CMS-1429-P-3800

Submitter : Mr. Darrell Reed **Date & Time:** 09/24/2004 03:09:40

Organization : University Rehabilitation and Sports Medicine

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I disagree with the suggested change, please see attached word document.

CMS-1429-P-3800-Attach-1.doc

UniversityHospitals HealthSystem
Rehabilitation & Sports Medicine

Highlands Corporate Office
4480 Richmond Rd.
Warrensville Hts, Ohio 44128
(216)595-2880 fax (216) 595-2879

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including **certified athletic trainers**) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.

- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.

- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.

- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.

UniversityHospitals HealthSystem
Rehabilitation & Sports Medicine

Highlands Corporate Office
4480 Richmond Rd.
Warrensville Hts, Ohio 44128
(216)595-2880 fax (216) 595-2879

- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide "incident to" services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide "incident to" care in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

- In Ohio, **Athletic Trainers** are licensed to provide the complete management, treatment, disposition, and reconditioning of Acute Athletic Injuries upon referral. In a physician's office, an athletic trainer would be appropriately licensed to provide rehabilitation.

- CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.

- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.

- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.

- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Darrell Reed, ATC

Staff Athletic Trainer

Submitter : Anthony Giordano **Date & Time:** 09/24/2004 03:09:33

Organization : Trager International

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

CMS-1429-P-3802

Submitter : Ms. Amy S-R **Date & Time:** 09/24/2004 03:09:40

Organization : Ms. Amy S-R

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I strongly support the proposed personnel standards for physical therapy services that are provided "incident to" physician services in a physician's office. I am a licensed physical therapist who has worked in the profession for thirty in two different States. I have worked in outpatient hospital settings, private practice, & most recently, in skilled nursing facilities.

I would like to also point out that both my parents are in their eighties & regularly visit physicians. They often ask me "What do you think about..." a treatment they received in a physician office. They often state that they did not know the qualifications of the staff the provided the treatment. They have now decided that they will go to a hospital department or private practice, because they now know that the standards for personnel in those settings are stricter than in a physician's office.

Both my parents & I understand that physical therapy delivered by unqualified personnel is not the best way to protect the consumer. I believe that CMS has the opportunity to protect the consumer much more with the proposed revision. All settings for practice should require the same standards when a service is provided. A consumer should not have to stop & think,"Is the person here better qualified to do this treamtnet that the person there?" Physical therapy is physical therapy. The same qualifications should exist across all settings. The consumer does not compartmentalize the profession of physical therapy into practice settings.

For the past fifteen years I have worked primarily with the geriatric population & have treated many Medicare beneficiaries. Physical therapists are professionally educated at the college or university level, & are licensed in every jurisdiction in which they practice. The Medicare beneficiaries have every right to expect that physical therapy will benefit them as much as possible. This cannot be done if some or all of the treatment is rendered by an unlicensed person. The impact of this would be especially bad if and when a financial limitation of physical therapy services (the therapy cap) might mean that a beneficiary could exceed the cap without ever seeing a licensed physical therapist. I sincerely hope that the therapy cap does not get reinstated in 2006, but if it does the consumer would loose out twice.

Thank you for your consideration of my comments. I hope that you will support the proposed personnel standards concerning physicial therapy in a physician's office.

CMS-1429-P-3803

Submitter : Mr. Chris John **Date & Time:** 09/24/2004 03:09:39

Organization : Mr. Chris John

Category : Congressional

Issue Areas/Comments

Issues 10-19

SECTION 952

September 24, 2004

The Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Room 445, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator McClellan:

I am concerned about the proposed regulations contained in the Medicare physician fee schedule related to section 952 of the Medicare Modernization Act (MMA) ? Revisions to Reassignment Provisions.

In Louisiana, many hospitals work with emergency physician groups that use independent contractors to provide quality emergency care to all their patients, including Medicare beneficiaries. This complex and technical Medicare issue was brought to my attention some years ago. In 2000, I supported asking the independent General Accounting Office to look at this issue. In 2003, when the GAO recommended Medicare enrollment for physician groups with independent contractors in 2003, I knew that that enrollment of these groups was the right policy decision.

I worked hard to assure that this provision was included in the final MMA package which I supported. I am concerned that the proposed reassignment regulations could undermine the Congressional intent of the statute ? to streamline enrollment. I have heard from my provider constituents that there is significant backlog to enroll in the Medicare program. I would urge you to reconsider whether these proposed regulations are necessary.

Sincerely,

Chris John Member of Congress

Submitter : Mr. Gary Brownlee **Date & Time:** 09/24/2004 03:09:50

Organization : Trager(r) International

Category : Other Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please DO NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

CMS-1429-P-3805

Submitter : Celia Regina Maluf **Date & Time:** 09/24/2004 03:09:45

Organization : USTA TRAGER ASSOCIATION SOUTHEAST

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

To Whom it May Concern:

As a TRAGER PRACTITIONER I have helped countless patients referred to me by Orthopedic Surgeons, Neurologists, Chiropractors who have recognized the value of the work that Massage Therapy and Bodywork can bring to their clientele.
It has been a terrible surprise the acknowledgment about considering banning from LMTs the benefit of join their skills to medical doctors and establishments after so many years of hard work we have done in Florida and other states to bring awareness of the benefits of such rich association of forces.
Let's not forget that to this time and age when the most prestigious medical hospitals and Universities bring our profession as a valid ally to their fight to better serve their purpose to a wholesome approach of healthcare.
Blocking this alliance is to go back years of pure common sense.
We have proved Massage Therapy and Bodywork are a true source of speeding up the healing process of so many conditions, cutting down the dosage of medication, bringing down the expenses of medical bills.
Keep the doors open to better serve patients and doctors.
Do not set back what has been proved valid source of joined forces to better serve healthCARE.

CMS-1429-P-3806

Submitter : Miss. Amy Cantore **Date & Time:** 09/24/2004 03:09:35

Organization : University of Medicine and Denistry of New Jersey

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 24, 2004

Dear CMS Officials,

My name is Amy Cantore. I am a student in Doctorate of Physical Therapy program at the University of Medicine and Dentistry of New Jersey (UMDNJ), at the Newark campus. I wanted to take an opportunity to voice my opinion pertaining to proposed law which will allow unqualified individuals to provide physical therapy services and bill patients for these services. I am strongly against this proposed law for the following reasons. Firstly, by allowing unqualified individuals to provide such services could cause a delay the amount of progress that patients make, or even worse seriously injure patients. Physical Therapists are qualified individuals who have been thoroughly instructed in the nervous, sensorimotor, and musculoskeletal systems; and therefore have the ability to make sound professional decisions, and treat patient safely and quickly. Secondly, since unqualified individual do not possess the specialized training and knowledge of physical therapists, patients may need to be treated longer for impairments and functional limitations. This in turn would cost both healthcare services and patients more money. Thirdly, if this law is passed the need for physical therapists will be void, because other health care professional or employees with minimal training will take on physical therapy duties.

Although I am still a student, in two years I will be joining the population of licensed physical therapists. As physical therapists, we are responsible to provide the best care possible for our patients. Consequently, if this law is passed we will no longer be providing the best care. We will not only be driving up the cost of healthcare, but also jeopardizing the health and quality of life in each of our patients.

Sincerely,

Amy Cantore, SPT

Submitter : Tanya Allen **Date & Time:** 09/24/2004 03:09:48

Organization : AMTA

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am opposed to the proposed policy change that would eliminate any provider except physical therapists from providing "incident to" medical professional's services to patients. I am a licensed, nationally certified massage therapist, and this will adversely effect the way I may treat my clients, and my level of health care when I eventually use Medicare.

Submitter : Dr. R.T. Floyd **Date & Time:** 09/24/2004 03:09:44

Organization : The University of West Alabama

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

CMS-1429-P-3808-Attach-1.doc

R.T. Floyd, EdD, ATC, CSCS

Station # 14 The University of West Alabama
Livingston, AL 35470
(205) 652-3450 Office (205) 652-6185 Home (205) 652-3799 Fax

September 23, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing in response to the recent proposal that would limit providers of "incident to" services in physician clinics. This proposal, if adopted, would be detrimental to our health care system and would reduce the quality of care received by Medicare patients.

For the past twenty four years I have worked as a certified athletic trainer for the University of West Alabama, providing quality health care for hundreds of elite athletes. Furthermore, my work has included directing the University of West Alabama Athletic Training & Sports Medicine Center. Through this Center our staff of certified athletic trainers and I have provided a wide range of care for patients from the very young to those in the ninth decade of life. To imply that I am not qualified to provide this same level of service to our active, senior athletes is insulting. To deny our senior population access to qualified health care providers would be unfortunate, and could cause a host of problems. In our service area alone, we are the only provider educated and skilled to handle the majority of the pathologies we routinely see. The physicians and patients in our service area depend on us greatly for this care and would be at a loss in terms of finding other providers should we be restricted from continuing as we have for so long.

The United States is experiencing a shortage of qualified health care providers and this is particularly true in rural areas such as ours which are challenged by poverty and limited resources to attract such professionals. This proposal would exacerbate this shortage by eliminating quality providers of these important services. In turn, it would reduce the quality of health care for our Medicare patients, increase the costs associated with this service and place an undue burden on the health care system.

Physicians have utilized "incident to" to provide services to patients since the inception of the Medicare program in 1965. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. ***It is imperative that physicians continue to make decisions in the best interests of the patients.***

Certified athletic trainers work under the direct supervision of a physician and operate as part of the total health care team. My colleagues are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to **prevent, assess, treat and rehabilitate** injuries sustained during athletic competition. Dozens of athletic trainers accompanied the U.S. Olympic Team to Athens, Greece to provide these services to the top athletes from the United States. In addition, many more will provide services to participants during the upcoming Senior Olympic Games. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent. Thank you for considering my comments.

