, including measure definitions, should be transparent and readily available to physicians.

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

The AOA recognized early on the need for quality improvement and the national trend toward quality improvement programs. In 2000, our association introduced the web-based Clinical Assessment Program, or CAP, to measure the quality of care in primary care osteopathic residency programs. CAP's goal is to improve patient outcomes by providing valid and reliable assessments of current clinical practices. CAP provides evidence-based measurement sets on eight clinical conditions including diabetes, coronary artery disease, hypertension, women's health screening, asthma, COPD, childhood immunizations, and low back pain. CAP is widely acknowledged as a tool to improve quality in ambulatory care in residency programs and allows programs to demonstrate improvement and conduct research on health care delivery methods that measurably improve care.

In December 2005, the CAP became available for physician offices and offers initial measurement sets on diabetes, coronary artery disease, and women's health screening. Measures on Asthma and COPD will be added this summer. Performance in CAP is measured by abstraction of required data elements from patient's medical records, and includes demographic information and clinical information. Clinical measures in CAP are 'harmonized' with the National Quality Forum's definitions and the AQA where applicable.

The AOA recently did a comparison of the CAP quality measures with the PQRI measures. Seventeen of the 74 PQRI measures are included in the CAP. These 17 measures are consistent with the primary care measures of the PQRI. As an organization that represents osteopathic physicians in all specialties, the AOA plans to expand the CAP to include specialty care measures.

The proposed CMS rules allow a flexible framework to evaluate potential interfaces between existing registries and CMS for future payment (beyond 2008). The framework provides an opportunity to evaluate the CAP regarding operational changes necessary to satisfy potential reporting requirements and also provides an opportunity to interface with CMS on behalf of CAP-reporting physicians and programs in an effort to shape how registries may be used in the future.

The CAP satisfies the CMS definition of a clinical registry as an observational study collecting clinical information in a systematic manner for quality improvement or pay for performance purposes. The current PQRI uses modified claims data submitted for each patient encounter providing a snapshot of the patient during the encounter whereas registries collect data on a longitudinal basis and evaluate care over longer time frames.

The AOA reviewed the five proposed options in relation to the CAP:

> Option 1: This option would require the CAP to collect or synthesize information necessary to be consistent with the CPT G codes and modifiers, in addition to unique patient

identifiers (Beneficiary HIC Number, Date of Birth) along with the date of service and the NPI and Tax ID.

Option 2: This option would require the addition to the CAP of practitioner identifiers (NPI and Tax ID) and the beneficiary ICD-9 and CPT codes. The HCPCS G-Code could be calculated and attached to the file. This option would require the addition of elements, along with potential double entry of ICD-9 and CPT codes into the practice billing system and CAP. Electronic submission and linkage could be considered.

Option 3: This option would only require the CAP to collect and calculate the measures in a manner specified by CMS, with current constructs this would be possible now. More precise definitions of Medicare Beneficiaries would be necessary and the collection of program, or practice NPI and TAX ID would also be necessary.

Option 4: This option would have the CAP functioning as a claims processor for the practice and pass these claims on to CMS.

Option 5: This option would require the transmission to the AOA of a unique patient identifier to allow CMS to link the data between the practice and CMS claims. These identifiers could include Beneficiary ID (HIC), date of birth, and date of service. In addition to the patient identifiers, physician identifiers including the NPI and Tax ID would be required.

In reviewing the five options proposed by CMS for the use of registries, the AOA believes that Option 3 would provide the best opportunity for the CAP registry to interface with PQRI.

CAP presently collects de-identified information to be compliant with HIPAA. One of the challenges that the AOA would need to address would be the ability of CAP to collect and transmit data with unique patient identifiers in a HIPAA compliant manner. To provide CMS with unique identifiers would require:

1. Additional elements to be added to the data collection forms including patient identifiers (HIC number and date of birth) and some date of visit to link to claims.
2. An evaluation of security of the CAP website on both the physician and residency sides to ensure HIPAA compliance.
3. A business agreement between the AOA and the physician's office authorizing release of the patient identified data to CMS.

Upon finalization of the various options for the use of registries, the AOA would be interested in participating in the testing of the registry-based quality data submission mechanism.

Concerns from the AOA regarding the proposed rule

1. The rules do not address the percent of the Medicare patients under the physicians' care that CMS would require to be reported from the registry. Present rules for the PQRI require at least 80% of physicians' eligible patients to be submitted with codes in order to be eligible for enhanced reimbursement. The CAP collects data on broader aspects of care within a clinical entity but uses a sampling strategy to reduce the burden of data

collection for the physician. Further clarification on the sample size needed by CMS for the PQRI for registry inclusion is needed.

2. The model of reporting process and outcomes measures CMS uses with the Hospital Compare program has a detailed set of algorithms governing case selection, inclusion and exclusion criteria and analytic methods. Clarification on these issues would enhance the reliability and validity of any information generated from the registry data. Does CMS intend on publishing algorithms?

3. The CAP program collects information regarding care delivery over specified time frames to match clinical guidelines (i.e. ADA recommendations of yearly foot exams for diabetic patients). The PQRI currently collects information on an episode of care basis. Clarification of eligible timelines for indicators would be needed to ensure consistent collection of information from registries.

Thank you for the opportunity to provide comments. We look forward to working with CMS on this and other issues of importance to the osteopathic community.

Sincerely,

Peter B. Ajluni, DO
President

shm
Society of Hospital Medicine

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August 31, 2007

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

Attention: CMS-1385-P

Dear Mr. Kuhn:

The Society of Hospital Medicine (SHM) is pleased to offer comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule *Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions [CMS-1385-P],* published in the Federal Register on July 12, 2007. SHM represents more than 6,000 hospitalists, physicians whose primary focus is caring for hospitalized patients. Our comments will focus on the section of the proposed rule pertaining to the Physician Quality Reporting Initiative (PQRI).

TRCHA – SECTION 101(b): PQRI

SHM commends the CMS effort to encourage continued improvement in the efficiency and quality of health care delivered to our nation's Medicare beneficiaries. SHM is an organization dedicated to promoting the highest quality care for all hospitalized patients, and we share your commitment to improve quality and coordinate care. We are eager to continue to work

with you on initiatives that create incentives and reward providers for efficient use of resources.

SHM supports the 2007 PQRI and has encouraged its members to participate in the program. We appreciate the broad array of educational resources CMS has made available to groups like ours. These resources were extremely helpful in educating our members about successful performance reporting and participation in the PQRI. We plan to survey our members to learn about their PQRI reporting experiences and gain feedback that will be useful in identifying any areas that should be modified.

SHM has been an active participant in the measure development process for the PQRI. Working through the AMA Physician Consortium for Performance Improvement (PCPI), we have joined other medical specialties to develop performance measures in geriatrics, emergency medicine, outpatient parenteral antimicrobial therapy, and anesthesiology topics such as perioperative normothermia and critical care. SHM has submitted feedback during public comment periods on perioperative care, chronic kidney disease, and other measures as they have been released and comments solicited.

We appreciated that CMS and the PCPI accepted our recommendations to make changes in several of the performance measure specifications for the 2007 PQRI to allow for reporting by hospitalists. The addition of inpatient E&M codes to several of the measures related to conditions commonly treated by hospitalists gave our members the opportunity to participate in the PQRI. Of the 74 measures included in the 2007 PQRI, the following 11 have specifications that enable reporting by hospitalists:

- Heart Failure: ACE Inhibitor or ARB Therapy for Left Ventricular Systolic Dysfunction,
- Oral Antiplatelet Therapy for Patients with Coronary Artery Disease,
- Beta-blocker for Patients with Prior Myocardial Infarction,
- Beta-blocker at Time of Arrival for Acute Myocardial Infarction,
- Stroke and Stroke Rehabilitation Measures, including, DVT Prophylaxis, Discharge on Antiplatelet Therapy, Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge, Tissue Plasminogen Activator Considered on arrival, Screening for Dysphagia, and Consideration of Rehabilitation Services,
- Documentation of an Advanced Care Plan.

<u>Recommendations for 2008</u>
SHM supports the 2008 PQRI, and we recommend that CMS and the AMA PCPI continue to re-evaluate the proposed measures to allow for inpatient performance reporting.

Several of the performance measures included in the 2007 PQRI and those proposed for 2008 are relevant to the inpatient care provided by hospitalists. However, the measure specifications do not include inpatient E&M Codes in the measure

denominators that allow for hospitalist reporting. SHM would specifically request that the following measures be included for inpatient reporting for the 2008 PQRI:

2007 PQRI Measures

- Medication Reconciliation
- Vital Signs for Community-Acquired Bacterial Pneumonia
- Assessment of Oxygen Saturation for Community-Acquired Bacterial Pneumonia
- Assessment of Mental Status for Community-Acquired Bacterial Pneumonia
- Empiric Antibiotic for Community-Acquired Bacterial Pneumonia

2008 PQRI Measures

- Prevention of Ventilator-Associated Pneumonia—Head elevation
- Stress Ulcer Disease (SUD) Prophylaxis in Ventilated patients
- Assessment of Thromboembolic Risk Factors in patients with Atrial Fibrillation
- Perioperative Cardiac risk assessment (history)
- Perioperative Cardiac risk assessment (current symptoms)
- Perioperative Cardiac risk assessment (physical examination)
- Perioperative Cardiac risk assessment (electrocardiogram)
- Perioperative Cardiac risk assessment (continuation of Beta Blockers)

SHM would also advocate for CMS to expand the 2008 PQRI measure set to include a measure for prophylactic treatment of medical patients at risk for VTE, as this is typical care provided by a hospitalist.

Furthermore, SHM favors an approach that harmonizes both existing and future individual physician-level measures with hospital system-level measures. The ultimate goal would be to effect system-wide change resulting in improved quality of care and patient safety. Whenever possible, candidate measures for physicians should align with those developed as part of the inpatient PPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. This would allow for an effective alignment of physician-level and hospital-level efforts toward improvement in quality of care and quality of service to hospitalized patients.

Measures for Care Transitions

SHM has been designated to take the lead in the development of performance measures around the important process of care transitions. Hospital discharge is a potentially stressful and sometimes dangerous process for patients. The current hospital discharge process impacts patient satisfaction and health outcomes. As facilitators of care coordination, hospitalists are poised to serve as key change agents to improve care transitions for their patients through a consistent and coordinated approach to this important process. The goal of the SHM lead PCPI Workgroup will be to develop and implement care coordination measures to improve care transitions.

SHM is collaborating with several national stakeholders, including the NQF, CMS, and other professional societies, to engage in this groundbreaking work. The result will be 6-8 care transitions measures for inclusion in the 2009 PQRI.

SHM appreciates the opportunity to offer comments on the Proposed Rule. Please feel free to contact myself or Laura Allendorf, Senior Advisor, Advocacy and Government Affairs, at 703-242-6273 or LAllendorf@hospitalmedicine.org, if you have any questions regarding our comments.

Sincerely,

Russell Holman, MD
President, SHM

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CMS-1392-P-187

Submitter : **Mr. John Shliapa** **Date: 08/27/2007**

Organization : **South County Physical Therapy**

Category : **Other Health Care Professional**

CoP

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is John Shliapa and I am employed by South County Physical Therapy in Auburn, MA. I do clinical work in the clinic for approximately 15-20 hours a week and work in a secondary school for approximately 20-25. I attended Northeastern University where my education consisted of cooperative education, clinical rotations, as well as a intense curriculum. I earned a Bachelor of Science in Athletic Training and am now certified by the National Athletic Trainers Association Board of Certification.

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

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

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

Sincerely,

John Shliapa, ATC

Dorothy Shannon

~~Scott Cooper~~

Alberta

FERNANDEZ • RENNER • SCAIA

Physical Therapy Clinic, Inc.