Sincerely,

R.T. Floyd, EdD, ATC
Station #14, UWA
Livingston, AL 35470
(205) 652-3714
(205) 652-3799 Fax
rtf@uwa.edu

CMS-1429-P-3809

Submitter : Ms. Barbara Mykalcio **Date & Time:** 09/24/2004 03:09:10

Organization : RN

Category : Health Care Industry

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

To go forth with this proposal and eliminate athletic trainers as treatment practitioners in PT facilities would severly limit the health care available to patientS, as well as extend the time for treatment in already overcrowed treatment centers. This would be a hardship on patients and probably cause them to opt for less care and slow or retard their full recovery. Case in point...I recently had knee surgery.
I chose an excellent PT facility for care that uses athletic trainers....
the practitioner there assists the physical therapists...monitors that i am adequately balanced and not overstraining while the PT's are busy and this assists my recovery guarding that i am protected from any bad movements that would possibly hurt me. The PT's are extremely busy and need theIR ATHLETIC TRAINERS OBSERVATIONS, ASSISTANCE and KNOWLEDGE for ultimate patient care.
As it is now...the facility is SOOOOO busy! I should be in and out in about an hr....but never get out under 2 hrs...and that is with this extra help. With the loss of these wonderful trainers...I would be there for well over 3 hrs...this is not acceptable!! *I could never go to PT with that kind of time lost in my day. MY RECOVERY WOULD BE RETARDED...EVEN POSSIBLY REGRESSED IF I MISSED TREATMENT DUE TO TIME CONSTRAINTS!! I would suffer and be out of work longer....POSSIBLY LOSING MY JOB BECAUSE OF SLOWER RECOVERY. THEN THE GOV. WOULD BE PAYING MY UNEMPLOYMENT..BURDENING OUR GOV. BUDGET!!
PLease realize the repercussions of this ridiculous proposal. Go to facilities ...lIve a day as a patient and see if you don't change YOUR mind!!!

CMS-1429-P-3810

Submitter : Mr. Larry Commons **Date & Time:** 09/24/2004 03:09:09

Organization : Mr. Larry Commons

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See attached letter.

CMS-1429-P-3810-Attach-1.doc

Larry J. Commons
2207 Brookside Drive
Arlington, TX 76012

September 24, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1476-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Sir/Madam:

I am writing to express my concern over recent discussions about limiting providers of "incident to" in physician clinics. If adopted, this proposal would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.

- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.

- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.

- To allow *only* physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide "incident to" services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide "incident to" care in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

- The list of providers being recommended for this Medicare reimbursement is arbitrary. Any number of providers who can administer therapy in a physician's office have education and credentials that exceed those held by PTAs and OTAs – such as certified athletic trainers, nurses, nurse practitioners and physician assistants. This is not to suggest PTAs and OTAs are not qualified, but simply that other practitioners are at least as qualified.

- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

The physician signs off on an "incident to" bill. This is a sufficient stamp of quality assurance for those procedures and no other means is needed. It would be highly counterproductive and unethical for a physician to designate unqualified providers to administer in-office therapy. ***It is imperative that physicians continue to make decisions in the best interests of the patients.***

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Larry J. Commons

Submitter : Mrs. Nordia Hall **Date & Time:** 09/24/2004 03:09:43

Organization : University of Medicine and Dentistry of New Jersey

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 24, 2004

Dear Sir/Madam:
I do not support the use of unqualified personnel to provide services described and billed as physical therapy. It is my belief that such practices are not only harmful to patients and clients but also creates a false perception, that physical therapy as a profession is unnecessary.

The depth and quality of education received by physical therapists about the musculoskeletal system and its associated pathologies exceeds that of many specialties of medicine and other allied health fields. Allowing other healthcare providers (i.e. physicians, nurses, aides) to provide services for which physical therapists are specifically trained thereby places the patient at a disadvantage (because they are not receiving the best possible care), may potentially increase healthcare cost (since a lower quality of care may result in longer recovery times) and will make physical therapy education of null effect.

As a student physical therapist, a rule requiring only physical therapists to provide physical therapy services will create a sense of security not only because I will feel valued as a professional, but also as a possible patient (receiving physical therapy) because I will be certain that I will be treated by the most qualified individual. On the contrary, the prospect of a future without such a rule, may potentially lead to the elimination of physical therapy as a profession. Physical therapists are trained to be autonomous professionals; the state of NJ has recognized that fact by legally granting them direct access to patients, nevertheless, such recognition will be useless if physical therapists are denied ownership of their profession.

Please consider these comments as you make your decision about the 2005 Medicare physician fee schedule rule.

Sincerely,

Nordia Hall, SPT

Submitter : Ms. Laura Edwards **Date & Time:** 09/24/2004 03:09:39

Organization : American Academy of Dermatology Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments letter.

CMS-1429-P-3812-Attach-1.doc

CMS-1429-P-3812-Attach-2.doc

American Academy of Dermatology Association

1350 I St NW Ste 870
Washington DC 20005-3319
Phone 202/842-3555
Fax 202/842-4355
Web Site www.aadassociation.org

September 24, 2004

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS-1429-P

RE: CMS-1429-P, Medicare Program; Revisions in Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Dear Dr. McClellan:

I am contacting you on behalf of the 14,000 members of the American Academy of Dermatology Association to provide our comments on the proposed Medicare physician fee schedule for Calendar Year 2005. The Academy will address our concerns with the Sustainable Growth Rate (SGR) formula, the re-pricing of clinical practice expenses for equipment, practice expense inputs for photodynamic therapy (PDT), the proposed update to professional liability insurance (PLI) relative value units (RVU), and corrections that should be made in Addendum B and Addendum C.

The proposal, published on August 5, 2004, also addresses a number of provisions relating to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). In this comments letter, the Academy will address our concerns with incentive payment improvements for specialty physician services in workforce shortage areas and payment reform for covered outpatient drugs and biologicals.

The SGR Formula

It is a widely-acknowledged fact that the SGR formula for calculating the annual update in Medicare physician reimbursement is seriously flawed. In previous letters the Academy has shared our ideas for regulatory approaches to correcting these flaws in the formula. These administrative corrections include removing Medicare-covered outpatient drugs from the expenditure target for the physician payment update, or else properly accounting for the costs of these drugs.

Another administrative fix that could have been addressed in this proposal is properly and fully accounting for the impact on Medicare Part B spending due to changes in laws and regulations. Examples of these costs are the impact of the new “Welcome to Medicare”

physical established by the MMA, and the cost impacts of national coverage decisions and preventive benefits approved by Congress.

These administrative changes would assuage many of the problems linked to the current SGR formula. Since we believe that CMS has the statutory authority to make these changes, it is disappointing that the agency chose not to tackle them in this fee schedule proposal. Inaction by CMS, and for that matter by Congress which created the SGR formula, will only serve to increase the eventual cost of fixing or replacing the formula while jeopardizing older patients' access to covered health care services.

Re-Pricing of Clinical Practice Expense for Equipment

The appropriate valuation of medical supplies and equipment for CPT 36522 for Photopheresis is of importance to the Academy. For this reason, the Academy in conjunction with the American Society for Hematology will provide information to the AMA/Specialty Society Relative Value Update Committee (RUC) Practice Expense Subcommittee on medical supplies and equipment for this code, at the September RUC meeting – as identified and requested in the proposed rule.

Practice Expense Inputs for Photodynamic Therapy (PDT)

The Academy continues to be concerned regarding the significant decrease in payment for photodynamic therapy (PDT), CPT code 95657. We are aware that a reduction in the practice expense RVUs is occurring in part due to updates to the Medicare utilization data used in the practice expense methodology for the 2004 Medicare physician fee schedule. As a result of the updated utilization data, the practice expense methodology is now using the dermatology scaling factor (0.54) for supplies instead of the all physician average (1.29), which is one of the contributing factors to the reduction in payment for this code. We request that CMS reconsider this scaling factor issue.

We appreciate that physicians may now bill separately for the light-activating agent under the appropriate J code (Pub. 100-20 Transmittal: 90 June 25, 2004 SUBJECT: MMA Drug Pricing Update—Payment Limits for J7308 (Levulan Kerastick)). We also appreciate that CMS has removed this drug from the practice expense portion of the procedure. However, there are medical supplies that are not recognized in the current practice expense inputs. We request that CMS incorporate the missing medical supply data for these codes.

Dermatologists providing PDT note that the patients being treated tend to be those with the more severe cases of actinic keratosis, both in terms of the number of lesions treated and the severity of these lesions. This was not fully appreciated when the code was initially reviewed by the AMA RUC. The medical supplies listed are clinically necessary to lessen the reaction to the therapy and to control the resultant pain. For the typical patient, these medical supplies should be recognized and included as direct practice expense inputs:

Bacitracin—SJ008, quantity 0.5 of a 15gm size.
When the patient presents at the physician's office the following day to receive the light treatment, the patient's face if thoroughly cleaned and an anti-bacterial ointment is applied to the netire area of the face and/or scalp that will have light applied. This is done to lessen any likelihood of infection.

LMX 4% Topical Anesthetic Cream – 30 gm
To control burning or stinging from the light activation procedure, the physician will apply LMX topical anesthetic cream to the entire area.

Proposed Update to Professional Liability Insurance Relative Value Units

The Academy is disappointed with the proposal for the Five-Year Review of the Professional Liability Insurance (PLI) relative values. We understand that CMS is required by statute to update this component by January 1, 2005. However, we respectfully urge that CMS consider this implementation "interim" until the agency has worked with the medical community to ensure that the data and methodology utilized to calculate this small, but important component of Medicare physician payment are appropriate.

The proposal, as outlined in the August 5, 2004 *Federal Register*, and a July 30, 2004 report prepared by CMS contractor, Bearing Point, include results that are counter-intuitive and result in a lack of faith that the underlying assumptions have been fully explored. Most importantly, although Section 1848(C)(2)(B) of the Omnibus Budget Reconciliation Act of 1990 requires CMS to consult with organizations representing physicians when the agency comprehensively reviews all relative values at least each five years, no concerted effort has been made to do so with respect to the PLI relative values. In fact, as an active participant in the AMA/RUC process, we are aware that the RUC has made several attempts over the past year to offer suggestions to CMS. We found no evidence in either the Bearing Point report or this proposed rule that CMS seriously considered any of the AMA/RUC suggestions. Although this component of the Resource Based – Relative Value System (RBRVS) makes up a small percentage of overall physician reimbursement, it is a critical component and deserves appropriate consideration. We urge you to pay direct attention to this issue as it is very important to many specialties, some who face critical decisions regarding their ability to practice facing the medical liability insurance crisis in the United States today.

Academy review of the Bearing Point report indicates that CMS has used rating manuals from the various insurance carriers to calculate risk factors. Of more concern to the Academy is the decision to use rating manuals for dermatology when the report also indicates that there was dermatology survey data available.

In addition, the use of these particular insurers' manuals is questionable. In particular, St. Paul, which ceased writing professional liability insurance policies, and MLMIC, which is an outlier in the industry and withdrew from the A.M. Best Company in August, 2004 are suspect sources for the Bearing Point report. This coupled with the use of outdated premium data does not make any sense when more recent, reliable data is available.