August 30, 2007

Mr. Kerry N. Weems, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

RE: Physician Self-Referral Issues

Dear Mr. Weems:

I am a licensed physical therapist who practices in Canton, Ohio. I was licensed in 1976, and have been in a private physical therapy practice since 1981. The purpose of this letter is to comment on Medicare reimbursement for physical therapy services provided in a physician-owned physical therapy setting. Even with the most well-intentioned motive, I find it unethical for a physician to have an ownership interest in a for-profit physical therapy clinic. In my conversations with various physicians, it is clear that they are opening physical therapy centers in an effort to earn more money. I have had patients who were previously seen in physician-owned clinics, and they were clearly directed to go to that clinic without being informed that they have a choice in the matter. Additionally, these same patients frequently comment that the services rendered at our clinic (owned by physical therapists) were significantly more efficacious, allowing them to meet the treatment goals sooner.

Our clinic has seen a significant reduction in Medicare patients from those physicians who own physical therapy services. It would be interesting to compare the costs, numbers of treatments, and outcomes between our clinic and those of a physician-owned clinic.

I feel that it is in the best interest of Medicare patients and the Medicare program to remove physical therapy from the list of "in-office ancillary services" that physicians are permitted to provide.

Sincerely,

Paul Renner, P.T.

Paul Renner, P. T.

2405 FULTON ROAD N.W. • CANTON, OHIO 44709 • (330) 452-0049

COLORADO DEPARTMENT OF HEALTH CARE POLICY & FINANCING

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Bill Ritter, Jr., Governor • Joan Henneberry, Executive Director

August 30, 2007

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

Dear Mr. Kuhn:

On behalf of Colorado Medicaid beneficiaries, I am writing to express my concerns regarding CMS' proposed rule to bundle Medicare payment for Doppler Color Flow velocity mapping (CPT Code 93325) into all echocardiography services, thereby eliminating separate payment for these services effective January 1, 2008 ("*Proposed Revisions to Payment Policies under the Physician fee Schedule, and other Part B Payment Policies for CY 2008" [CMS-1385-P]).* Specifically, my concerns are aimed at the negative impact such action would have upon a distinctly non-Medicare population – pediatric cardiology – and the potential impact on patient access to care.

CMS' proposal to merge (or 'bundle') a specific cardiology procedure code (CPT code: 93325) into a range of other cardiology procedures for payment purposes will have a negative impact on pediatric cardiology. The 93325 procedure describes 'Doppler Color Flow' mapping. It is used along with other imaging procedures by pediatric cardiologists to look at structural abnormalities within the heart, in order to accurately diagnose a patient's medical condition. Because of the anatomical differences between adults and neonates or young children, the Doppler Color Flow procedure can be an absolutely essential tool in order for a physician to develop appropriate clinical decisions on treatment options.

By bundling Doppler Color Flow into other services and not addressing the extra time and work involved by a physician in conducting this separate medical procedure, CMS is effectively eliminating reimbursement for this procedure. In order to meet the needs of providers, it would be necessary for Colorado Medicaid to *unbundle* and allow additional reimbursement for this code, which would be contrary to correct coding guidelines. In addition, it is important to us to be able to distinguish the utilization of Doppler Color Flow imaging as compared to other echocardiography services.

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Massapequa NY 11726
August 30, 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

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

Dear Mr. Weems:

I am a Licensed Physical Therapist and have been practicing since 1986, for 21 years. I have been around to see many changes, some good and some bad, in the practice of Physical Therapy (PT). One aspect of PT I feel very strong about is the Stark for Referral Profit Laws. I remember the abuse which was happening when the laws were first passed. These laws protected the public from Physicians referring patients for tests and physical therapy strictly for their own profit and not for the well-being of the patient. The laws were passed and it seemed to help control unnecessary testing and therapy. Next Physical Therapy was removed from the exception and Physicians could own PT practices as long as they were within the same office location. Physical Therapy should be included in the regulation and I strongly oppose removing PT from the in-office ancillary services exception. Here are a few personal experiences as to why this would be a mistake.

My first year out of school after working in a hospital for one year, I decided I wanted to work in an outpatient PT office to see more of the challenging patients I liked. I worked in an orthopedist owned office which had PT in the same building. Back at this time, before the decreased insurance reimbursement, it was typical the see a patient every 30 minutes (2 patients an hour). This office scheduled 3 patients an hour. Being a new graduate, I thought I could handle the extra and still provide quality services. It turned out the office was not doing a good job of collecting the money for our services. So, in order to make more money, they told us we had to one time a day put 2 patients in the same time slot (double book). This could not possibly allow us to provide quality care and it was obvious they were not concerned for the patient, only their wallets. I decided to work part-time and open my own practice so I can better control the care of my patients. I completely left the office in just few months.

HeartPlace
The Future Of Cardiology Is Here
A Professional Association managed by Cardiovascular Provider Resources

Robert Bode, D.O., F.A.C.C.
Charles W. Cramer., M.D., F.A.C.C.
Michael T. Ferry, M.D., F.A.C.C.
Michael A. Graceffo, M.D., F.A.C.C.
Steven P. Havard, M.D., F.A.C.C.
Vinit R. Lal, M.D., F.A.C.C.
Stephen J. Lenhoff, M.D., F.C.P.S.A.
William H. Nesbitt, M.D.
Mark P. Teng, M.D., F.A.C.C.
Steven J. Vignale, M.D., F.A.C.C.
Richard A. Wray, M.D., F.A.C.C.

August 31, 2007

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

RE: **Docket Number & Title: CMS-1385-P – Revisions to Payment Policies Under the Physician Fee Schedule**

Dear Ms. Norwalk:

I am writing to comment on certain portions of the recently proposed revisions to payment policies under the CMS Physician Fee Schedule. Specifically, I am concerned with the proposal to eliminate or otherwise restrict the establishment of "under arrangements" services that hospitals on occasion enter into with third parties, some of whom include physicians and physician practices. Within the proposed rule, CMS expresses longstanding concern about the "risk of overutilization." This concern has apparently increased as a result of "anecdotal reports of hospital and physician joint ventures." The author of the proposed rule claims to be unaware of any legitimate reason for the existence of these arrangements other than a profit motive by physicians. I am concerned that CMS would enact reforms in this area on the basis of nothing more than anecdotal reports and a general suspicion of profit as a corrupting influence in medicine. In fact, there exist many sound reasons for hospitals to enter into service contracts with third parties, and especially with physicians.

In addition, it is not necessary to enact such sweeping reforms on the basis of anecdotal reports when tools and data exist to study and document whether there arrangements indeed reflect any abuse of the CMS payment system. A systematic analysis would likely identify some types of arrangements and actual agreements that are indeed suspect and need to be reformed or otherwise abandoned; however, in other cases,- the participants in these "under arrangement" relationships will be able to demonstrate significant benefits to Medicare beneficiaries and the physicians and hospitals that serve them – including lower cost, improved access, more timely care and higher quality.

I am concerned that the proposed rule may also have numerous unintended consequences. For example, in many instances of "under arrangement" service contracts, a hospital elects to purchase a service for its patients from a third party because it can do so at a lower cost or with

849

FERNANDEZ • RENNER • SCAIA

FRS Physical Therapy Clinic, Inc.

August 29, 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

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

Physician Self-Referral Issues

I am a physical therapist in private practice and wish to comment on the 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in office ancillary services" exception.

Our practice is in the Midwest and we have seen the proliferation of physician owned physical therapy practices. There are physician owned practices that are run by companies such as Novacare which provides staffing for the doctors. We have seen a consistent reduction in our number of patients since the physicians direct as many Medicare and other patients to their own clinics. I questioned one physician in such a group and asked why they needed to start their own therapy services. He responded by saying we need to make more money.

The above goes to the heart of the matter that physicians with an inherent financial incentive will be more inclined to overutilize these services for financial reasons. Patients have relayed experiences to me where their doctors encourage them to come to their clinics because they can better monitor their physical therapy progress. When the patients go to the physician's clinic, they find someone different working with them on every occasion. Also, older patients have told me that they do not want to offend their doctor by not going to his clinic for fear they will not be liked by the physician. Nothing like subtle intimidation on the elderly.

Our private physical therapy clinics provide convenient times for patients, and consistent reports are provided to their doctors. CMS can reduce the temptation for overutilization of physical therapy services under the Medicare program and close this loophole (in which physicians utilize physical therapy as just another source of income) by removing physical therapy from the "in-office ancillary services" exception to the federal physician self-referral laws.

Sincerely,

Denis Scaia PT

Denis Scaia, P. T.

4426 WHIPPLE AVE. N.W. • CANTON, OHIO 44718 • (330) 492-1222

850

August 31, 2007

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

Subject: **Tempting Physician Self-Referral Issues**

Dear Mr. Kerry Weems,

I am writing to you to express my **strong support** of the efforts **to remove physical, occupational and speech therapy from the designated health service exception.** As a physical therapist, I urge you to take a closer look at this issue. I believe that removing the exception, the way that many other ancillary services have been, will help potential therapy patients to receive the best care, from the right place, only when it is needed. The current exception makes the likelihood for abuse is too great.

As you know, checks and balances are an essential part of every facet of governmental affairs. When a physician is able to own their office, see a patient, and refer them to a therapy clinic they own, the checks and balances are gone. Regardless of the quality of therapy at the physician-owned therapy clinic, the physician will refer their patients to it. This develops the potential for patients to go to a sub par therapy clinic that does not make them any better. It would be much like a physician profiting from the prescriptions they write- **there is too much of a profit incentive.**

Thank you for your time and consideration in this matter.

Seth Harrell, DPT

08/31/07

Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

Re.: CMS-1385-P

I am a physician in Western North Carolina, and I am writing to express my support for the proposed amendment to §424.24 regarding outpatient therapy certifications. This change would extend the length of time for updated treatment plans from 30 to 90 days. My patients, staff and I will all benefit from this extension, as it will increase the amount of time my staff and I can spend delivering patient care.

I agree that adjusting the first recertification interval from 30 to 90 days would allow me to:

- Approve a plan of care that represents the clinically appropriate length of treatment
- Discourage routine 30-day plans
- Encourage professional determination of a CMS-1385-P 391 appropriate length of treatment at the time of the initial certification.

In addition, the amendment will:

- Protect the patient's access to needed treatment if I am not available at the 30-day interval
- Reduce the administrative burden on our staff.

Therefore, I support the proposal to amend §424.24 to require recertification every 90 days after beginning treatment.

Thank you very much for your consideration,

C. Michael Buechle, MD
Director of Trauma Surgery
Mission Hospitals
Asheville, NC 28801

852

August 31, 2007

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

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

Dear Sir:

My name is Chris Throneberry and I am a Physical Therapist who owns a Physical Therapy clinic. I am writing to you to voice my concern regarding **Physician Self Referral Issues**. I have been in the therapy business for over 20 years, and I can assure you that it is not an easy one. Everyday there is more and more competition and I work hard to ensure that our patients receive the best care possible and that we stand apart from our competition.

Physician-owned clinics are inherently at risk for over utilization when self-referral leads to monetary gain. Patients should have freedom of choice and be directed to facilities that offer the best care instead of facilities which make the referring physician a profit. I would strongly encourage CMS to support the removal of PT services from the in-office ancillary exception to reduce fraud and abuse that is occurring in the PT profession in these settings.

Respectfully submitted,

Chris Throneberry, PT
President
Therapy & Rehab Solutions, Inc.

August 31, 2007

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

Subject: Eliminating OT and PT as a DHS

To Whom It May Concern:

My name is Michelle Rhodes, and I have been a occupational therapist for over 5 years. I practice at Conway Regional Therapy Center, and I am writing you to comment on the July 12th proposed 2008 physician fee schedule rule, specifically the issue surrounding physician self-referral and the "in-office ancillary services" exception.

As an occupational therapist, I feel that allowing OT and PT to be considered a designated health service creates an opportunity for fraud and abuse of those services. The physicians who own a therapy clinic have a financial incentive to recommend OT and PT for their patients.

Eliminating OT and PT as a DHS would reduce the chance of fraud and ensure the best and proper referral for PT services, which is what Medicare and Medicaid beneficiaries deserve.

Thank you for your consideration in this matter.

Sincerely,

Michelle Rhodes

Michelle Rhodes, OTR/L

Clinical Urology Associates, P.C.

Chester C. Hicks, Jr., M.D., FACS
John F. Pirani, M.D., FACS
Manish Shah, M.D.
Merle L. Wade, Jr., M.D.

August 28, 2007

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: July 2, 2007 Medicare Physician Fee Schedule Proposed Regulations

Ladies and Gentlemen:

We are a four man urology group in rural northeast Alabama. We have three offices in three counties. One of the counties has no other urologic services and two of the counties have only one other single practitioner. We are also owners in a joint venture partnership that provides lithotripsy services. By being owners in this partnership we are able to provide improved access for patients, advanced technology and the benefit of QA and outcome programs. We feel that this greatly enhances the quality of care that we are able to deliver to our patients.

We realize that there is a concern with regard to over utilization. While we understand the concern, it should be pointed out that this is not a diagnostic procedure. It is therapeutic. Kidney stones can be objectively identified. Therefore, there is no risk of over utilization.

Today's for profit hospitals in rural areas are unwilling and at times unable to accept capital risks for new equipment and replacement equipment as technology improves. This is especially true when they are unable to predict the volume of such cases. Physicians, on the other hand are willing to accept the capital risks inherent in a per procedure lease to a hospital, because of improved patient care.

In the history of Stark legislation, Congress has clearly intended to preserve per procedure fees. We would ask that CMS not contradict this intention. We would ask that the per procedure prohibition not apply to the Stark indirect compensation arrangement that is currently relied upon by our joint venture partnership. Stark legislative history also indicates that Congress intended under arrangement contracting to only require a compensation exception and not an ownership exception.

300 Medical Center Drive Suite 200 Gadsden, Alabama 35903 (256) 492-4040 Fax (256) 492-4017

We are also concerned that the in-office ancillary services exception be maintained. We have CT imaging in our office. The enhancement in the quality of care delivered to our patients has been dramatic. For instance, the patient with a very painful kidney stone is no longer asked to leave our office to wait to be admitted to another facility, wait for the service to be performed, and wait for the report on the service to be prepared. In our office that patient is able to see the physician, have the Ct performed, a diagnosis delivered and treatment provided in a much more efficient and timely manner. This also allows the urologist to have control and influence in the total care of the patient.

In summary, we would ask that the Stark Statue not be revised to remove the exceptions of percentage fee arrangements and in-office ancillary services. We believe that to do so would substantially affect the quality of care provided to our patients. It would have a detrimental effect on patient access to services, reduce the availability of improved technology and would limit the ability to provide quality assurance and outcomes programs.

Thank you or your attention to this matter.

Sincerely,

Chester C. Hicks, Jr., M.D., F.A.C. S.

John F. Pirani, M.D., F.A. C. S.

Manish Shah, M. D.

Merle L. Wade, Jr., M.D.

SAUNDERS
THERAPY CENTERS

A member of THERAPY PARTNERS

August 16, 2007
Kerry N. Weems
Administrator – Designate
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS – 1385 – P
P.O. Box 8018
Baltimore, MD 21244-8018

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

PHYSICIAN SELF-REFERRAL ISSUES

To Whom It May Concern:

I am a physical therapist practicing in Minneapolis/St. Paul, Minnesota. I did my post-graduate work at Mayo and later completed an additional specialty degree in orthopedics at La Trobe University, in Melbourne, Australia. I have been in practice for 24 years and have owned a private practice for 19 years. I have three offices and 21 employees.

I would like to comment on the July 12th proposed 2008 physician fee schedule rule, specifically about physician self-referral and the "in office ancillary services" exception.

Over the years I've been in practice, I've seen this issue from several angles. At one time I had a small office just outside of the Metro area, with a majority of the referrals coming from a single physician. That physician hired a business manager who convinced him he could make more money if he had his own physical therapy department. He hired a therapist and I eventually had to close my office. Soon after that, Stark II was passed and the physician ended up selling his practice to the therapist he had hired.

Over the years we have seen a weakening of Stark II, or the creation of a loophole with the "in-office ancillary services" exception. We are again seeing an expansion of physician-owned arrangements that offer physical therapy services. I am aware of solo practitioners, orthopedic practices and a couple of other group practices that have started in-house physical therapy departments that directly affect my practice, and there are rumors of more.

These practices are not starting because there are problems with access to quality providers or so that the physicians can directly supervise treatment. In fact, direct supervision is not needed to administer physical therapy services. The motivation is development of an additional profit center for the physicians. There is an inherent conflict of interest and potential for fraud and abuse when referring a patient for a service that you can directly profit from, which is the same reason physicians can not own a pharmacy. There is a financial incentive to over utilize those services, which I believe is exactly what was shown in the Florida study done some years ago, prior to Stark II.

The "in-office ancillary services" exception is so broadly defined that it allows the creation of potentially abusive referral arrangements and physicians have a captive referral base. Patient choice, at a time when comparative shopping and consumer awareness are starting to take place in the health care market, is critical. Competition is crucial to keep healthcare costs down, but as a private practice owner I can not compete when these types of arrangements create a closed loop.

This issue has affected my practice greatly over the years, causing me to close an office early in my career and it is now threatening me again. I am feeling the loss of patients each time a physician or group of physicians decides to start their own physical therapy practice. Not dealing with this issue threatens all of us who own independent private physical therapy practices.

Thank you for considering my comments on this issue.

Respectfully,

Daniel T. Wolfe PT GDMT

Daniel T. Wolfe PT, GDMT

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6550 York Ave. S., Ste. 520
Edina, MN 55435
Phone: 952-924-0199
Fax: 952-924-0314

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Fax: 763-315-1297

www.saunders-therapy.com

856

CMS-1392-P-171

Submitter : Dr. John Braun **Date:** 08/24/2007

Organization : Meridian Anesthesiology P.A

Category : Physician

Data.

Issue Areas/Comments

OPPS: Conversion Factor

OPPS: Conversion Factor

RE: Medicare Pay Increases for Anesthesia Services

Dear Sir:

I would very much like to thank you, in advance, for the planned increase in 2008 reimbursement for anesthesia services! The 32% work undervaluation and underpayment for anesthesia services, due to the flawed conversion factor formula, along with the across-the-board yearly reductions in Medicare/Medicaid payments, has been exceedingly painful for all anesthesia providers. It seems particularly unfair and ironic that Medicare recipients get annual COLAs (cost of living adjustments), while their Doctors get annual pay cuts.

If I may, I would like to make one last comment. I understand that it is planned to give the CRNAs (Certified Registered Nurse Anesthetists) a 12% pay increase, while giving the Anesthesiologists only a 4% increase. This is a 300% larger pay increase to the nurse that the doctor. Since the anesthesiologist has gone to medical school for 4 years and completed a 4 year Anesthesiology/Critical Care/Pain Management residency, and the CRNA has never attended medical school and has only two years of anesthesia training, there seems to be no basis for this discrimination. Doctors are always held to a higher standard of care than nurses, have higher malpractice premiums, and of course have higher malpractice judgments against them than nurses. It seems only fair that the anesthesiologist should get the 12% increase, not the nurse anesthetists, to help defray
these additional expenses.

I know that you will give careful consideration to these genuine concerns. Let me thank you once again for any and all help in rectifying the inequities in anesthesia reimbursement.

Respectfully,

John C. Braun, DDS, MD

Anita (2)
Carol
Alberta

PFS

CMS-1392-P-8

Submitter : Dr. Donald Laryc

Date: 07/19/2007

Organization : Welborn Clinic

Category : Physician

Data

Issue Areas/Comments

GENERAL

GENERAL

I would like to urge CMS to collaborate with Congress to find an alternative to the SGR methodology for calculating the annual conversion factor for Medicare physician payments. To be blunt - it doesn't work. It does not reflect trends in practice cost, and if implemented will reduce access to ambulatory care for Medicare beneficiaries. We physicians understand how burdensome and expensive medical care can be, and we are willing to do our part. However, we cannot continue to have Part B reimbursement be the "plug factor" that brings Medicare to budget neutrality. Trust me - physicians are not becoming wealthy off Medicare. We see the patients we see, as walking away is not ethically palatable. However, the number of new Medicare patients is going to increase. For the baby boomers to receive Medicare services, we must recognize nationally the long term value of accessible, prompt high quality care. Properly organized and funded, health care is an excellent use of public resources. Let us avoid the annual 11th hour Congressional fix and work towards a permanent solution for the benefit of our elderly.

Anita (2)
Carol
Alberta

plus FS

858

CMS-1393-P-99

Submitter : Dr. Vernon Via **Date:** 08/12/2007

Organization : Wellcare

Category : Physician

Data,

Issue Areas/Comments

Conversion Factor

Conversion Factor

I am a primary care physician, an Internist, and am writing to you regarding the present method of calculation of physician fees under Medicare, the sustainable growth rate (SGR). This method was instituted in 1997 and is extremely flawed. For the past five or six years, this formula would have reduced physician reimbursement four to five percent. Thank heavens, Congress stepped in and averted this except in 2001-2003, or I would be unable to see Medicare patients without losing money. My costs of doing business rise two to three percent each year. Currently CMS informs us that payments to physicians will decrease by 9.5% in 2008 unless Congress intervenes. A decrease of this magnitude would be catastrophic and would result in many doctors turning away Medicare patients or cutting back on the number of Medicare patients in their practices. I would ask that CMS encourage Congress to adopt a new formula that recognizes the following facts.

1. America is getting older and older Americans generate more medical costs
2. Our understanding of each disease and its treatment is becoming more sophisticated and more expensive
3. Older Americans have more diseases.

All of this adds up to the treating senior patients is becoming more complex and I as a primary care doctor have to make increasingly sophisticated judgements as to what is the best treatment. I need to be paid more, rather than less. I also need to be reimbursed for the cost of inflation.

The constant threat of reducing reimbursements is quite harrowing. I find the prospect of a yearly 10% decrease in 2008 to be particularly frightening. It makes it impossible for me to plan how to increase my use of technology because I am unsure if I can afford it. I also find it difficult to hire more office personal to make appointments and make sure patients have a smooth visit. I don't know what my income stream will be until Jan of February when Congress sets to negate the effects of SGR.

Please encourage Congress to fix the formula so we can have a reasonable approximation of our reimbursement and so plan how to invest in future upgrades of technology and other resources to improve patient outcomes. I would ask especially that CMS recommend Congress take action soon on the impending reimbursement cut planned for 2008 to reassure doctors to relieve physician anxiety about 2008.

If congress fails to act to ameliorate the proposed pay decrease, I would ask that CMS do what it can to lessen the blow.

I fear with the current system of last minute rescues from pay cuts, doctors will begin to curtail their acceptance of medicare patients into their practices.

Vernon Via, Jr.

Anita (2)
Carol
Alberta

859

CMS-1392-P-83 **Medicare**

Package

Anita (2)
Tamar
Carol
Alberta
Sheila

Submitter : Dr. Wyman Lai **Date & Time:** 08/01/2007

Organization : American Society of Echocardiography

Category : Physician

Issue Areas/Comments
GENERAL

GENERAL

Re: CMS--1385--P; Proposed Physician Fee Schedule and other Part B Payment Policies for CY 2008

Dear Sir or Madam:

I am writing regarding the CODING (ADDITIONAL CODES FROM 5-YEAR REVIEW) issues before your committee. I am a pediatric cardiologist practicing at an academic medical center in New York City. Approximately 1/2 of my practice is with patients on Medicaid, and the fees for the rest are significantly affected by the Medicare payment schedule.

I provide cardiac imaging services to children with congenital heart disease, most with echocardiography. The proposed CMS rule to "bundle" color flow Doppler (CPT Code 93325) with other echocardiography codes would reduce the reimbursement for an echocardiogram by approximately 30% in our group. This, quite literally, could put us out of business.