The assignment of specialty risk factors appears to more be complicated than in the past, with new sources introduced and based on a different core group of specialties than in the original study. CMS has also used different crosswalks than in the past for specialties where direct premium data is not available. We question whether this has led to many risk factors that are counter-intuitive.

For example, the contractor has suggested a dramatic increase in the dermatology surgical risk factor by incorporating the highest major surgical data found in a rating manual. The questionable rationale for this shift is buried in a footnote where all procedures performed by dermatologists are now classified as major surgery. We acknowledge that the volume and scope of dermatologic surgery has expanded, particularly in the area of the treatment of cutaneous oncology. However, considering that rating manuals rather than survey data was used, it is doubtful that it in any way accurately reflects current PLI premiums for dermatologic surgeons performing more invasive dermatologic surgery. It is certainly not reflective of the typical dermatologist practice of performing minor surgery in the office.

While we believe that the malpractice RVUs for surgical dermatology have been undervalued, considering the number and types of surgical procedures currently provided by dermatologists, we do not believe it should be valued the same as general surgery. Furthermore, the complexity of non-surgical work or many dermatologists prescribing drugs such as methotrexate, anti-malarials, biologics, or isotretinoin suggests to us that the non-surgical RVUs for dermatology are also low.

We therefore urge CMS to work with the AMA/RUC to ensure that the medical community has input into the refinement of the PLI relative values. The PLI relative values in the proposed rule should remain interim until this input is seriously considered.

Addendum B Error in Practice Expense RVU for CPT 17307

We identified an error in the practice expense RVU assigned to CPT code 17307, found on page 47585 of the proposed rule. The non-facility PE/RVU was reduced from the 2004 PE/RVU value of 3.78 to 2.63. The error appears to be created by the omission of clinical labor time in the PE calculation. We have been advised by CMS staff that the error will be corrected in the final rule. We therefore include this comment to ensure that the appropriate PE/RVU will be inserted in the CY2005 fee schedule so that there are no rank order anomalies in the CPT code family represented by CPT codes 17304 – 17310.

Correction to Addendum C

On page 47705 of the proposed rule, CPT code 96902 is listed with the incorrect descriptor of “ultraviolet light therapy”. The correct descriptor for CPT 96902 is “Trichogram of Microscopic Examination of Hair”. In addition, this code is listed with a B status code which we believe is in error. It has a physician work RVU value of 0.41 and a Total Non-Facility RVU value of 0.57, and therefore should not be considered a bundled service. It had been

recognized as a separate service at the RUC, not a component of an evaluation and management visit, and should be separately payable.

Section 413 – Incentive Payments in Specialty Physician Shortage Areas

We appreciate that Section 413(a) of the MMA provides a new 5 percent incentive payment to physicians furnishing Medicare-covered services in physician scarcity areas. In addition, the MMA also provides for specialty physicians furnishing services in a specialist care scarcity county, an additional incentive payment equal to 5 percent of the amount paid for these services. These two new incentive payments are in addition to the existing 5 percent payment made to physicians furnishing care in health professions shortage areas (HPSAs). Thus, eligible physicians furnishing care in an area qualified as a physician shortage area (PSA) for purposes of Section 413(a) and as a HPSA would be entitled to receive a total of a 15 percent bonus payment. These incentives should be powerful tools for improving access to care in communities that at present do not have enough specialists – such as dermatologists – to serve the needs of older patients.

According to the MMA, the proposed and final rules for the CY2005 fee schedule are supposed to include a list of PSA counties identified by ZIP code. The August 5, 2004 proposal obviously does not include this list. The proposal also does not provide any guidance on how CMS plans to publicize the new incentive payment programs or work with the medical societies and other stakeholder groups to ensure the new programs realize their full potential, and bring specialty services to underserved communities. We urge CMS to develop and include the PSA list in the final rule so that interested specialty physicians will have adequate information about these important opportunities, and sufficient time in which to decide whether they will furnish services in underserved areas.

Payment Reform for Covered Outpatient Drugs and Biologicals

The Academy is concerned by the lack of information in the proposed rule concerning Medicare payments for drugs and biologicals that are scheduled to take effect in 2005. Biological therapies prescribed primarily for psoriasis patients are affected by this new payment system.

In addition to incomplete drug pricing information, doubts about the reliability of some proposed drug payments are worrisome, too. These doubts raise serious concerns about the reliability of the entire new payment system only a few months from the implementation date. We urge CMS to provide reliable 2005 drug payment information by the time the final rule is published, so that dermatologists and other physicians affected by these new payment rules for outpatient drugs and biologicals can make informed decisions about their practices.

Conclusion

The American Academy of Dermatology Association appreciates the opportunity to comment on these issues of concern to us in the proposed Medicare physician fee schedule for CY 2005. Thank you for considering our views. Please contact either Laura Saul Edwards (at ledwards@aad.org or 202-842-3555) or Norma Border (at nborder@aad.org or 847-330-0230) if you have questions about our comments and recommendations. Thank you.

Sincerely,

James A. Zalla, MD
Chair, Health Care Finance Committee

JAZ/lse

CC: Boni E. Elewski, MD, President
Clay J. Cockerell, MD, President-Elect
David M. Pariser, MD, Secretary-Treasurer
Brett Coldiron, MD, Vice Chair, Health Care Finance Committee
Daniel M. Siegel, MD, AADA Representative to the AMA/RUC Committee
Stuart J. Salasche, MD, President, American College of Mohs Micrographic Surgery and Cutaneous Oncology
Pearon G. Lang, Jr, MD, President-Elect, ACMMSCO
Ronald J. Moy, MD, President, American Society for Dermatologic Surgery
Robert S. Bolan, PhD, Interim Executive Director
Ron A Henrichs, CAE, Executive Director Designate
John D. Barnes, Associate Executive Director, GAHP
Judith Magel, Director, Health Policy and Practice
Norma Border, Senior Manager, Health Policy and Practice
Laura Saul Edwards, Assistant Director, Federal Affairs

American Academy of Dermatology Association

1350 I St NW Ste 870
Washington DC 20005-3319
Phone 202/842-3555
Fax 202/842-4355
Web Site www.aadassociation.org

September 24, 2004

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS-1429-P

RE: CMS-1429-P, Medicare Program; Revisions in Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Dear Dr. McClellan:

I am contacting you on behalf of the 14,000 members of the American Academy of Dermatology Association to provide our comments on the proposed Medicare physician fee schedule for Calendar Year 2005. The Academy will address our concerns with the Sustainable Growth Rate (SGR) formula, the re-pricing of clinical practice expenses for equipment, practice expense inputs for photodynamic therapy (PDT), the proposed update to professional liability insurance (PLI) relative value units (RVU), and corrections that should be made in Addendum B and Addendum C.

The proposal, published on August 5, 2004, also addresses a number of provisions relating to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). In this comments letter, the Academy will address our concerns with incentive payment improvements for specialty physician services in workforce shortage areas and payment reform for covered outpatient drugs and biologicals.

The SGR Formula

It is a widely-acknowledged fact that the SGR formula for calculating the annual update in Medicare physician reimbursement is seriously flawed. In previous letters the Academy has shared our ideas for regulatory approaches to correcting these flaws in the formula. These administrative corrections include removing Medicare-covered outpatient drugs from the expenditure target for the physician payment update, or else properly accounting for the costs of these drugs.

Another administrative fix that could have been addressed in this proposal is properly and fully accounting for the impact on Medicare Part B spending due to changes in laws and regulations. Examples of these costs are the impact of the new “Welcome to Medicare”

physical established by the MMA, and the cost impacts of national coverage decisions and preventive benefits approved by Congress.

These administrative changes would assuage many of the problems linked to the current SGR formula. Since we believe that CMS has the statutory authority to make these changes, it is disappointing that the agency chose not to tackle them in this fee schedule proposal. Inaction by CMS, and for that matter by Congress which created the SGR formula, will only serve to increase the eventual cost of fixing or replacing the formula while jeopardizing older patients' access to covered health care services.

Re-Pricing of Clinical Practice Expense for Equipment

The appropriate valuation of medical supplies and equipment for CPT 36522 for Photopheresis is of importance to the Academy. For this reason, the Academy in conjunction with the American Society for Hematology will provide information to the AMA/Specialty Society Relative Value Update Committee (RUC) Practice Expense Subcommittee on medical supplies and equipment for this code, at the September RUC meeting – as identified and requested in the proposed rule.

Practice Expense Inputs for Photodynamic Therapy (PDT)

The Academy continues to be concerned regarding the significant decrease in payment for photodynamic therapy (PDT), CPT code 95657. We are aware that a reduction in the practice expense RVUs is occurring in part due to updates to the Medicare utilization data used in the practice expense methodology for the 2004 Medicare physician fee schedule. As a result of the updated utilization data, the practice expense methodology is now using the dermatology scaling factor (0.54) for supplies instead of the all physician average (1.29), which is one of the contributing factors to the reduction in payment for this code. We request that CMS reconsider this scaling factor issue.

We appreciate that physicians may now bill separately for the light-activating agent under the appropriate J code (Pub. 100-20 Transmittal: 90 June 25, 2004 SUBJECT: MMA Drug Pricing Update—Payment Limits for J7308 (Levulan Kerastick)). We also appreciate that CMS has removed this drug from the practice expense portion of the procedure. However, there are medical supplies that are not recognized in the current practice expense inputs. We request that CMS incorporate the missing medical supply data for these codes.

Dermatologists providing PDT note that the patients being treated tend to be those with the more severe cases of actinic keratosis, both in terms of the number of lesions treated and the severity of these lesions. This was not fully appreciated when the code was initially reviewed by the AMA RUC. The medical supplies listed are clinically necessary to lessen the reaction to the therapy and to control the resultant pain. For the typical patient, these medical supplies should be recognized and included as direct practice expense inputs:

Bacitracin—SJ008, quantity 0.5 of a 15gm size.
When the patient presents at the physician's office the following day to receive the light treatment, the patient's face if thoroughly cleaned and an anti-bacterial ointment is applied to the netire area of the face and/or scalp that will have light applied. This is done to lessen any likelihood of infection.

LMX 4% Topical Anesthetic Cream – 30 gm
To control burning or stinging from the light activation procedure, the physician will apply LMX topical anesthetic cream to the entire area.