We use color Doppler to examine the heart for abnormal flow jets that result from valve abnormalities, holes in the heart, or abnormal blood vessels that children are born with. This is above and beyond the screening that we can do with 2D imaging and spectral Doppler evaluation. Not everyone needs this screening, and many providers are not performing this type of detailed screening on all echocardiograms.

One proposed solution would be to increase payment for the general echocardigoraphy codes. The amount would need to be significant to cover our costs for the expertise and time required to perform the color Doppler portion of the examination. Moreover, color Doppler is also used for fetal cardiac examinations and transesophageal echocardiogarms in my laboratory. The proposed "bundling" and elimination of a color Doppler code would severely affect our ability to perform these other services for the underprivileged population that we serve.

Most academic pediatric echocardiography laboratories are barely breaking even under the current system of reimbursement. The loss of color Doppler reimbursement would drive us to reduce our adoption of newer technologies that would benefit our patients.
Therefore, I ask that you please re-examine the negative effects of the proposed "bundling" of CPT Code 93325 on the care of patients.

Sincerely,

PFS

Wyman W. Lai, MD, MPH
Divison of Pediatric Cardiology
Mount Sinai Medical Center
wyman.lai@mssm.edu

August 31, 2007

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

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

Dear Sir:

My name is Teresa Smith and I am very concerned regarding **Physician Self referral Issue.** I have serious concerns regarding the potential for future and the current abuse that occurs in the profession regarding Physician referrals for Physical Therapy services in Physician owned practices.

I would strongly encourage CMS to support the **removal of PT services from the in-office ancillary exception** to reduce fraud and abuse that is occurring in the PT profession in these type clinical settings.

Thank you for your consideration of this very serious matter.

Sincerely,

Teresa Smith

Teresa Smith, MS

BLAIR ORTHOPEDIC ASSOCIATES & SPORTS MEDICINE
http://www.blairortho.com

- ANDREW W. GURMAN, M.D.
- CHARLES J. HARVEY, D.O., F.A.O.A.O.
- JOSHUA PORT, M.D.
- ROBERT J. SINGER, D.O.
- GREGORY J. FULCHIERO, M.D.
- ANGELA W. ROWE, D.O.
- MICHAEL W. MOLTER, D.O.
- CHAD W. RAPPAPORT, D.P.M.

August 28, 2007

Donald Romano, Director
Division of Technical Payment Policy
Center for Medicare Management
Center for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop: C4-25-01
Baltimore, MD 21244-1850

RE: Stark in-office ancillary exception

Dear Mr. Romano,

On behalf of Blair Orthopedic Associates and Sports Medicine, I would like to take this opportunity to offer comments to the Center of Medicare and Medicaid Service (CMS) as the agency continues its evaluation of incident to provisions for physical and occupational therapy services. Blair Orthopedic Associates and Sports Medicine is a private orthopedic practice offering both physical and occupational therapy services.

Our practice has expanded into these services in order to provide the best continuum of care for our patients. Having in-house therapy services, our physicians and therapists can work more closely together to insure the patient is progressing and receiving the most appropriate care at the proper time. We have not found this to always be the case when using outside providers. While we are up front with our patients regarding our ownership of the rehab component of our practice, and offer alternative rehab choices, we have found that most patients prefer to receive therapy services in our office. Our patients tell us they prefer working with therapists that closely interact with their physician.

The physical and occupational therapists employed at Blair Orthopedic Associates and Sports Medicine are professionals and determine not only the appropriateness of rehabilitation, but also the frequency and duration of required care. Our practice is very supportive of their continuing educational needs as demonstrated by the multiple specialty certifications awarded to our therapists.

Our experience has convinced us that in-house rehabilitation services have improved the overall quality of our patient care. We believe that any change in the in-house ancillary exception to the

3000 FAIRWAY DRIVE • P.O. BOX 30 • ALTOONA, PA 16603 • (814) 942-1166 • FAX (814) 942-6222

Stark II law would be detrimental to our patients by denying them the choice of receiving the comprehensive care offered by our practice.

We thank you for the opportunity to provide comment on this issue. We would welcome the opportunity to further discuss this issue and our experiences. Please feel free to contact our practice at your convenience.

Sincerely,

Gregory Fulchiero, M.D.

August 30, 2007

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

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

Dear Mr. Kuhn:

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

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

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

Thank you for your consideration of these comments

Sincerely,

James B Arvin, II
President/CEO
ARMAR, Inc.
d.b.a. White Rose Ambulance

From: Bernice Hecker[bernice.hecker@noridian.com]
Subject: NPRM: CORF

A monumental undertaking. Thank you for all efforts to sort out the many issues that puzzle so many providers and put Contractors in no win situations.
A few comments offered for you always thoughtful consideration
1. The issue of pulmonary rehabilitation *programs*. It would appear that such programs are allowable in CORF as *programs.* Clarification would be useful.
2. Nursing services. What would be payable as such a service in CORF? Catheter change? Unskilled. Injection? Administration codes. Checking a patient's V/S? Unskilled and/or part of other evaluation. I would suggest that there are no separately payable nursing services in CORF; especially since labor overhead is reimbursed via the PE in non-facility fees that you clarified would be paid to CORF.
3. Definition of "physician". Since physician defines different practitioners at different parts of the SSA, what is the definition here? I see no reason that NPP (NP or CNS) may not supervise, administer, review and/or certify PoC, etc. Based on BBA 1997, why would one expect anything else? . With regard to PA, the requirement that PA work under MD would not necessarily preclude PA from fulfilling the tasks but one would have to scrutinize the arrangements a bit
4. Psych/social services. Based on the strict specifications of the CoP and the reasons the Behavioral Health codes were brought to the AMA in the first place, it seems to me that the only appropriate codes billed by CORF are the Behavioral Health series (excluding that that describes family work in the absence of the patient).
5. As it appears that CORFs may provide therapy services in the home, please clarify what the oversight of those services needs to be. For example, Home Health Agencies have accrediting bodies for their work in homes, a fundamentally different type of work than in-facility work.

From: Bernice Hecker [bernice.hecker@noridian.com]
Subject: NPRM OFS: CORF

On behalf off myself, several providers and not a few other CMDS, I would ask you to further clarify the services that a nurse (RN) may provide in the CORF setting. For example, may CORF bill the "G" code for the delivery of respiratory services in CORF. I believe that the difference in the CORF benefit from the physicians services benefit and "incident to" must be discussed. Thank you for any consideration you may give to this request.

865

August 20, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
P. O. Box 8018
Baltimore, MD 21244

Attn: CMS-1385-P

To Whom It May Concern:

I am a Medicare recipient who is currently having physical therapy. Physical therapy is enabling me to get back to my regular activities of daily living. In fact, I am surprised at the progress I'm making, so I am very glad my doctor referred me to physical therapy.

I am writing to you out of concern over a Medicare proposal I just heard about that would cut reimbursement rates for physical therapy. According to the explanation of benefits paperwork that I am receiving from Medicare, the reimbursement amounts for physical therapy are already very low. If the reimbursement rates are cut even more, I hate to think what will happen to physical therapy clinics in our area and across the nation.

Without physical therapy, I would be on a lot more pain medications, I know my progress would be much slower, and I would have to return to my other doctors a lot more often. So I am asking you to please reconsider the proposed rate cut. It will wind up costing all of us a lot more in the long run!

Sincerely,

James Wheeler

8-24-07

866

August 20, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
P. O. Box 8018
Baltimore, MD 21244

Attn: CMS-1385-P

To Whom It May Concern:

I recently heard about a proposed revision to the Medical fee schedule for physical therapy, and am writing to express my concern. I am a Medicare recipient who has benefited greatly from physical therapy.

I've seen the reimbursement amounts for my physical therapy on the explanation of benefits I've received from Medicare, and I think the amounts were way too low for the amount of quality care I've received. If the reimbursement rates are cut even more, I am afraid physical therapists, such as the ones who treated me, will not be able to continue their practice.

If physical therapy services had not been available, my doctor would no doubt have prescribed more pain medications, and my recovery time would have been much longer. So for the sake of myself and all other Medicare recipients of physical therapy, I am asking you to please not cut reimbursement rates for physical therapy.

Sincerely,

Martha L. Brackin

867

August 20, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
P. O. Box 8018
Baltimore, MD 21244

Attn: CMS-1385-P

To Whom It May Concern:

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Sincerely,

A. H. Sobrell

August 20, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
P. O. Box 8018
Baltimore, MD 21244

Attn: CMS-1385-P

To Whom It May Concern:

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Sincerely,

William C. Andrews

August 20, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
P. O. Box 8018
Baltimore, MD 21244

Attn: CMS-1385-P

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If physical therapy services had not been available, my doctor would no doubt have prescribed more pain medications, and my recovery time would have been much longer. So for the sake of myself and all other Medicare recipients of physical therapy, I am asking you to please not cut reimbursement rates for physical therapy.

Sincerely,

Shirley W Ponton

870

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

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

Purpose: Physician Self- Referral Issues

Dear Mr. Weems,

I am a physical therapist and practice owner writing on behalf of my therapy staff which consists of 18 physical therapists. I have been practicing for 14 years and have owned my own practice for 5 years. My two partners and I, who collectively have been treating patients for over 40 years, were recently named 2007 SC Small Business Persons of the Year by the SBA. Throughout the years we have witnessed and weathered many changes in the Medicare system regarding physical therapy and appreciate this opportunity to express our opinion and experiences with the abuse relating to physical therapy's inclusion as an "in-office ancillary service".

Approximately 6 years ago, physicians in the upstate of SC and other areas of the country began to realize that there was a loophole in the Stark II laws that allowed them to increase their revenue potential- open therapy clinic in-house under the "in-office ancillary services" exception. Because of Medicare referral requirements, the physicians had a captive referral base of physical therapy patients in their offices. Disgusted with corporate healthcare- I was in the process of opening my own private practice and was meeting with various physicians whom I had had long standing professional relationships with, to gain support for my practice. I was told that due to my positive outcomes, they would continue to refer me patients no matter where I worked. I was also offered three opportunities to "come work for us- we can send you more patients than you can handle". I declined the opportunity to work for a physician because I follow the ethical standards of the American Physical Therapy Association. However, I find it very interesting that 2 of the physicians that "had more patients than I could handle" never referred any patients to therapy. (Not just my practice- I have had discussions with other local clinics and hospital locations). But once they were able to find a therapist that would work in their "in-office ancillary service office", a "clinic" in a treatment room, suddenly that physician referred 2-3 new patients daily. Did they all of a sudden get an influx of patients with new diagnosis that required therapy? It appears strange to me that none of these physicians believed therapy was an appropriate treatment option when the clinic

was across the street and there was no profit sharing, and then all of a sudden there was a huge need for therapy.

Other first hand experiences have included patients that I have treated in past years, suddenly being pulled from my clinic (where they are reaching their goals and displaying positive outcomes) and told by their physicians that they would prefer to have them see "their therapists" so they can "keep a closer watch on their progress". In later discussions with these patients, not one of them ever saw their physician in the therapy area and they were not as happy with the services, but were afraid to anger their physician by asking to return to my facility.

I have had patients travel over 30 minutes to go to the physician clinic because the doctor refused to give them options of other providers. This physician had been one that had been a strong supporter of my practice until they opened their own.

It was all summed up one day at a golf outing, when an orthopedic surgeon playing in our party said- "I make money 3 ways- MRI's, Physical Therapy and Surgery. The beautiful thing is I only have to work at one of them."

I witnessed two of my colleagues- also in private practice- lose 50% of their business each, when their top referring physicians, with whom they had long standing professional relationships, suddenly decided to keep the patients in-house. They had read the numerous articles on the internet about how they could add greater than 25% to their bottom line if they converted a treatment room into a therapy clinic. In areas of North Carolina and Tennessee a therapist can no longer live the American dream and open their own private practice, because the practice of physician self-referral is so prevalent in the medical community that all private practices have been forced out of business. Physicians are keeping to "good paying" insurances in their own practices and referring the uninsured or Medicaid patients to the hospitals.

Our practice continues to grow, based on our attention to customer service and quality of care. Also, South Carolina is only the second state in the US that the therapy state practice act does not allow therapists to work for referral sources. When challenged, the physical therapists in South Carolina were able to convince the legislatures and Attorney General to close the loophole and protect patients from fraud and abuse. I hope that this letter helps you make the decision to eliminate physical therapy as a designated health service furnished under the in-office ancillary services exception and reduce programmatic abuse, over utilization of physical therapy services under the Medicare program and enhance the quality of patient care.

Sincerely,

A Concerned Practice Owner responsible for the livelihood of 48 employees and dedicated to improving health care in the US
Zip code- 29650

THE UNIVERSITY of TENNESSEE
Graduate School of Medicine
Department of Surgery
1924 Alcoa Highway
Knoxville, TN 37920-6999

August 21, 2007

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

RE: Physicians Self-Referral Provisions

Ladies and Gentleman:

My name is Bruce Woodworth, M.D. I am a urologist that practices in Knoxville, Tennessee and am on the faculty of the school of Graduate Medical Education at the University of Tennessee. I know that my colleagues in urology have been providing quality lithotripsy, prostatic brachytherapy and other therapeutic services to Medicare patients through urology joint ventures all over the country. My colleagues and I are concerned about changes in regulations that will strongly affect legitimate position joint ventures.

The CMS proposals that are most worrisome are called Under Arrangements, Per Click Fee, Percentage Free Agreements, Stand in the Shoes and Burden of Proof.

Changes in Under Arrangements would prohibit the hospital from billing Medicare for any referrals made by a physician for designated health service provided by the hospital. If the service was provided to the hospital Under Arrangements by the physician or any entity in which a physician is an investor, CMS should limit the reach of Stark to only those arrangements that are known to be abusive and that Congress intended to reach. CMS seems to be concerned about physician joint measures that provide radiology equipment. There has been no evidence of any abuse by urology joint ventures that provide therapeutic services, but there appears that there is an attempt to eliminate these joint ventures. There are other joint ventures that offer laser prostate ablation and cryotherapy that are providing a valuable service to the community and should not be prohibited just because they are done at the hospital. This is particularly true in the situation where there has been no evidence of abuse. Many times these joint ventures allow newer technologies to be placed in communities that cannot otherwise afford them.

In therapeutic procedures such as where a referring physician performs a professional portion of the procedure the professional fee is greater than the profit distribution payment for the technical fee that the referring physician will earn from his investment

and interest in the joint venture. This ability to drive a portion of the technical fee does not institute a significant inducement to make referrals. Prohibition on services furnished under these arrangements should not apply to services where the investor position performs a professional portion of the procedure. Again abuse needs to be shown.

CMS proposals to ban Per Click Fee do not appear to be in line with congressional intent. Therefore, I strongly feel CMS should not prohibit a compensation method that Congress has specifically allowed. Sometimes the patients need procedures that are less often performed and are difficult to calculate in the compensation agreement. Physician joint ventures have brought new innovative therapeutic technology to small communities because doctors are willing to bear the risk of failure. Hospitals are often risk adverse and physicians groups have bared the risk of low volume. In order to allow compensation that is reasonable, hospitals have entered in to Per Click Agreements in order to protect themselves. This allows essential new technologies to be brought to small communities while allowing cash strapped hospitals to shift their risk to the doctor.

Percentage Free Reimbursement again is helped in a way that has allowed payments to occur in doctor joint ventures without risk of failure to the hospital and placing more of the risk on the doctor. This is another way of allowing compensation. If this fee arrangement is denied there will mostly likely be a loss of available technology to small towns.

Changes in the Stand in the Shoe regulations would appear to make it impossible for legitimate physician joint ventures to provide services in ambulatory surgical centers and this would mean that physicians would have to draw from hospital ASC and build additional ASC's and would likely cause the demise of the efficiencies of current methodology and further harm hospitals.

Pertinent Proof Rules are also appearing to be changed and the proposal that any action involving Stark Regulations is the provider would have to prove that referrals were not made in violation in Stark appears to be completely against the Constitution of the United States. It also appears that Stark penalties would be extended to anyone who causes a claim to be submitted in violation of regulation. This could be interpreted to a contract that CMS believes is in violation would be subject to huge fines. I strongly believe that the current laws in place are quite clear and that if there is abuse being taking place this should be handled in the courts, (civil and tort) and would prevent CMS to sit as judge and jury.

In conclusion, I would ask CMS to differentiate between beneficial therapeutic joint ventures, which are not of themselves questionable diagnostic ventures that physicians in hospitals may have propagated. Certainly both CMS and the urology community can say that our therapeutic joint ventures have broadened access to new technology to Medicare patients and brought needed efficiency to the market. At that same time, we have saved CMS hundreds of millions of dollars. To jeopardize this at a time where we have a tested

and proven model seems to be an usually foolish idea. I have stressed CMS needs to have a more rational approach to eliminate bad behaviors, but the current plans do not appear to be the correct way to do so.

Sincerely,

Bruce E. Woodworth, M.D.
Assistant Professor
Division of Urology

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Suite 475, Medical Building C
Knoxville, Tennessee 37920
Tel (865) 544-9270
Fax (865) 544-9860

1108 Fox Meadows Boulevard
Fox Meadows at Middle Creek Road
Sevierville, Tennessee 37862
Tel (865) 908-4946
Fax (865) 908-2946

11440 Parkside Drive, Suite 302
Knoxville, Tennessee 37934
Tel (865) 544-9740
Fax (865) 377-1002

CC: Congressman John J. Duncan, Jr.
800 Market Street, Suite 110
Knoxville, TN 37902

872

August 31, 2007

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

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

Dear Sir:

My name is Jerri McPherson and I am employed by a physical therapist owned therapy company. I am very concerned about the **Physician Self referral Issue.** I have serious concerns regarding the potential for future and the current abuse that occurs in the profession regarding Physician referrals for Physical Therapy services in Physician owned practices.

I would strongly encourage CMS to support the **removal of PT services from the in-office ancillary exception** to reduce fraud and abuse that is occurring in the PT profession in these type clinical settings.

Thank you for your consideration of this very serious matter.

Sincerely,

Jerri McPherson

Jerri McPherson

August 31, 2007

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

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

Dear Sir:

My name is Scott Terrell and I am in school fulfilling the requirements to become a physical therapist. I am very concerned regarding **Physician Self referral Issue.** I have serious concerns regarding the potential for future and the current abuse that occurs in the profession regarding Physician referrals for Physical Therapy services in Physician owned practices.

I would strongly encourage CMS to support the **removal of PT services from the in-office ancillary exception** to reduce fraud and abuse that is occurring in the PT profession in these type clinical settings.

Thank you for your consideration of this very serious matter.

Sincerely,

Scott Terrell

August 31, 2007

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

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

Dear Sir:

My name is Kristy Taylor and I am an athletic trainer who is very concerned regarding **Physician Self referral Issue.** I have serious concerns regarding the potential for future and the current abuse that occurs in the profession regarding Physician referrals for Physical Therapy services in Physician owned practices.

I would strongly encourage CMS to support the **removal of PT services from the in-office ancillary exception** to reduce fraud and abuse that is occurring in the PT profession in these type clinical settings.

Thank you for your consideration of this very serious matter.

Sincerely,

Kristy Taylor, ATC

Kristy Taylor, ATC

August 31, 2007

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

Subject: **Tempting Physician Self-Referral Issues**

Dear Mr. Kerry Weems,

I am writing to you to express my **strong support** of the efforts **to remove physical, occupational and speech therapy from the designated health service exception.** As a physical therapist for over 20 years, I urge you to take a closer look at this issue. I believe that removing the exception, the way that many other ancillary services have been, will help potential therapy patients to receive the best care, from the right place, only when it is needed. The current exception makes the likelihood for abuse is too great.

As you know, checks and balances are an essential part of every facet of governmental affairs. When a physician is able to own their office, see a patient, and refer them to a therapy clinic they own, the checks and balances are gone. Regardless of the quality of therapy at the physician-owned therapy clinic, the physician will refer their patients to it. This develops the potential for patients to go to a sub par therapy clinic that does not make them any better. It would be much like a physician profiting from the prescriptions they write- **there is too much of a profit incentive.**

Thank you for your time and consideration in this matter.

Danny Johnson, P.T.

Danny Johnson, PT
Conway Regional Medical Center

876

San Diego Pathologists Medical Group, Inc.

P.O. Box 880739, San Diego, CA 92168-0739
Phone: 619 –325-8710 • Fax 619-325-8731

David J. Bylund, M.D.
David J. Francis, M.D.
Nancy L. Harrison, M.D.
Slawomir T. Niewiadomski, M.D.
Bruce A. Robbins, M.D.
Ralph M. Shishido, M.D.
Carla Stayboldt, M.D.
William J. Watts, M.D.
Tyler P. Youngkin, M.D.

August 27, 2007

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

Ref: Physician Self-Referral Provisions

Thank you for the opportunity to submit comments on the Physician Self-Referral Provisions of CMS-1385-P entitled "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008." I am a board-certified pathologist and a member of the college of American Pathologists. I practice in San Diego, California as Part of a nine-member group practice in both a hospital and independent laboratory setting.

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

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

Sincerely,

Ralph Shishido

Ralph M. Shishido, M.D.

RADIOLOGY ASSOCIATES

OF SAN ANTONIO, P.A.

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BARBARA M. SULLIVAN, M.D.
JORGE VELEZ, M.D.
BEATRIZ E. ESCOBAR, M.D.

• • •

CONSULTANT RADIOLOGISTS FOR:
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P.O. BOX 101500
SAN ANTONIO, TX 78201
TEL. (210) 733 4400
FAX (210) 733 4401

August 31, 2007

CMS

RE: Comments on New STARK and NON STARK Regulations regarding Radiology

To Whom It May Concern,

Stark Proposal:

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti Mark up Provision)

We absolutely agree that the use of a centralized operation that does become an integrated part of the physician's practice is in direct conflict with Stark. If the supplier is required to be a full time employee of the billing entity, the physicians would have to integrate the service into their own individual or group practice and that is the intent of the regulation. The current regulations allow for an outside service that is provided for the purpose of siphoning additional money out of an already under funded payment system.

The same is true if you allow a mark up on professional services. What is the purpose of this markup? It has no legitimate purpose unless additional services are provided and, unless the additional services involve professional services, then they should be covered by a separate contract between the two parties and not be billed to the Medicare system.

Burden of Proof where claim is denied based on Prohibited Referral

This provision is appropriate as long as there is reasonable cause to believe that the claim is for a Prohibited Referral so that the carrier cannot arbitrarily deny the claim. This would create substantial new costs for the healthcare provider and the CMS.

Restriction on Unit of Service Payments in Space and Equipment Leases

If a practice is integrating the DHS into their own service, this includes accepting risk for the services they are willing to provide. The per-click arrangement is nothing more than a scheme to make a profit. Part of the risk associated with providing a service is the risk that you must NEED enough of that service to pay for the investment. The ability to provide it on a per-click basis guarantees a profit on it and provides the security to perform as many of these cases as possible without risk because each one is profitable. I realize that taking the full risk also potentially drives over utilization but the service must be a sufficient part of the physician's practice to make them want to fund the risk and integrate it into their practice. The per-click arrangement makes it easy to provide this as a side-line money maker that is not integrated into the practice which is in the face of Stark's intention.

878

CoP

CMS-1392-P-187 **Medicare**

Submitter : **Mr. John Shliapa** **Date & Time:** **08/27/2007**

Organization : **South County Physical Therapy**

Category : **Other Health Care Professional**

Scott Cooper
Alberta

Issue Areas/Comments
GENERAL

GENERAL

Dear Sir or Madam:

My name is John Shliapa and I am employed by South County Physical Therapy in Auburn, MA. I do clinical work in the clinic for approximately 15-20 hours a week and work in a secondary school for approximately 20-25. I attended Northeastern University where my education consisted of cooperative education, clinical rotations, as well as a intense curriculum. I earned a Bachelor of Science in Athletic Training and am now certified by the National Athletic Trainers Association Board of Certification.