Proposed Update to Professional Liability Insurance Relative Value Units

The Academy is disappointed with the proposal for the Five-Year Review of the Professional Liability Insurance (PLI) relative values. We understand that CMS is required by statute to update this component by January 1, 2005. However, we respectfully urge that CMS consider this implementation "interim" until the agency has worked with the medical community to ensure that the data and methodology utilized to calculate this small, but important component of Medicare physician payment are appropriate.

The proposal, as outlined in the August 5, 2004 *Federal Register*, and a July 30, 2004 report prepared by CMS contractor, Bearing Point, include results that are counter-intuitive and result in a lack of faith that the underlying assumptions have been fully explored. Most importantly, although Section 1848(C)(2)(B) of the Omnibus Budget Reconciliation Act of 1990 requires CMS to consult with organizations representing physicians when the agency comprehensively reviews all relative values at least each five years, no concerted effort has been made to do so with respect to the PLI relative values. In fact, as an active participant in the AMA/RUC process, we are aware that the RUC has made several attempts over the past year to offer suggestions to CMS. We found no evidence in either the Bearing Point report or this proposed rule that CMS seriously considered any of the AMA/RUC suggestions. Although this component of the Resource Based – Relative Value System (RBRVS) makes up a small percentage of overall physician reimbursement, it is a critical component and deserves appropriate consideration. We urge you to pay direct attention to this issue as it is very important to many specialties, some who face critical decisions regarding their ability to practice facing the medical liability insurance crisis in the United States today.

Academy review of the Bearing Point report indicates that CMS has used rating manuals from the various insurance carriers to calculate risk factors. Of more concern to the Academy is the decision to use rating manuals for dermatology when the report also indicates that there was dermatology survey data available.

In addition, the use of these particular insurers' manuals is questionable. In particular, St. Paul, which ceased writing professional liability insurance policies, and MLMIC, which is an outlier in the industry and withdrew from the A.M. Best Company in August, 2004 are suspect sources for the Bearing Point report. This coupled with the use of outdated premium data does not make any sense when more recent, reliable data is available.

The assignment of specialty risk factors appears to more be complicated than in the past, with new sources introduced and based on a different core group of specialties than in the original study. CMS has also used different crosswalks than in the past for specialties where direct premium data is not available. We question whether this has led to many risk factors that are counter-intuitive.

For example, the contractor has suggested a dramatic increase in the dermatology surgical risk factor by incorporating the highest major surgical data found in a rating manual. The questionable rationale for this shift is buried in a footnote where all procedures performed by dermatologists are now classified as major surgery. We acknowledge that the volume and scope of dermatologic surgery has expanded, particularly in the area of the treatment of cutaneous oncology. However, considering that rating manuals rather than survey data was used, it is doubtful that it in any way accurately reflects current PLI premiums for dermatologic surgeons performing more invasive dermatologic surgery. It is certainly not reflective of the typical dermatologist practice of performing minor surgery in the office.

While we believe that the malpractice RVUs for surgical dermatology have been undervalued, considering the number and types of surgical procedures currently provided by dermatologists, we do not believe it should be valued the same as general surgery. Furthermore, the complexity of non-surgical work or many dermatologists prescribing drugs such as methotrexate, anti-malarials, biologics, or isotretinoin suggests to us that the non-surgical RVUs for dermatology are also low.

We therefore urge CMS to work with the AMA/RUC to ensure that the medical community has input into the refinement of the PLI relative values. The PLI relative values in the proposed rule should remain interim until this input is seriously considered.

Addendum B Error in Practice Expense RVU for CPT 17307

We identified an error in the practice expense RVU assigned to CPT code 17307, found on page 47585 of the proposed rule. The non-facility PE/RVU was reduced from the 2004 PE/RVU value of 3.78 to 2.63. The error appears to be created by the omission of clinical labor time in the PE calculation. We have been advised by CMS staff that the error will be corrected in the final rule. We therefore include this comment to ensure that the appropriate PE/RVU will be inserted in the CY2005 fee schedule so that there are no rank order anomalies in the CPT code family represented by CPT codes 17304 – 17310.

Correction to Addendum C

On page 47705 of the proposed rule, CPT code 96902 is listed with the incorrect descriptor of “ultraviolet light therapy”. The correct descriptor for CPT 96902 is “Trichogram of Microscopic Examination of Hair”. In addition, this code is listed with a B status code which we believe is in error. It has a physician work RVU value of 0.41 and a Total Non-Facility RVU value of 0.57, and therefore should not be considered a bundled service. It had been

recognized as a separate service at the RUC, not a component of an evaluation and management visit, and should be separately payable.

Section 413 – Incentive Payments in Specialty Physician Shortage Areas

We appreciate that Section 413(a) of the MMA provides a new 5 percent incentive payment to physicians furnishing Medicare-covered services in physician scarcity areas. In addition, the MMA also provides for specialty physicians furnishing services in a specialist care scarcity county, an additional incentive payment equal to 5 percent of the amount paid for these services. These two new incentive payments are in addition to the existing 5 percent payment made to physicians furnishing care in health professions shortage areas (HPSAs). Thus, eligible physicians furnishing care in an area qualified as a physician shortage area (PSA) for purposes of Section 413(a) and as a HPSA would be entitled to receive a total of a 15 percent bonus payment. These incentives should be powerful tools for improving access to care in communities that at present do not have enough specialists – such as dermatologists – to serve the needs of older patients.

According to the MMA, the proposed and final rules for the CY2005 fee schedule are supposed to include a list of PSA counties identified by ZIP code. The August 5, 2004 proposal obviously does not include this list. The proposal also does not provide any guidance on how CMS plans to publicize the new incentive payment programs or work with the medical societies and other stakeholder groups to ensure the new programs realize their full potential, and bring specialty services to underserved communities. We urge CMS to develop and include the PSA list in the final rule so that interested specialty physicians will have adequate information about these important opportunities, and sufficient time in which to decide whether they will furnish services in underserved areas.

Payment Reform for Covered Outpatient Drugs and Biologicals

The Academy is concerned by the lack of information in the proposed rule concerning Medicare payments for drugs and biologicals that are scheduled to take effect in 2005. Biological therapies prescribed primarily for psoriasis patients are affected by this new payment system.

In addition to incomplete drug pricing information, doubts about the reliability of some proposed drug payments are worrisome, too. These doubts raise serious concerns about the reliability of the entire new payment system only a few months from the implementation date. We urge CMS to provide reliable 2005 drug payment information by the time the final rule is published, so that dermatologists and other physicians affected by these new payment rules for outpatient drugs and biologicals can make informed decisions about their practices.

Conclusion

The American Academy of Dermatology Association appreciates the opportunity to comment on these issues of concern to us in the proposed Medicare physician fee schedule for CY 2005. Thank you for considering our views. Please contact either Laura Saul Edwards (at ledwards@aad.org or 202-842-3555) or Norma Border (at nborder@aad.org or 847-330-0230) if you have questions about our comments and recommendations. Thank you.

Sincerely,

James A. Zalla, MD
Chair, Health Care Finance Committee

JAZ/lse

CC: Boni E. Elewski, MD, President
Clay J. Cockerell, MD, President-Elect
David M. Pariser, MD, Secretary-Treasurer
Brett Coldiron, MD, Vice Chair, Health Care Finance Committee
Daniel M. Siegel, MD, AADA Representative to the AMA/RUC Committee
Stuart J. Salasche, MD, President, American College of Mohs Micrographic Surgery and Cutaneous Oncology
Pearon G. Lang, Jr, MD, President-Elect, ACMMSCO
Ronald J. Moy, MD, President, American Society for Dermatologic Surgery
Robert S. Bolan, PhD, Interim Executive Director
Ron A Henrichs, CAE, Executive Director Designate
John D. Barnes, Associate Executive Director, GAHP
Judith Magel, Director, Health Policy and Practice
Norma Border, Senior Manager, Health Policy and Practice
Laura Saul Edwards, Assistant Director, Federal Affairs

Submitter : Mr. C. Brian Freeman **Date & Time:** 09/24/2004 03:09:41

Organization : North Colorado Sports Medicine

Category : Other Health Care Professional

Issue Areas/Comments

Issues 10-19

SECTION 642

Please see attachment

SECTION 952

Please see attachment

CMS-1429-P-3813-Attach-1.doc

CMS-1429-P-3813-Attach-1.doc

September 24, 2004

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1429-P

P.O. Box 8012

Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician offices and clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- "Incident to" has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY "incident to" service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. ***It is imperative that physicians continue to make decisions in the best interests of the patients.***

- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.

- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.

- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.

- Athletic trainers are highly educated. ALL certified or licensed athletic trainers ***must have a bachelor's or master's degree*** from an accredited college or university. Foundation courses include: human physiology, human anatomy, kinesiology/biomechanics, nutrition, acute care of injury and illness, statistics and research design, and exercise physiology. Seventy (70) percent of all athletic trainers have a master's degree or higher. This great majority of practitioners who hold advanced degrees is comparable to other health care professionals, including physical therapists, occupational therapists, registered nurses, speech therapists and many other mid-level health care practitioners. Academic programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) via the Joint Review Committee on educational programs in Athletic Training (JRC-AT).

- To allow *only* physical therapists, occupational therapists, and speech and language pathologists to provide "incident to" outpatient therapy services would improperly provide these groups exclusive rights to Medicare reimbursement. To mandate that only these practitioners may provide "incident to" outpatient therapy in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

- CMS, in proposing this change, offers no evidence that there is a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.

- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. ***In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of therapy services.***

- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.

- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to **prevent, assess, treat and rehabilitate** injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of walking in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

C. Brian Freeman ATC EM-B

North Colorado Sportsmedicine

Acceleration Coordinator

Certified Athletic Trainer Platte Valley High School

970-392-21047

brian.freeman@bannerhealth.com

Submitter : Dr. Larry Levin **Date & Time:** 09/24/2004 03:09:08

Organization : Santa Cruz Medical Foundation

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I object to the current regulations which have kept Santa Cruz County designated as a rural county (locality 99). This will result in physicians in Santa Cruz County getting reimbursed 25% less than physicians in our neighboring counties of Santa Clara and San Mateo. The cost of living and doing business in Santa Cruz County is not significantly less than our neighboring counties. The median cost of a home in our county is $630,000. We will not be able to retain current physicians and attract new physicians if this policy is not corrected. Santa Cruz County should have its own locations with reimbursement levels that are appropriate for the cost of living here.