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,

John Shliapa, ATC

880

SUMMIT
Physical Therapy & Rehab
PHYSICAL, OCCUPATIONAL & SPEECH THERAPY SPECIALISTS

Sean Cox, RPT/owner • Bret McGuire, RPT/owner
Brent Foster, RPT • Scott Hamel, RPT • Rod McCaslin, RPT • Anissa McGuire, RPT
Wendi Schaffitzel, RPT, CHT • Audra Steinbrook, PT • Erin Herrman, ATC
Colleen Caton, OTR • Robyn Foxworth, MA

www.ptsummit.com

August 28, 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

Physician Self-Referral Issues

Dear Mr. Weems:

My name is Natalie Young and I am a Physical Therapist Assistant at Summit Physical Therapy in Catoosa, OK. I have been practicing for four years at Summit Physical Therapy.

I am writing today to express my opinion concerning the July 12 proposed 2008 physician fee schedule rule. The issue I am most concerned with is our Medicare/ Medicaid patients who budget due to low income and have to choose a physical therapy clinic that is closer to home for them. On many occasions, Medicare/Medicaid patients have told me that they were first requested to perform their therapy at a "Physician owned clinic." Only when the patient says he can not afford to drive to Tulsa three times a week, are other clinics or options offered.

I work at a small PT clinic and feel we lose many referrals due to this type of practice. Physician direct supervision is not needed to administer physical therapy services. In fact, an increasing number of physician-owned physical therapy clinics are using the reassignment of benefits laws to collect payment in order to circumvent "incident-to" requirements.

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

Sincerely,

Natalie Young, PTA

CLAREMORE OFFICE
1110 W. Will Rogers Blvd. • Claremore, OK 74017
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Physician Self-Referral Issues

Address to:

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

Subject:

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

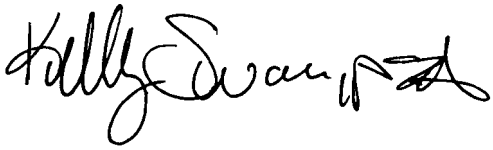
My name is Kelly Swan and I'm an Assistant Physical Therapist. I have practiced in an out-patient facility for 3 years.

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. I wish to bring notification to several topics of concern. Patients should never be directed away from appropriate health care to profit a physician-owned facility. Patients have been and are being redirected from local clinics for false reasons by physicians to benefit personally owned facilities. Patients should be provided a choice of appropriate healthcare according to their diagnosis, location, and status. I support the removal of physician-owned PT facilities under the in-office ancillary exception to help protect patient care.

Key Points:

- **Abuse and over use of physical therapy services with patients.**
- **Inconveniencing patients by clinic location, cost for driving, and reducing healthcare choices.**

Sincerely, **Kelly Swan**



Physician Self-Referral Issues

Address to:

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.

From:

Melissa Havenstrite, HR and Payroll Coordinator
Summit Physical Therapy
1110 W. Will Rogers Blvd.
Claremore, OK 74017

Subject:

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

I have worked for Summit Physical Therapy for 2.5 years and hold a bachelor degree in Business Administration. Summit Physical Therapy has three clinics which serve Rogers County within Northeast Oklahoma.

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. The physician self-referral issue sets the stage for fraud and abuse, higher insurance premiums, while at the same time taking away the patients' control of their health care.

Key Points:

- **When a physician writes a prescription for medication there is no financial gain for the physician. However, a prescription written for physical/occupational therapy involves great financial gain to the physician when the patient is informed that the therapy must be administered only at the facility which the physician is associated with. The possibility for over-prescribing therapy exists when dealing this situation.**

- **If physical/occupation therapy is being over-prescribed in order to financially benefit the physician this will mean fraudulent claims being filed, insurance companies being taken advantage of which equals higher insurance premiums for everyone to cover this abuse.**
- **Control over health care is being taken away from the patient and given to the physician. Allow me to give you a personal example: I have a friend who informed me three months ago that she would be having knee replacement surgery soon and that after recovery she would be visiting Summit Physical Therapy for her prescribed therapy. Two months after her surgery I visited with her and this is what she told me: After surgery her physician wrote a prescription for physical therapy but informed her that it MUST be administered at the facility which he was associated with (which was in the same building as his medical office). She explained to him that she knew the owners and staff at Summit Physical Therapy and would like to receive her therapy there. He then became upset with her and left room. The next day she received a phone call from the physician's office staff and they informed her that she was REQUIRED to see their physical therapist and could not go outside the physician's "medical group" for physical therapy. She reluctantly began and finished her physical therapy at the facility she was told she MUST go to. As a society how can we allow this to continue?**

Thank you for your time.

Sincerely,

Melissa Havenstrite

883

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

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

As a speech pathologist, I have treated with many good and excellent physical therapists. I believe that the only way to find an excellent therapist is to ask someone from a different discipline. Therapists don't usually observe each other, so it is through co-treating that we all gain a knowledge and respect of whom is a good therapist and who is a great therapist. I can recommend many speech pathologists that I think that are great but how do I really know-I haven't seen them in treatment. By contrast, I can recommend many excellent physical and occupational therapists because I have worked closely with them over the past 15 years.

Therefore, when my father needed a physical therapist last year, I had a definite opinion on who he should see and where he should go. However, his physician referred him to a "colleague". I do not believe that my father received substandard care by any means; however, I do believe that his request to see a physical therapist that specialized in his area of need should have been honored instead of being referred to a physical therapist that worked with his doctor.

The fact remains that excluding physical therapy from the "in-office ancillary services" that physicians provide does not allow patients to seek out the best possible care for themselves. There is also a concern that the treatment these patients receive can be dictated by the financial gains of the providers instead of the treatment needs being determined by an unbiased, licensed physical therapist.

Again, I do not believe that my father received substandard care, but I do not believe that he received that best possible care that he could have if he would have been able to choose where he received physical therapy. He continues to have pain but his response to my encouragement to talk to his doctor about it is "Why bother?" Is that really the impression that a physical therapist wants to leave?

Sincerely,
Kym Claborn, M.S., CCC-SLP Kym Claborn CCC-SLP

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Pamela Stanfield, PT
726 Winter Lane
Claremore, OK 74017

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 currently employed at a private Physical Therapist owned outpatient clinic within the state of Oklahoma. I graduated with a Bachelor of Science degree in Physical Therapy from the University of Texas Health Science Center in Dallas, Texas, in 1986. I have been employed in a variety of settings for 21 years and currently have a license to practice Physical Therapy in Oklahoma, Texas and Louisiana.

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. During my years of practice I have witnessed the abusive nature of physician-owned physical therapy services. The "in-office ancillary services" exception is too broadly defined in the regulations that it facilitates the creation of abusive referral arrangements. We have witnessed an increase in the number of physician-owned physical therapy practices which leads to fraud and abuse from referring for the wrong reasons and over utilization of services. Because of Medicare referral requirements, physicians have a captive referral base of physical therapy patients in their offices. The physician's direct supervision is not needed to administer physical therapy services. In fact, an increasing number of physician-owned physical therapy clinics are using the reassignment of benefits laws to collect payment in order to circumvent "incident-to" requirements.

I support physical therapy services removal from permitted services under the in-office ancillary exception. I would like to thank you, Mr. Weems, for your consideration on this matter.

Sincerely,

Pamela Stanfield, P.T.
Pamela Stanfield, PT

885

Beth A. Cassody
10140 E. Pin Oak Lane
Claremore, OK 74019
(918) 341-0899 (H)

August 30, 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.

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

Dear Mr. Weems:

I am a physical therapist's assistant in Claremore, OK. I work for Summit Physical Therapy outpatient clinic. I have been a physical therapist's assistant for 5 years at this clinic.

I wish 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.

As a practicing therapist's assistance I would like to ask that the physical therapy services be removed from permitted services under the in-office ancillary exception. The reason this should be removed is because of the occurrence of fraud and abuse this may cause and other loopholes. Also, this will cause an inconvenience for the patients we see in our clinic. Our community is an outlying suburb to some of our patients practicing physicians. This would cause a hardship for them to have to travel to the physician's site rather than obtain therapy in their hometown.

Sincerely,

Beth A. Cassody, PTA

886

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Anita Sen-Fields, OTR/L • Pam Stanfield, RPT • Rachel Woodward, RPT, MS

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ATTN: MR. KERRY N. WEEMS
ADMINISTRATOR- DESIGNATE

CENTERS FOR MEDICARE AND MEDICAID SERVICES
US DEPARTMENT OF HEALTH AND HUMAN SERVICES
ATTN: CMS-1385-P
PO BOX 8018
BALTIMORE,MD 21244-8018

Mr. Weems,

I am a physical therapist working in a rural outpatient pediatric facility in Claremore, OK. I have practiced in skilled nursing, home health, outpatient, and neuro-rehabilitation settings. As well as practicing in physical therapy, my family and I have participated in outpatient physical therapy services. As a professional in this field, I have a strong opinion towards who/whom provides care to my family. I believe that every family deserves to choose who will be taking care of their loved ones in a time of healing.

I am writing in response to the comment on the July 12 proposed 2008 fee schedule rule, specifically the issue surrounding physician self-referral and the "in office ancillary services" exception. In a time when healthcare and freedom are scrutinized in the United States, I feel that a change toward providing improved care is medically necessary for all involved. Financial feasibility or profit should not be the driving factor in my profession. Physicians are abusing their power as referring providers and harboring ignorance in our profession.

In Tulsa, OK there are two strong outpatient facilities run by orthopedic physicians. Patients receiving surgery or orthopedic care are encouraged to receive services at their facilities. At these facilities, protocols are widely used. This is an insult to my profession and understanding of the healing art of physical therapy.

I am in full support for Physical therapy services removal from permitted services under the in-office ancillary exception.

Rachel Woodward, MPT
Licensed Physical Therapist

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ATTN: MR. KERRY N. WEEMS
ADMINISTRATOR- DESIGNATE

CENTERS FOR MEDICARE AND MEDICAID SERVICES
US DEPARTMENT OF HEALTH AND HUMAN SERVICES
ATTN: CMS-1385-P
PO BOX 8018
BALTIMORE,MD 21244-8018

Mr. Weems,

I am a physical therapy assistant working in a rural outpatient pediatric facility in Claremore, OK. I have practiced in skilled nursing, home health, outpatient, and neuro-rehabilitation settings. As well as practicing in physical therapy, my family and I have participated in outpatient physical therapy services. As a professional in this field, I have a strong opinion towards who/whom provides care to my family. I believe that every family deserves to choose who will be taking care of their loved ones in a time of healing.

I am writing in response to the comment on the July 12 proposed 2008 fee schedule rule, specifically the issue surrounding physician self-referral and the "in office ancillary services" exception. In a time when healthcare and freedom are scrutinized in the United States, I feel that a change toward providing improved care is medically necessary for all involved. Financial feasibility or profit should not be the driving factor in my profession. Physicians are abusing their power as referring providers and harboring ignorance in our profession.

In Tulsa, OK there are two strong outpatient facilities run by orthopedic physicians. Patients receiving surgery or orthopedic care are encouraged to receive services at their facilities. At these facilities, protocols are widely used. This is an insult to my profession and understanding of the healing art of physical therapy.

I am in full support for Physical therapy services removal from permitted services under the in-office ancillary exception.

Lori Gastor-Murray, RPTA
Licensed Physical Therapy Assistant

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Brent Foster, RPT • Scott Hamel, RPT • Rod McCaslin, RPT • Anissa McGuire, RPT
Wendi Schaffitzel, RPT, CHT • Audra Steinbrook, PT • Erin Herrman, ATC
Colleen Caton, OTR • Robyn Foxworth, MA

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Physician Self-Referral Issue

August 21, 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

Mr. Weems:

My name is Bret McGuire and I am a doctor of physical therapy and co-owner of Summit Physical Therapy and Rehab in Claremore, Oklahoma. The intent of this letter is to address the need to exclude physical and occupational therapy as a designated health service which is now permissible under the in-office ancillary exception of the federal self-referral laws.

Several years ago, physician-owned physical therapy practices proliferated in our area which has created several concerns not only from a standpoint of patient service but also from a standpoint of potential abuse and fraud in our medical system. Below are a few issues which we have seen as physician-owned physical therapy have been allowed to proliferate under the current legislative environment:

- Our clinic is 30 – 40 minutes outside of a large metropolitan area. Since relaxation in the interpretation of the STARK laws, we have seen fixed-income medicare clients be required to bypass our facility and drive 30 – 45 minutes one-way to physician-owned clinics in the Tulsa region. These patients have not even been given an option to attend one of our locally owned facilities. In fact, some physicians, when asked if the patient can attend a local facility, put us in a negative light not because we have a poor- quality clinic but to clearly steer the patient to their facility. In one conversation I had w/ a physician group office manager, she said that in the physician's view, they owned the patient and that we had no right to see the patient. This is simply not true as this removes the patient from determining their own course of treatment, which can and should include an ability to choose to attend a facility which is more convenient and better equipped to handle their needs within their own community.
- When physicians are allowed to refer to their own clinic, an important check-and-balance is removed from the already over-burdened medical system. According to a CMS study, it is projected that by the year 2013, one in every 5 dollars spent

in the United States will be spent on healthcare. We simply have to create a less burdensome healthcare system and the removal of a check-and-balance does not improve this efficiency. Referral to physician-owned facilities creates an environment for potential abuse and fraud which decreases healthcare delivery efficiency. Previously, before physician-owned clinic proliferation, a patient was referred to physical therapy only when this service was indicated. Currently, due to the obvious financial incentives, physical therapy services may be over-utilized. This is one reason why STARK was legislated in the first place.

- Many physician-owned physical therapy services utilize non-licensed physical therapists or physical therapy assistants to perform, and bill for, physical therapy services. Physical therapy services should only be provided for by properly trained and licensed physical therapists or physical therapy assistants. As a privately-owned facility, it is not only required but is our responsibility to ensure that a patient receive treatment only by a properly licensed physical therapy professional. Under current legislation, physicians can utilize non-licensed staff for physical therapy service provision and billing.

In short, the relaxed interpretation of the STARK laws has allowed for inefficiencies for the healthcare delivery system and has, in many cases, inconvenienced medicare beneficiaries by reducing access to locally owned physical and occupational therapy services. Although currently legal, these practices are also unethical as they do not place the patient's needs above the provider's needs. In fact, it does just the opposite. Some physician's might argue that a patient gets better care under his or her direct supervision within his own clinic. This simply is not the case as physical therapists are currently well and more appropriately trained to provide physical therapy services.

Please understand, I do not intend to cast a negative shadow on all physicians who provide physical therapy services as this simply is not the case. There are many who provide care within excellent legal and ethical parameters and for this I am grateful. However, since the relaxation of the STARK interpretation, we have seen a continual downward spiral in how our local patients are being handled as it relates to access to physical and occupational therapy services. In my opinion, removing physical and occupational therapy services as a designated health service will provide better access of patients to highly trained physical and occupational therapy services as well as improve the efficiency of the healthcare delivery model.

Thank you for your time regarding this matter. If you have any further questions, please do not hesitate to call me at 918-342-3800. Thank you.

Sincerely,

Bret McGuire, DPT,RPT

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Robert Bode, D.O., F.A.C.C.
Charles W. Cramer., M.D., F.A.C.C.
Michael T. Ferry, M.D., F.A.C.C.
Michael A. Graceffo, M.D., F.A.C.C.
Steven P. Havard, M.D., F.A.C.C.
Vinit R. Lal, M.D., F.A.C.C.
Stephen J. Lenhoff, M.D., F.C.P.S.A.
William H. Nesbitt, M.D.
Mark P. Teng, M.D., F.A.C.C.
Steven J. Vignale, M.D., F.A.C.C.
Richard A. Wray, M.D., F.A.C.C.

August 31, 2007

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

RE: **Docket Number & Title: CMS-1385-P – Revisions to Payment Policies Under the Physician Fee Schedule**

Dear Ms. Norwalk:

I am writing to comment on certain portions of the recently proposed revisions to payment policies under the CMS Physician Fee Schedule. Specifically, I am concerned with the proposal to eliminate or otherwise restrict the establishment of "under arrangements" services that hospitals on occasion enter into with third parties, some of whom include physicians and physician practices. Within the proposed rule, CMS expresses longstanding concern about the "risk of overutilization." This concern has apparently increased as a result of "anecdotal reports of hospital and physician joint ventures." The author of the proposed rule claims to be unaware of any legitimate reason for the existence of these arrangements other than a profit motive by physicians. I am concerned that CMS would enact reforms in this area on the basis of nothing more than anecdotal reports and a general suspicion of profit as a corrupting influence in medicine. In fact, there exist many sound reasons for hospitals to enter into service contracts with third parties, and especially with physicians.

In addition, it is not necessary to enact such sweeping reforms on the basis of anecdotal reports when tools and data exist to study and document whether there arrangements indeed reflect any abuse of the CMS payment system. A systematic analysis would likely identify some types of arrangements and actual agreements that are indeed suspect and need to be reformed or otherwise abandoned; however, in other cases,- the participants in these "under arrangement" relationships will be able to demonstrate significant benefits to Medicare beneficiaries and the physicians and hospitals that serve them – including lower cost, improved access, more timely care and higher quality.

I am concerned that the proposed rule may also have numerous unintended consequences. For example, in many instances of "under arrangement" service contracts, a hospital elects to purchase a service for its patients from a third party because it can do so at a lower cost or with

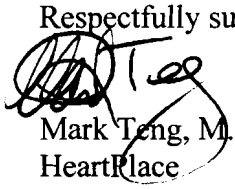
higher quality than it is able to do on its own. This is increasingly true as modern medicine becomes more specialized and capital intensive and general hospitals find it harder to maintain deep levels of expertise in all areas. In addition, many U.S. hospitals have low or negative profit margins and cannot afford to invest in the technology that will help them remain competitive on basic services.

Rather than seeking to invalidate partnerships between hospitals and physicians, the opposite should happen. In many instances, it can make financial and clinical sense to partner with individuals or companies that can provide capital, shared risk, and operational expertise to a hospital striving to improve its specialty services and programs. The fact that physicians can sometimes bring these resources to a hospital should not automatically exclude them as participants in these efforts. In fact, in many ways, physicians are ideal hospital partners and offer benefits to hospitals far beyond mere referral of patients – such as careful cost control and quality improvement expertise. Accordingly, I can see no qualitative difference between a well structured "under arrangement" contract that conforms to all fraud and abuse standards under the Anti-kickback statute and other programs that CMS and other government entities are supporting such as the various "gainsharing" and pay-for-performance initiatives. The essential task is to make sure that increased value is being delivered to Medicare beneficiaries in terms of cost and quality.

It is clear that throughout the U.S., there are instances of both over and under-utilization of effective care. This is due to the well documented and widespread variation in hospital and physician practice patterns that are often random in nature. It also follows that much can be done to reduce the costs and simultaneously increase the quality of healthcare. However, the mere "risk of overutilization" is not sufficient grounds to enact the policy reform being proposed for "under arrangement" hospital relationships. In fact, adequate tools and data sources exist to create measures that will allow CMS policy to be created based on facts and not on suspicion of corruption and anecdotal reports. Eminent researchers in the field of Medicare claims analysis have also demonstrated that Medicare claims can be used to provide illness-adjusted, population based measures of resource inputs, use and Medicare spending for cohorts of Medicare patients. This research indicates that answers to important questions raised in the proposed rule are obtainable. Further, by having a hospital participate in sample surveys, CMS should be able to separate those hospital-physician relationships that are beneficial from those that serve no other purpose other than a transfer of profits from one party to another.

I believe that in order to understand the true impact of "under arrangement" agreements for the provision of certain services, it would be appropriate for CMS to study the issue by availing itself of the tools and data described above. This will allow CMS to educate itself of benefits of the hospital-physician partnerships before enacting sweeping policy reforms.

Respectfully submitted,



Mark Teng, M.D.
HeartPlace

890

CMS-3887-P-1 **Medicare Program; Revisions to Conditions for Coverage for Ambulatory Surgical Centers**

misdirected comment 1385-P

Submitter : **Ms. Linda Zoller-McKibbin** **Date & Time:** **08/27/2007**

Organization : **Alice Peck Day Hospital**

Category : **Critical Access Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I work at Alice Peck Day Hospital in Lebanon, NH. We are a 14 bed Critical Access Hospital with a 50 bed extended care facility. We have been short staff 2-3 physical therapists for 4 years. It is getting more difficult to meet the demands of our patients with this chronic staffing issue. I am an athletic trainer and a physical therapy assistant and use my athletic training skills with almost every patient that I treat. There are so many skills that over lap with both of my professions.

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,

Linda Zoller-McKibbin ATC, PTA

891

CMS-3887-P-2 **Medicare Program; Revisions to Conditions for Coverage for Ambulatory Surgical Centers**

Submitter : **Dr. Dean Ornish** **Date & Time:** **08/29/2007**

Organization : **Preventative Medicine Research Institute**

Category : **Health Care Industry**

misdirected comment
1338-P

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3887-P-2-Attach-1.DOC

August 27, 2007

BY ELECTRONIC DELIVERY

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1385-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008)

Dear Acting Deputy Administrator Kuhn:

Dr. Dean Ornish and the Preventive Medicine Research Institute (PMRI) appreciate this opportunity to comment on a proposal related to the reporting of cardiac rehabilitation services contained in the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding revisions to payment policies under the physician fee schedule and other Part B payment policies for calendar year 2008 (the "Proposed Rule").[1] Next week, we also will submit to CMS comments on your proposed rule regarding payments to hospital outpatient departments (HOPD) under Medicare. The favorable implementation of both the Proposed Rule for physician payment and the proposed rule for HOPD are critical to allowing patients to benefit from our program and other proven programs for reversing heart disease.

The Dr. Dean Ornish Program for Reversing Heart Disease is a comprehensive lifestyle modification program based on a low-fat, whole foods eating plan, moderate exercise, stress management and group support. During the past 30 years of conducting randomized controlled trials and demonstration projects, Dr. Ornish and his colleagues have consistently shown that they can motivate people throughout the U.S. to make and maintain bigger changes in diet and lifestyle, achieve better clinical outcomes and larger cost savings than have ever before been reported. Specifically, these studies demonstrated the following benefits: (a)decreased size and severity of ischemic myocardial perfusion abnormalities (blood flow to the heart) using cardiac positron emission tomography (PET), exercise thallium scintigraphy, and exercise radionuclide ventriculography (1-6); (b) regression of coronary artery stenosis using quantitative coronary arteriography (5); (c) safe avoidance of revascularization procedures such as coronary bypass surgery, angioplasty, and intracoronary stents in almost 80% of those who were eligible for these procedures, with comparable clinical outcomes (7); (d) significantly greater exercise capacity (1-2, 6, 8-11); (e) substantial cardiac risk factor improvements, such as reductions in LDL-

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[1] 72 Fed. Reg. 38,122 (July 12, 2007).

cholesterol comparable to what can be achieved with statin drugs without the costs and potential side-effects as well as significant reductions in weight, BMI, blood pressure and fasting blood glucose (1-3, 6, 8-11); (f) marked, rapid, and often dramatic decreases in the frequency and severity of angina (1-3, 6, 8); (g) substantial improvements in quality of life by a variety of measures (including decreased emotional stress and depression and increased vitality, physical function, and well-being) (3, 6, 8-11); and (h) 2.5 times fewer cardiac events (6). In addition, significant improvements in other chronic diseases prevalent in the Medicare population, including obesity, diabetes, hypertension, hypercholesterolemia, depression, prostate cancer, and related illnesses have been recorded. (1-13)

These findings were published in the leading peer-reviewed medical journals, including *Journal of the American Medical Association, The Lancet, American Journal of Cardiology, The New England Journal of Medicine, Circulation, Journal of Cardiopulmonary Rehabilitation, Yearbook of Medicine, Yearbook of Cardiology, Homeostasis, Journal of the American Dietetic Association, Hospital Practice, Cardiovascular Risk Factors, World Review of Nutrition and Dietetics, Journal of Cardiovascular Risk, Obesity Research, Journal of the American College of Cardiology,* and others.