Submitter : Ms. Katharine Ayres **Date & Time:** 09/24/2004 04:09:40

Organization : CLMA (Clinical Laboratory Management Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-9

CODING-GLOBAL PERIOD

Coding-Bone Marrow Aspiration

We understand that in the physician final rule published on June 28, 2002 (67 FR 43863), CMS previously proposed a G-code that reflects a bone marrow biopsy and aspiration procedure performed on the same date, at the same encounter, through the same incision.
We also understand that due to comments received in response to that final rule, CMS elected to take the code through the CPT process and to date; CPT has not addressed the issue. As a result, the agency is again proposing to create a G-code for the above service in 2005.
In the absence of action on the part of CPT, CLMA is supportive of the G-code proposal for 2005. We are in favor of the use of one code when one incision is made.

SECTION 612

Section 612-Cardiovascular Screening Blood Tests

Statute provides that the Secretary shall establish frequency standards for coverage of cardiovascular screening tests not to exceed a frequency of more than once every 2 years.
However, based upon a review of scientific literature, CMS is recommending coverage of cardiovascular screening tests once every 5 years.
Other screening tests as defined by statute are covered annually. Again, having different frequency limitations for cardiovascular screening tests, and particularly a frequency limitation as long as every 5 years, creates an additional burden on laboratories to determine if the limitations are met or exceeded.

SECTION 613

Section 613-Diabetes Screening Tests

CMS is proposing that Medicare beneficiaries diagnosed with ?pre-diabetes? be eligible for the maximum frequency allowed by law, that is, 2 screening tests per 12 month period. The agency proposes to define ?pre-diabetes? as having a previous fasting glucose of 100-125 mg/dl, or a 2-hour post-glucose challenge of 140-199 mg/dl. Individuals not meeting the ?pre-diabetes? criteria would be limited to one diabetes screening test per individual per year.
CLMA has concerns regarding the issue of determining ?pre-diabetes.? The definition proposed by CMS is based on ?previous results,? that is, a laboratory result first would set the diagnosis. This may create confusion in terms of the proper coding of these services.
Secondly, how will CMS determine if the beneficiary receiving the service is ?pre-diabetic?? This would require a specific ICD-9-CM code in order for CMS to make that determination.

CLMA would like to propose that any patient with an ICD-9-CM diagnosis code of 790.29, Other abnormal glucose, Abnormal glucose NOS, Abnormal non-fasting glucose, Pre-diabetes NOS, be considered ?pre-diabetic? and allowed 2 diabetes screening tests per 12-month period.
Lastly, we want CMS to be aware that having different frequency requirements for those meeting the ?pre-diabetic? criteria and for those who do not, creates an additional burden on the laboratories. The laboratory must not only to determine if the frequency limitations are met or exceeded, but also which frequency limitation of the two options applies to a particular beneficiary.

CLMA
THE RESOURCE FOR LABORATORY PROFESSIONALS

989 Old Eagle School Rd., Suite 815
Wayne, PA 19087-1704
tel 610 995 9580
fax 610 995 9568
www.clma.org

September 24, 2004
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Dear Sirs,

The CLMA (Clinical Laboratory Management Association) is an international professional association of executives, administrators, managers, and supervisors who are responsible for laboratory operations and clinical services in hospitals and other health care organizations. We are comprised of approximately 5,500 members that represent all laboratory settings and many ancillary industries that support laboratories. CLMA and its members are dedicated to the provision of the highest quality clinical laboratory services regardless of the clinical setting. We are writing to you today regarding a Proposed Rule that revises payment policies relevant to the physician fee schedule, and addresses certain provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2004 (MMA) (Pub. L. 108-173).

Coding-Bone Marrow Aspiration

We understand that in the physician final rule published on June 28, 2002 (67 FR 43863), CMS previously proposed a G-code that reflects a bone marrow biopsy and aspiration procedure performed on the same date, at the same encounter, through the same incision.
We also understand that due to comments received in response to that final rule, CMS elected to take the code through the CPT process and to date; CPT has not addressed the issue. As a result, the agency is again proposing to create a G-code for the above service in 2005.
In the absence of action on the part of CPT, CLMA is supportive of the G-code proposal for 2005. We are in favor of the use of one code when one incision is made.

Section 613-Diabetes Screening Tests

CMS is proposing that Medicare beneficiaries diagnosed with "pre-diabetes" be eligible for the maximum frequency allowed by law, that is, 2 screening tests per 12 month period. The agency proposes to define "pre-diabetes" as having a previous fasting glucose of 100-125 mg/dl, or a 2-hour post-glucose challenge of 140-199 mg/dl. Individuals not meeting the "pre-diabetes" criteria would be limited to one diabetes screening test per individual per year.
CLMA has concerns regarding the issue of determining "pre-diabetes." The definition proposed by CMS is based on "previous results," that is, a laboratory result *first* would set the diagnosis. This may create confusion in terms of the proper coding of these services.
Secondly, how will CMS determine if the beneficiary receiving the service is "pre-diabetic?" This would require a specific ICD-9-CM code in order for CMS to make that determination.

CLMA
THE RESOURCE FOR LABORATORY PROFESSIONALS

989 Old Eagle School Rd., Suite 815
Wayne, PA 19087-1704
tel 610 995 9580
fax 610 995 9568
www.clma.org

CLMA would like to propose that any patient with an ICD-9-CM diagnosis code of 790.29, Other abnormal glucose, Abnormal glucose NOS, Abnormal non-fasting glucose, Pre-diabetes NOS, be considered "pre-diabetic" and allowed 2 diabetes screening tests per 12-month period.
Lastly, we want CMS to be aware that having different frequency requirements for those meeting the "pre-diabetic" criteria and for those who do not, creates an additional burden on the laboratories. The laboratory must not only to determine if the frequency limitations are met or exceeded, but also which frequency limitation of the two options applies to a particular beneficiary.

Section 612-Cardiovascular Screening Blood Tests

Statute provides that the Secretary shall establish frequency standards for coverage of cardiovascular screening tests not to exceed a frequency of more than once every 2 years.
However, based upon a review of scientific literature, CMS is recommending coverage of cardiovascular screening tests once every 5 years.
Other screening tests as defined by statute are covered annually. Again, having different frequency limitations for cardiovascular screening tests, and particularly a frequency limitation as long as every 5 years, creates an additional burden on laboratories to determine if the limitations are met or exceeded.

Conclusion

CLMA appreciates the opportunity to submit comments on this Proposed Rule, and urges CMS to consider our comments and those of individuals and other organizations within the clinical laboratory community.
If you should have any questions concerning our comments, please do not hesitate to contact Katharine I. Ayres, Director of Legislative and Regulatory Affairs, at 610.995.2640, extension 232, or Jeff Boothe at 202.828.1896.

Sincerely,

Judy A. Lien
President

CMS-1429-P-3816

Submitter : Mr. William Walsh **Date & Time:** 09/24/2004 04:09:41

Organization : American Society of Hand Therapists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the PDF attachment for ASHT's comments.

CMS-1429-P-3816-Attach-1.pdf

AMERICAN SOCIETY OF HAND THERAPISTS

September 23, 2004

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1429-P
P.O. Box 8012
7500 Security Boulevard
Baltimore, MD 21244-8012

Dear CMS Representative,

On behalf of the American Society of Hand Therapists (ASHT), we wish to issue an official statement of support regarding the proposed revisions to 42 C.F.R, part 410, specifically 410.26, 410.59, 410.60 and 410.62 to reflect that Occupational Therapy and Physical Therapy services provided incident to a physician's professional services shall only be administered by those who meet the qualifications of Occupational Therapists and Physical Therapists, and Occupational Therapist Assistants and Physical Therapist Assistants who are properly supervised by qualified Occupational Therapists and Physical Therapists. ASHT explicitly supports the aforementioned proposed changes and recommends that CMS accept them as final and implement starting January 1, 2005.

The American Society of Hand Therapists (ASHT) has represented hand therapists, comprised of licensed Occupational and Physical Therapists specializing in the treatment of the upper extremity for the past twenty-six (27) years. Our 3,000 plus members are committed to providing the best quality of care and service, while working within the regulations set by Medicare. While CMS is clearly committed to supporting quality health care, ASHT encourages CMS to continue to explore every effort to allow health care providers to offer therapy services efficiently. Specifically, ASHT urges CMS to permanently release the $1500 cap on outpatient rehabilitation services and oppose the consideration of a competitive bidding system for orthoses and durable medical equipment, as these short-term cost-cutting solutions could result in a great expense in healthcare spending for future years and a decrease in quality of care.

In the proposed rule, CMS proposes to change the occupational therapy assistant (OTA) supervision requirements for the private practice setting from "personal" supervision to "direct" supervision. ASHT unequivocally supports this proposal and urges CMS to finalize it. ASHT also agrees with the proposal to restore the qualifications of OTAs at 42 § 410.59, which had been inadvertently removed.

We sincerely appreciate the time and effort that CMS has put forth in considering the revisions to payment policies under the physician fee schedule for calendar year 2005, specifically rendering clarifications to the policies affecting therapy services. We also appreciate CMS allowing ASHT to make recommendations regarding the L-Codes billing system during our July meeting with you in South Carolina. If there is any additional information we can provide regarding our position or our Society, please do not hesitate to contact us directly at (312) 321-6866.

Respectfully,

William W. Walsh, MBA, MHA, OTR/L, CHT
2004 ASHT President

CMS-1429-P-3817

Submitter : **Date & Time:** 09/24/2004 04:09:56

Organization :

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I support the CMS proposed stipulation that physical therapy provided in a physician's office be administered by a licensed physical therapist. A physical therapist is a graduate of an approved physical therapy program and is licensed in the practicing state. In addition, those treatments rendered by a physical therapy assistant must be under the supervision of a physical therapist.

In the community where I practice, orthopedic surgeons have opened clinics of their own in conjunction with companies like Novacare. The more these physicians refer to themselves, the more revenue they generate for themselves. How can physician groups, Novacare, and the personnel they employ all make money unless by high referral numbers and high charges to such entities as the Medicare system? I am told by patients that they are walked from the physician's office right to the physician's physical therapy clinic before they leave the building and are signed up for treatment. The prescriptions for treatment are kept by the physician's staff, making it difficult for the patient to go elsewhere for their rehabilitation needs. Physician owned practices used to be illegal because of the potential abuse that can occur.