In addition to these randomized controlled trials, Dr. Ornish has conducted three demonstration projects that confirmed these findings in over 2,000 patients throughout the U.S. In the first demonstration project, Mutual of Omaha found that almost 80% of patients who were eligible for bypass surgery or angioplasty were able to safely avoid it for at least three years, saving almost $30,000 per patient in the first year (7). In the second demonstration project, Highmark Blue Cross Blue Shield found that their overall health care costs were reduced by 50% in the first year and by an additional 20-30% in subsequent years (personal communication with Highmark Blue Cross Blue Shield, 13). The Ornish program achieved similar improvements in Medicare patients as in these earlier demonstration projects and randomized controlled trials.

We are writing to comment on the proposal regarding reporting of cardiac rehabilitation services under the physician fee schedule. We are pleased that CMS in its proposed rule recognized the need to clarify coding and payment for these services that can dramatically improve the health and quality of life for the growing numbers of Medicare beneficiaries with heart disease. However, we believe that CMS must do more to support the expanded use of cardiac rehabilitation programs – especially those with published, peer-reviewed research showing that they achieve quantifiable results.

PMRI appreciates the time and effort CMS has dedicated considering our recommendations for ensuring that Medicare beneficiaries can participate in proven cardiac rehabilitation programs under the national coverage determination (NCD) issued last year.[2] Under that revised NCD, Medicare requires cardiac rehabilitation programs to provide a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education, and counseling. This contrasts markedly with the prior NCD for cardiac rehabilitation, under which only exercise was reimbursed by Medicare. In addition, the revised

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[2] NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10.

NCD contemplates contractors extending coverage, on a case-by-case basis, to 72 sessions. Under the former NCD, coverage of more than 36 sessions was highly exceptional, with contractors required to have significant documentation of the need for sessions beyond 36. By explicitly citing the Ornish program, in fact, the NCD made clear that it was the intention of CMS to provide coverage under Medicare for this program.

Without several further clarifications and modifications, however, we are concerned that Medicare's current reimbursement for cardiac rehabilitation services may make it difficult for providers to offer effective programs, such as the Ornish Program, to Medicare beneficiaries in a sustainable manner. Therefore, we have worked closely with CMS since the NCD was issued in March 2006, and recommended that CMS take certain specific steps to ensure that beneficiaries have meaningful access to these programs, as intended by CMS in issuing the NCD.

We are pleased to see that in the Proposed Rule CMS proposes to implement one of our recommended steps by creating two new Level II Healthcare Common Procedure Coding System (HCPCS) G-Codes for cardiac rehabilitation services.[3] These codes are Gxxx1, Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour), and Gxxx2, Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour), and would replace the Current Procedural Terminology (CPT) codes, 93797 and 93798, respectively, for these services when billed under the Medicare physician fee schedule.[4] The G-codes would have the same descriptions as 93797 and 93798, except that they would apply to an hour of cardiac rehabilitation services instead of a "session."

We agree that this change will help to "clarify the coding and payment for these services"[5] by more accurately describing the services provided. Those furnishing cardiac rehabilitation will be able to use these codes to bill for one hour of a modality of cardiac rehabilitation identified in the NCD, such as prescribed exercise or education, rather than an undefined "session" of services. We support this proposal and we ask CMS to implement it in the final rule. We do however, respectfully request that the description in the payment tables included in the proposed rule be modified to ensure the Medicare fiscal intermediaries and carriers/Medicare Administrative Contractors (MACs) do not misinterpret the codes as requiring physician presence. To avoid any confusion or any unwarranted reading by MACs that immediate physician supervision is required for the provision of these services, the term "cardiac rehabilitation services", as has been used in previous payment tables in relation to the CPT codes 93797 and 93798, should be used in those tables in lieu of the term "physician services."

While we applaud CMS's proposal to create new G-codes, we believe that beneficiary access to proven cardiac rehabilitation programs will be limited unless CMS implements our other recommendations. First, we strongly urge CMS to state clearly and explicitly in the final rule that multiple sessions of cardiac rehabilitation can be covered on the same day. We believe that this was in fact CMS' intent in proposing the two new G-codes in the proposed rule. But a

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3 72 Fed. Reg. at 38,419.

4 Id.

5 Id.

more explicit statement to this effect would go a long way toward avoiding any confusion in the future on the part of MACs, providers and beneficiaries. In the Ornish program, patients participate in several modalities of cardiac rehabilitation, such as a medical evaluation, prescribed exercise, education, and counseling, in a single day. Providers of the program should be reimbursed for each hour of each modality a beneficiary receives. Fortunately, Medicare already has a mechanism to recognize when a code is billed multiple times in a single day for distinct services. Modifier 59 indicates that "a procedure or service was distinct and independent for other services performed on the same day."[6] CMS should facilitate payment for these services by clearly stating in the final rule that payment may be made for each session when modifier 59 is used and documentation in the patient's record explains that each use of the code represents an hour of a component of the cardiac rehabilitation program.

Second, CMS proposes to crosswalk the new G-codes to payment for 93797 and 93798, respectively. We recommend that both codes be crosswalked to payment for 93798 to ensure that Medicare reimbursement is adequate to support the full range of modalities provided in these programs. The non-exercise components of our program should be reimbursed at this higher payment rate, whether services are provided through a physician, clinic or hospital-based program. Further, we believe that this higher payment rate would apply whether or not a patient needed EKG monitoring for the non-exercise sessions, as determined by the supervising physician. The rationale for making payments consistent across provider settings is that Medicare's payment rates under the physician fee schedule appear to have been calculated based only on the resources needed to provide supervised exercise—but not the other, more intensive components of the Ornish program and other similar programs. To allow the full range of programmatic elements specifically outlined in the NCD to be made available to patients in the physician office setting as well as the HOPD setting, these payments need to be consistent.

Third, we ask CMS to explain in the final rule that it is likely to be reasonable and necessary to cover 72 cardiac rehabilitation sessions when multiple sessions are provided in one day. The NCD gives contractors the discretion to cover up to 72 sessions of cardiac rehabilitation.[7] Unlike many cardiac rehabilitation programs in which "patients generally receive 2 to 3 sessions per week,"[8] which has traditionally been comprised of only exercise, in our program, patients typically receive multiple sessions per day, not just limited to exercise. When a beneficiary participates in a program of several one-hour sessions of various modalities in a single day, coverage of 72 sessions is necessary to provide enough hours of each modality for the patient to receive the full benefit of the program. By advising contractors that 72 sessions are likely to be reasonable and necessary for programs providing multiple sessions per day, CMS will ensure that the goals behind the revised, expanded NCD can be met. In view of the fact that 36 sessions – only of exercise – were covered under the prior NCD, it makes little sense to limit coverage to 36 sessions for programs such as Ornish. We ask CMS, in the final rule or other

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6 American Medical Association, CPT 2007, at 438.

7 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(D).

8 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(B)(1)(a).

guidance, to remind contractors of their discretion to cover up to 72 sessions and to explain that 72 sessions are likely to be reasonable and necessary where beneficiaries receive cardiac rehabilitation from programs that provide several one-hour sessions per day of the various modalities that are included in the cardiac rehabilitation NCD.

Finally, we ask CMS to encourage contractors to factor the proven results of a program into their coverage decisions. For example, 72 sessions should be presumptively covered when they are provided by a program, such as the Ornish program, with extensive peer-reviewed and published research showing that it achieves quantifiable results on important metrics, such as reductions in LDL-cholesterol, triglycerides, blood pressure, blood glucose, and weight, or that it affects the progression of coronary heart disease and/or reduces the need for bypass surgery, angioplasty, or stents and/or the need for medication. This consideration of a program's proven results would help to prevent over-utilization of programs that have not demonstrated positive results and is consistent with CMS's goals of furthering evidence-based medicine and improving actual health outcomes.

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PMRI greatly appreciates the opportunity to comment on the proposed changes to coding for cardiac rehabilitation services and to recommend additional changes that will help Medicare beneficiaries to receive the benefits of successful cardiac rehabilitation programs, such as the Ornish Program. Please feel free to contact Dean Ornish, MD at 415-332-2525 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Dean Ornish

Dean Ornish, MD
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References

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CMS-1392-P-528 **Medicare**

Devices

Submitter : Dr. Steven Zimmet **09/10/2007**

Organization : Zimmet Vein and Dermatology Physician

Category :

PFS

Anita (2)
Carol
Alberta
Sheila

Issue Areas/Comments

Device-Dependent APCs

Device-Dependent APCs

I appreciate the effort CMS has undertaken to establish a comprehensive process for APC and ASC payment.

I have reviewed RVUs as well as the facility cost to provide services for CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser, first vein treated). I am concerned about equipment expense. New technologies frequently require the purchase of capital equipment. This cost of capital, to be absorbed into the cost of doing business, must be compensated in a manner that is affordable to physicians in all practice settings as well as be reasonable to the payor.

Based on the CMS utilization formula for equipment cost per minute, I find a discrepancy in the equipment expense.

The Federal Register, Volume 72, July 12, 2007 identifies equipment expense for □all physicians□ at 4.08. Based on the CMS equation:

(1/(minutes/yr * usage)) * price * ((interest rate/(1-(1/(1 + interest rate) * life of equipment))))

+ Maintenance)

The allowed equipment expense is 4.08. When calculated using the ASP for the equipment used, the calculation is 4.75.

Payment for CPT code 36478, in the hospital outpatient department is in APC 0092 with an unadjusted national average payment of $1,684.02. Other procedures in that category include:
a. 37650: Ligation femoral vein
b. 37760: Ligation of perforator veins

c. 37765: Stab phlebectomy of varicose veins
d.
I request that 36478 be moved to APC 0091 with an unadjusted national average payment of ís $2,780.84. Other procedures in this category include:
e. 37700: Ligation and division of long Saphenous vein at SFJ or distal interruptions
f. 37718: Ligation, division and stripping, short saphenous vein
g. 37722: Ligation, division and stripping GSV from SFJ to knee or below
h. 37735: Ligation, division and complete stripping of GSV or LSV with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia

i. 36478: Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency, first vein treated

CPT code 36478 is more clinically related to the procedures in APC 0091 than to those in APC 0092.

In previous years, low cost laser fibers (not matched to the laser for compatibility) were available from various companies. A successfully litigated patent infringement suit resulted in these fibers being removed from the market in March 2008. Although there has been no increase in fiber cost, the potential to reduce cost through the use unmatched fibers has been removed. We believe resource consumption for CPT code 36478 is more closely related to APC 0091.

I request that you move CPT code 36478 from APC 0092 to APC 0091.

CPT code 36478 has been moved form ASC group 9 to ASC group 8. I request that CPT code 36478 be placed back into group 9.

AYAZ MAHMUD DURRANI, MD, FRCS

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August 29, 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

Dear Mr. Kuhn,

I am a urologist who is in solo practice at 7777 Southwest Freeway, Suite 1068, Houston, TX 77074 and 146 Hospital Drive Suite 205, Angleton, TX 77515. I am writing you 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 test rules.

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

The proposed "under arrangement" rule will prohibit the provision of IMRT and Laser. Joint Venture in Lithotripsy has made it convenient for the patients with the use of mobile units. Hospitals do not want to spend money on expensive equipments and their maintenance.

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

Thank you for your consideration,

A.M. Durrani MD.

Ayaz Mahmud Durrani, MD, FRCS
Urologist

AMD/shd