Currently physician offices are billing "incident to" for physical therapy services. These services should meet the same requirements for outpatient physical therapy services required in all settings. Otherwise there is no oversight as to whether the person treating the patient is a licensed physical therapist from an accredited university program. This situation promotes the delivery of alleged physical therapy services by unqualified personnel to the detriment of the Medicare patient.

Thank you for your support of the proposed CMS requirement that physical therapists practice physical therapy, not doctors who want to further their own financial gain.

Submitter : Ms. Kathy Dodson **Date & Time:** 09/24/2004 04:09:48

Organization : American Orthotic

Category : Device Association

Issue Areas/Comments

Issues 10-19

SECTION 302

September 24, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Sirs:

The American Orthotic and Prosthetic Association (AOPA), the leading business trade group in the orthotics and prosthetics industry with a full-range of services that support patient care facilities and the companies that manufacture and distribute O&P products, would like to submit comments (Attachment A) on L. Section 302 of the Proposed Rule for Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005,

Of particular importance, we find no legislative authority or requirement in the Medicare Modernization Act (MMA) for applying these new clinical conditions of coverage to orthotic and prosthetic devices. This proposed regulation cites Section 1832(a)(1)(E) of the MMA for the establishment of clinical conditions of coverage standards only for items of durable medical equipment.

Further, this section also requires the Secretary of Health and Human Services (HHS) to first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered or consistent findings of falsification of documentation. We find no evidence that the Secretary has attempted to categorize and prioritize items of DME as required by this section. The blanket application of new clinical standards to all DMEPOS is contrary to the intent of Section 1832 9a)(1)(E).

We also provide specific comments in Attachment A to demonstrate why attempts to expand these additional clinical conditions of coverage to orthotic and prosthetic devices would have a severe impact on patient care and could significantly increase the cost to both the patient and to the Medicare program.

If you need further information about our comments, please contact Virginia Torsch, Senior Manager of Regular Affairs, by phone (571) 431-0812, or by email vtorsch@aopanet.org.

Sincerely,

Kathy Dodson
Senior Director, Government Affairs

CMS-1429-P-3818-Attach-1.doc

Attachment A

Proposed Federal Rule CMS-1429-P
Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005
August 5, 2004

A. General Comment on L. Section 302:

AOPA finds no legislative authority or requirement in the Medicare Modernization Act (MMA) for applying these new clinical conditions of coverage to orthotic and prosthetic devices.
This proposed regulation cites a legislative requirement in Section 1832(a)(1)(E) of the Medicare Modernization Act, which requires the establishment of clinical conditions of coverage standards for items of durable medical equipment. This section of the MMA amends Section 1834(a) 1 of the Social Security Act which provides general rules of payment for durable medical equipment. Section 1834(a) 1 covers only those items covered in paragraph (13) of Section 1834, which refers to items of durable medical equipment as defined in Section 1861 (n) and Section 1861 (m)(5) of the Social Security Act. Section 1861 (n) clearly defines durable medical equipment, but this section does not include orthotic or prosthetic devices. Section 1861 (m)(5) only refers to medical supplies such as catheters and ostomy bags. Again there is no reference to orthotic or prosthetic devices as defined in Section 1861(s).

Section 1832 (a)(1)(E) also requires the Secretary of Health and Human Services (HHS) to first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered or consistent findings of falsification of documentation to provide for payment of covered items. **AOPA finds no evidence in these proposed provisions that the Secretary has attempted to categorize and prioritize items of DME as required by this section. Rather these proposed provisions seem to apply to all DME items as well as orthotic and prosthetic devices with no distinction made as to particular items of concern. This blanket application of new clinical standards to all DMEPOS is contrary to the intent of Section 1832 9a)(1)(E).**

As provided in our comments below on the specific proposed provisions in Section 302, to erroneously expand these additional clinical conditions of coverage to orthotic and prosthetic devices will have a severe impact on patient care and could significantly increase the cost to both the patient and to the Medicare program.

B. Comments on specific provisions of L. Section 302 – Clinical Conditions for Coverage of Durable Medical Equipment

- Establishes a requirement for a face-to face examination by a physician, physician assistant (PA), clinical nurse specialist or nurse practitioner to determine the medical necessity of DME, orthotics and prosthetics;
  Comment: This blanket requirement for a face to face examination is contrary to accepted medical practice. Although the majority of patients do see a physician or other practitioner before receiving a prescription for an orthotic or prosthetic device, there are instances where it is acceptable

for a physician to write a prescription for a device without having to see the patient face to face. In many cases, patients are lifetime patients and need replacement devices. Many physicians maintain only a general knowledge of prosthetics and orthotics, and rely on the clinical expert - the orthotist and/or prosthetist, to recommend specific treatment rationale and recommendation for device changes. This process occurs frequently. Requiring the patient to have a face to face examination by the physician for repairs, adjustment or replacement of components will only delay the provision of necessary services.

For instance, a patient may have worn a below-the-knee prosthesis for years, at which time the prosthesis may have reached the end of its useful life. The patient returns to the prosthetist, thinking that only minor "fitting" adjustments are necessary. The prosthetist examines the prosthesis for fitting and evaluates the function and safety of the entire prosthesis. He then finds that the prosthesis has a structural flaw and calls the patient's physician. The physician now has a choice. He can either give a verbal order to begin replacing the prosthesis, and follow that up with a detailed written order, or he can request that the patient come see him/her for a general follow-up examination. Typically, the physician will request the patient to come to a follow-up examination <u>only</u> if they are unfamiliar with the patient or their current condition. If the physician is comfortable with a previous examination of the patient as the basis of recommendation for replacement of the device, he will usually authorize replacement of the device without a face-to-face encounter. Similar scenarios apply for orthoses that need to be replaced.

There are other times when other healthcare providers provide the information conduit between the physician and the orthotic and/or prosthetic practitioner. For example, a physical therapist who is part of a coordinated rehabilitation team may recommend to a physician that a patient be prescribed an orthosis without the physician having to see the patient directly. This is a frequent occurrence in skilled nursing facilities where it would be difficult to have the patient make an actual office visit. To change the policy to require all patients see a physician or other prescribing practitioner before being authorized an orthotic or prosthetic device imposes a hardship and added expense on the patient, and increases the expense to the Medicare program.

- Requires that the prescribing physician or practitioner be independent from the DMEPOS supplier and may not be a contractor or employee of the supplier;
  No comment.

- Establishes a requirement that the face-to face examination should be for the purposes of evaluating and treating the patient's medical condition and not for the sole purpose of obtaining the prescribing physician's or practitioner's order for DMEPOS;
  Comment: If patients are required to visit a physician every time they need a repair, adjustment or replacement for the orthotic or prosthetic device, this provision will force the physician to perform an unnecessary medical examination before writing a new prescription. This will be burdensome for

the physician and the patient, and increase the cost to Medicare. It is also extremely unfair to the patient who is now placed in the position of making sure his physician does a whole new examination and documents it appropriately. Furthermore, this provision appears unenforceable unless the physician will be penalized for failing to properly perform and then document a visit. It is also unclear about what kind of documentation is required for CMS to be satisfied that this was not just a visit to obtain a new prescription.

- Requires an order prior to delivery for all items of DMEPOS;
  No comment.

- Requires that the order be dated and signed within 30 days after the face to face examination and include verification of the examination *(seeking comments on the appropriate verification process);*
  Comment: AOPA cannot support the limitation of 30 days. This is simply not enough time for a signed order from the physician after the initial examination. For example, a recent amputee is seen by a physician who then refers the patient to a prosthetist for an artificial limb. The prosthetist sees the patient, determines the type of limb that is required, and makes recommendations to the treating physician, who then writes a detailed prescription and signs and dates it. If the physician, or the prosthetist cannot see the patient in a timely manner (for example, one goes on vacation for two weeks); or the patient is not able to make it to the prosthetist in a timely manner, then meeting the 30 day deadline will be difficult. AOPA recommends that at least ninety (90) days be allowed after he initial examination before the detailed written prescription must be signed by the physician.

- Requires the prescribing physician to maintain appropriate and timely documentation in the medical records that support the need for all DMEPOS ordered;
  Comment: AOPA supports CMS in encouraging proper documentation by the physician. Currently, the provider/supplier is at significant financial risk of non-payment for medically necessary services when no accountability is required for the physician. Requiring the physician to maintain the proper documentation, but putting the supplier at financial risk, jeopardizes the clinical physician/supplier relationship. This can only lead to more delay in medically appropriate treatment for the beneficiary.

  AOPA recommends that CMS and the DMERCs increase efforts to educate physicians and other practitioners on how to properly document requirements for orthotic and prosthetic devices so that patients get the care they need without unfairly penalizing the supplier. We further recommend that the physician should be held accountable for lack of documentation, not the orthotic or prosthetic supplier, since the supplier has no control over the contents of the physician's records.

- Provides that CMS promulgates through contractor instructions other criteria required for prescription renewals; repairs, minor revisions and replacement (want comments on whether CMS should establish national renewal requirements or permit contractor discretion);
  Comment: Although AOPA appreciates the need for a certain amount of flexibility in coverage determinations set by each Durable Medical Equipment Carrier (DMERC), we strongly recommend that CMS establish national renewal requirements that are adhered to by each DMERC. Permitting total contractor discretion would only result in four different criteria for prescriptions for renewals; repairs, minor revisions and replacement. This would be extremely confusing to the O&P supplier and to the patient, especially if the supplier has facilities in different DMERC regions, or the patient moves from one DMERC region to another.

- Provides that CMS promulgate through the national coverage process or through the local coverage determination process additional clinical conditions for items of DMEPOS.
  No comment.

Submitter : Mr. Jim Whitehead **Date & Time:** 09/24/2004 04:09:42

Organization : American College of Sports Medicine

Category : Other Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Comment from American College of Sports Medicine attached.

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

CMS-1429-P-3820

Submitter : **Date & Time:** 09/24/2004 04:09:38

Organization :

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 23, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Subject: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.

Dear Mr. McClellan,

This letter is a comment regarding standards for personnel providing physical therapy services in physician offices. I am most eager to comment on the 'Therapy-Incident To' clause proposed by CMS and I strongly support that proposal.

I am a physical therapist practicing in a small out patient clinic in rural western Nebraska. I have owned my practice for over 20 years and have some very strong opinions regarding the profession which I love. As a member of the Nebraska Board of Physical Therapy and the Federation of State Boards of Physical Therapy (FSBPT), I also have a passion for protection of the public.

CMS is proposing that any services provided as 'physical therapy incident to' in a physician's office should be delivered only by persons who meet the personnel qualifications for physical therapist in 42 CFR S484.4. This would align with the recently adopted position of the FSBPT, which is that any services represented, in any way, as 'physical therapy' be provided only by a physical therapist or a physical therapist assistant working under the supervision of a physical therapist.

As a physical therapist, I know that only members of my profession have the education and training for delivery of physical therapy services.

As a protector of the public, I know that the consumers of health care are confused and misled when a non-qualified person represents himself/herself as a physical therapist or represents the services he/she provides as physical therapy.

As an advocate for my patients, as well as my friends and family members who are covered under Medicare, I have a great concern that when the annual cap on physical therapy services is reinstated, as is scheduled to occur in 2006, much, or all, of a persons physical therapy annual allowance may very well be wasted away on 'incident to' charges without that beneficiary ever having actually received the services of a physical therapist.

I thank you for allowing this comment period and for considering my comments.

Sincerely,

Karen S. Brown, PT

CMS-1429-P-3821

Submitter : Mr. John Wallace **Date & Time:** 09/24/2004 04:09:32

Organization : Mr. John Wallace

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

As a physical therapist for 25 years of practice in rehabilitation hospitals as well as private practice, I have come to learn that the Medicare population depends heavily on Medicare to assure that they are seeing qualified practitioners for services.

Because this is true, I strongly support the proposed requirement that physical therapists working in physician offices be graduates of accredited professional physical therapist programs. At the state level, all 50 states attach enough importance to this issue that physical therapists are required to be licensed. Further, Section 1862(a)(20) of the SSA requires that in order for physicians to bill ?incident to? for physical therapy services, those services must meet the same requirements for outpatient therapy services in all settings. This means that individuals who are graduates of accredited professional physical therapist education programs must perform the services.

Physical therapists and physical therapist assistants, working under the supervision of physical therapists, are the only practitioners who have the education and training to furnish physical therapy services to Medicare beneficiaries. Medicare should not spend its money paying for services that are delivered by unqualified personnel.

CMS-1429-P-3821-Attach-2.doc

CMS-1429-P-3821-Attach-1.doc

John G. Wallace, Jr., PT, MS, OCS
209 Westvale Road
Duarte, Ca 91010 626 253-1262

Mark B. McClellan, MD, PhD
Administrator
CMS
US Department of HHS
Attention: CMS-1429-P
P.O. Box boi2
Baltimore, MD 21244-8012

Subject: Medicare Program revisions to Payment Policies Under Physician Fee Schedule for Calendar Year 2005

Dr. McClellan:

I am writing to comment on the **Therapy-Incident To** provision of the Revisions to Payment Under the Physician Fee Schedule for Calendar Year 2005.

As a physical therapist for 25 years of practice in rehabilitation hospitals as well as private practice, I have come to learn that the Medicare population depends heavily on Medicare to assure that they are seeing qualified practitioners for services.

Because this is true, I strongly support the proposed requirement that physical therapists working in physician offices be graduates of accredited professional physical therapist programs. At the state level, all 50 states attach enough importance to this issue that physical therapists are required to be licensed. Further, Section 1862(a)(20) of the SSA requires that in order for physicians to bill “incident to” for physical therapy services, those services **must meet the same requirements for outpatient therapy services in all settings**. This means that individuals who are graduates of accredited professional physical therapist education programs must perform the services.

Physical therapists and physical therapist assistants, working under the supervision of physical therapists, are the only practitioners who have the education and training to furnish physical therapy services to Medicare beneficiaries. Medicare should not spend its money paying for services that are delivered by unqualified personnel.

Thank you for your consideration in reviewing these comments.

Sincerely,

John G. Wallace, Jr., PT, MS, OCS (signature)

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : Mrs. Suzanne Halverson **Date & Time:** 09/24/2004 04:09:48

Organization : ATC/L, ACI at Northern Illinois University

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

PLEASE SEE ATTACHED FILE

CMS-1429-P-3822-Attach-1.doc

Via Electronic Mail -- http://www.cms.hhs.gov/regulations/ecomments

Suzanne Ramjattan Halverson
37W195 Hilly Lane
West Dundee, IL 60118

September 24, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:
I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician offices and clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

Athletic trainers are highly educated. ALL certified or licensed athletic trainers ***must have a bachelor's or master's degree*** from an accredited college or university. Foundation courses include: human physiology, human anatomy, kinesiology/biomechanics, nutrition, acute care of injury and illness, statistics and research design, and exercise physiology. Seventy (70) percent of all athletic trainers have a master's degree or higher. This great majority of practitioners who hold advanced degrees are comparable to other health care professionals, including physical therapists, occupational therapists, registered nurses, speech therapists and many other mid-level health care practitioners. Academic programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) via the Joint Review Committee on educational programs in Athletic Training (JRC-AT). To allow *only* physical therapists, occupational therapists, and speech and language pathologists to provide "incident to" outpatient therapy services would improperly provide these groups exclusive rights to Medicare reimbursement. To mandate that only these practitioners may provide "incident to" outpatient therapy in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services. CMS, in proposing this change, offers no evidence that there is a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services. CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. ***In fact, this action could be***

construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of therapy services.
Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists. Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to **prevent, assess, treat and rehabilitate** injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of walking in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified. These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.
In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,
Suzanne Ramjattan Halverson
Certified Athletic Trainer
Approved Clinical Instructor at Northern Illinois University

CMS-1429-P-3823

Submitter : Mr. Greg Spurling **Date & Time:** 09/24/2004 04:09:30

Organization : Virginia Intermont College

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I believe as Athletic Trainer's we should be able to treat the Elderly population. In our defense as Athletic Trainer's we deal with Athlete's in a competitive field, We deal with both children, teen's, and elderly in the outpatient settings. I think it would be an injustice to regulate the trainer and limiting him/her to specific populations. CPT codes are now being used on other populations why limit the scope of coverage by taking out Medicare. The Board of Medicine requires all athletic trainers to be licensed by Virginia, why not let us exercise our right to do so by providing quality care to the elderly. Thank you for your time.

Submitter : Mr. Jim Whitehead **Date & Time:** 09/24/2004 04:09:42

Organization : American College of Sports Medicine

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 24, 2004

To Whom This Matter Concerns:

The Centers for Medicare and Medicaid Services (CMS) published in the August 5, 2004 Federal Register, pages 47550-47551, a proposal that would restrict reimbursement of physicians for ?Therapy-Incident To? unless a CMS designated group of allied health providers were utilized. CMS regulations currently allow the physician the freedom to choose any qualified health care professional to perform therapy services at the physician?s office or clinic.

The American College of Sports Medicine (ACSM) ? a multidisciplinary association that represents thousands of physicians in the United States and around the world, plus additional thousands of allied health professions in more than 50 areas of specialization ? believes the physician is best equipped to make such medical decisions, and that such freedom serves the best interests of the patient.

Accordingly, ACSM does not support this proposal or similar ones contained in the Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (CMS docket # 1429-P). We believe the provisions, which will restrict the physician?s ability to determine the type of licensed or certified health care provider who administers ?Therapy-Incident To? services, could have a detrimental effect on the welfare of Medicare patients. We believe the health and well being of the Medicare beneficiary must be the primary consideration, and this proposal fails that test. Physicians and all other medical professionals authorized to order ?Therapy-Incident To? services should have the continued medical authority to determine proper care and treatment for the patient and select the best available and most appropriate health care professional to provide that care, including in the area of ?Therapy-Incident To? services. Complex factors always affect a physician?s choice of the most appropriate health care professional to provide ?Therapy-Incident To? services in his/her office or clinic, and this medical judgment as to what best serves the interests of the patient should be maintained and not diluted by this proposal.

Please feel free to contact ACSM if we can provide additional information on this matter. Thank you for your attention in this regard.

Jim Whitehead
Executive Vice President
American College of Sports Medicine
jwhitehead@acsm.org

Submitter : Miss. michele cunningham **Date & Time:** 09/24/2004 04:09:04

Organization : Miss. michele cunningham

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

we need massage therapy to be listed as a resource for medicade users to be able to access. there are too many people all ready that need this kind of therapy who cannot receive it because they cannot afford it. massage therapy is a powerful healing technique for patients of all kinds. it is helpful to patients that have MS to accident victims to rape victims to autistic children who can receive craniosacral therapy

CMS-1429-P-3826

Submitter : Dr. Gary Stein **Date & Time:** 09/24/2004 04:09:55

Organization : American Society of Health-System Pharmacists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-1429-P-3826-Attach-1.doc

September 24, 2004

American Society of Health-System Pharmacists®
7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-652-8278
www.ashp.org

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-1429-P**
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-1429-P: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the proposed rule and request for comments issued by the Centers for Medicare & Medicaid Services (CMS) in the *Federal* Register on August 5, 2004. ASHP is the 30,000-member national professional and scientific association that represents pharmacists and pharmacy technicians who practice in inpatient, ambulatory clinics, home-care, and long-term-care settings.

ASHP's members are extremely concerned about the reduction in reimbursement for Medicare Part B drugs because of the change in reimbursement methodology from Average Wholesale Price (AWP) to Average Sales Price (ASP). The preliminary information provided in the proposed rule indicates that of the 32 drugs listed by CMS, approximately 16 are cancer or supportive care drugs, and 12 of these are going to be reimbursed at a lower rate in 2005 than they were in 2004.

These reductions will have a serious negative impact on the continuum of care for Medicare beneficiaries who have cancer. If the significantly lower reimbursement for Part B drugs is not offset by adequate increases for drug administration and other services, patients will be refused treatment in outpatient settings such as oncologists' offices and will be compelled to seek treatment in hospitals. This will not only strain the resources of acute care hospitals, but also denies patients the right to choose the best treatment for their medical conditions. This will particularly impact rural residents, who may have to seek treatment in hospitals far from their homes.

Some of our members have already told us that their hospitals have had to close their outpatient infusion centers because of the continually reduced reimbursement for Part B drugs. The burden that this situation will place on inpatient facilities that will have to admit patients denied outpatient access will be enormous and untenable.

ASHP recognizes that there are significant differences in estimates of the projected percentage of the reimbursement reductions for Part B drugs. This alone suggests that CMS should wait until the anticipated MedPAC study on practice expense is completed so that the agency can appropriately respond to the findings of that report. We suggest that CMS postpone issuing a final rule until that report is completed.

ASHP appreciates the opportunity to present its comments on this important patient care issue. ASHP awaits further opportunities to assist CMS in ensuring that Medicare beneficiaries have access to appropriate care. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-657-3000 ext. 1316, or by e-mail at gstein@ashp.org

Sincerely,

Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

Submitter : Mr. Vincent Garramone **Date & Time:** 09/24/2004 04:09:05

Organization : Mr. Vincent Garramone

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

1. I oppose the proposed changes to "Incident to" billing regulations.
2. I support recognition of Certified Athletic Trainers as Providers of Rehabilitation Services.
Athletic Trainers provide a valuable service to high school athletes in this regard.

Submitter : Mr. David Moretto **Date & Time:** 09/24/2004 04:09:39

Organization : American Academy of Orthotists and Prosthetists

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 10-19

SECTION 302

American Academy of Orthotists and Prosthetists
526 King Street, Suite 201
Alexandria, VA 22314

September 24, 2004

Ms. Karen Daily
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
PO Box 8012
Baltimore, MD 21244-8012

Comments regarding file code CMS-1429-P
Issue Identifier: 302

Dear Ms. Daily:

The American Academy of Orthotists and Prosthetists is seriously concerned that the proposed changes to the Medicare Modernization Act Section 302(a)(2) will adversely affect the access, timeliness and quality of Orthotic and Prosthetic clinical care and related custom technology. The proposed requirement of an additional visit with a physician or authorized medical personnel and the delivery of such care within a further restricted time period, would create an undue burden on those requiring repair or replacement of existing orthoses and prostheses.

Orthotic and prosthetic care is regularly provided to the elderly and persons with a disability, for whom transportation is often onerous, and many will choose to forgo treatment rather than go through the necessary time and expense of an additional office visit.

For those requiring immediate assistance, the time to procure an office visit with a physician will result in the delay of medical treatment, with resultant potential harm to the patient, which will, in turn, raise medical costs.

Additionally, when working with patients who frequently require our care, it is often not feasible to provide treatment within a time period as short as 30 days, given the complexities of care, other medical conditions that may be affecting the patient and inherent transportation issues with this population.

As professionals who provide continuing care to individuals over many years, we believe that a physician evaluation is mandatory for the initiation of and the initial decision regarding type of treatment; however, in the best interest of the patient, we recommend that this change to the current Medicare policy in regards to the continuance of care not be implemented.

Sincerely,

David F. Moretto, CP, FAAOP
President
American Academy of Orthotists and Prosthetists

AMERICAN ACADEMY OF ORTHOTISTS AND PROSTHETISTS

526 KING STREET, SUITE 201, ALEXANDRIA, VA 22314 •(703) 836-0788 •(703) 836-0737•WWW.OANDP.ORG

September 24, 2004

Ms. Karen Daily
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
PO Box 8012
Baltimore, MD 21244-8012

Comments regarding file code CMS-1429-P
Issue Identifier: 302

Dear Ms. Daily:

The American Academy of Orthotists and Prosthetists is seriously concerned that the proposed changes to the Medicare Modernization Act Section 302(a)(2) will adversely affect the access, timeliness and quality of Orthotic and Prosthetic clinical care and related custom technology. The proposed requirement of an additional visit with a physician or authorized medical personnel and the delivery of such care within a further restricted time period, would create an undue burden on those requiring repair or replacement of existing orthoses and prostheses.

Orthotic and prosthetic care is regularly provided to the elderly and persons with a disability, for whom transportation is often onerous, and many will choose to forgo treatment rather than go through the necessary time and expense of an additional office visit.

For those requiring immediate assistance, the time to procure an office visit with a physician will result in the delay of medical treatment, with resultant potential harm to the patient, which will, in turn, raise medical costs.

Additionally, when working with patients who frequently require our care, it is often not feasible to provide treatment within a time period as short as 30 days, given the complexities of care, other medical conditions that may be affecting the patient and inherent transportation issues with this population.

As professionals who provide continuing care to individuals over many years, we believe that a physician evaluation is mandatory for the initiation of and the initial decision regarding type of

AMERICAN ACADEMY OF ORTHOTISTS AND PROSTHETISTS
526 KING STREET, SUITE 201, ALEXANDRIA, VA 22314 •(703) 836-0788 •(703) 836-0737•WWW.OANDP.ORG

treatment; however, in the best interest of the patient, we recommend that this change to the current Medicare policy in regards to the continuance of care not be implemented.

Sincerely,

David F. Moretto, CP, FAAOP
President
American Academy of Orthotists and Prosthetists

CMS-1429-P-3829

Submitter : Ms. Ana Gross **Date & Time:** 09/24/2004 04:09:20

Organization : Ms. Ana Gross

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

CMS-1429-P-3829-Attach-1.doc

Ana Gross, ATC,

Graduate Assistant Athletic Trainer

The University of Southern Mississippi

118 College Drive #5017

Hattiesburg, MS 39406

September 24,2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.

- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.

- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.

- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.

- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide "incident to" services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide "incident to" care in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

- CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.

- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.

- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.

- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Ana Gross, ATC,

CMS-1429-P-3830

Submitter : Mr. Jonathan Burch **Date & Time:** 09/24/2004 04:09:04

Organization : University of Mississippi Medical Center

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Jonathan Burch, ATC

September 24, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Dear Sir/Madam:
I am writing to express my concern over the recent proposal that would limit providers of ?incident to? services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.
During the decision-making process, please consider the following:
 Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician?s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician?s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
 It is imperative that physicians continue to make decisions in the best interests of the patients.
 In many cases, the change to ?incident to? services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
 Patients who would now be referred outside of the physician?s office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient?s recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
 To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide ?incident to? services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide ?incident to? care in physicians? offices would improperly remove the states? right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
 CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
 CMS does not have the statutory authority to restrict who can and cannot provide services ?incident to? a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
 Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Submitter : **Date & Time:** 09/24/2004 04:09:30

Organization :

Category : Other Technician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therpists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter : Patti Hoffman **Date & Time:** 09/24/2004 04:09:28

Organization : American HomePatient

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached for Sections 302 and 305.

Issues 10-19

SECTION 302

Please see attachment.

CMS-1429-P-3832-Attach-1.doc

CMS-1429-P-3832-Attach-1.doc

FILE CODE CMS-1429-P
COMMENTS FROM AMERICAN HOMEPATIENT, INC.

On August 5, 2004, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule in the *Federal Register* entitled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005," **file code CMS-1429-P.** Two of the provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") which the proposed rule addresses are: 1) Section 302 – clinical conditions for payment of covered items of durable medical equipment, and 2) Section 305 – payment for covered outpatient drugs and biologicals.

American HomePatient, Inc. (OTC: AHOM), one of the nation's largest home health care providers, has chosen to provide comments to CMS on these two sections.

SECTION 302

I. Face-to-Face Examinations

CMS is proposing to require a face-to-face examination by a physician or practitioner ("physician") within 30 days of the physician ordering any item of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) – for both initial orders and renewal orders. *CMS has asked for specific comments about whether specific items of DMEPOS should be exempt from the face-to-face examination requirement.*

American HomePatient believes that some items should be exempt from this face-to-face requirement and has summarized below the background for the DMEPOS items that currently require a face-to-face examination and the rationale for the current requirement. Consistent with the existing rationale, American HomePatient believes that, at most, only items that currently require a DMERC CMN and/or are Respiratory Assist Devices should be subject to the face-to-face examination requirement.

Background

There are currently three items of DMEPOS that require a face-to-face examination or some other documented method of evaluation of the patient for the initial order. These are:

1. Oxygen and oxygen equipment,
2. Parenteral nutrition, and
3. Enteral nutrition.

For oxygen patients, the 30-day proposal for the initial certification does not create any new burden since it would be consistent with the current local medical review policy

("LMRP") requiring this. A recertification is required at one year after the initial certification. Because the current LMRP requires the patient to be seen by the physician within 90 days prior to recertification, the proposed rule would add a new burden by reducing the 90-day period to 30 days.

For parenteral nutrition patients, the ordering physician is currently expected to see the patient within 30 days prior to the initial certification or required recertification (but not revised certifications). The medical necessity of continued parenteral nutrition must be recertified six months after the initial claim. If the physician does not see the patient within this timeframe, the physician must document the reason the patient was not seen and describe the alternative monitoring methods that were used to evaluate the patient's parenteral nutrition needs. Instead of personally seeing and evaluating a parenteral nutrition patient, a physician may rely on evaluations conducted by others, such as a nursing home, home care nurse or dietitian.

For enteral nutrition patients, The ordering physician is expected to see the patient within 30 days prior to the initial certification. The current LMRP permits a physician who does not see the patient within this timeframe to document the reason the patient was not seen and describe other monitoring methods that were used to evaluate the patient's enteral nutrition needs. Enteral nutrition does not have a recertification requirement; however, new initial certifications or revised certifications are required when there are changes in nutrients, methods of administration and routes of administration.

Comment

We believe that a face-to-face evaluation within 30 days of every order and every renewal order for DMEPOS is an unreasonable and unworkable expectation that could have severe and costly unintended consequences, not the least of which is the possibility of restricted access for beneficiaries to much-needed health care leading to an increase in costly hospitalizations and emergency care.

For example, patients currently do not need to have a face-to-face examination by a physician in order to get the surgical dressings they require. Evaluations for these items may be conducted by other professionals, including a nursing home or home care nurse. The Medicare rule requires a new order from the physician if a new dressing is added or if the quantity of an existing dressing to be used is increased. In addition, a new order is required at least every three months for each dressing being used even if the quantity used has remained the same or decreased. Requiring a face-to-face examination with a physician each time there is a change in dressing or every three months would be problematic for both the physician and the patient.

There are currently13 items that require a DMERC certificate of medical necessity ("CMN"). Three of these items – oxygen, parenteral and enteral nutrition – are discussed above. Four of the remaining 10 items require a written order prior to delivery ("WOPD"). These four items are: power-operated vehicles, seat lift mechanisms, group

3 pressure reducing support surfaces, and transcutaneous electrical nerve stimulators. (If a CMN contains all the required elements as a written order, the CMN can be used as a WOPD.) The remaining six items requiring a CMN for payment are: hospital beds, manual wheelchairs, lymphedema pumps, osteogenesis stimulators, and external infusion pumps.

We believe that the face-to-face requirement should be limited, at most, to those items that currently require a DMERC CMN and/or Respiratory Assist Devices. As discussed above, three items that require a CMN already have a face-to-face requirement, although in two of these cases it is not necessarily a physician face-to-face examination. From an historical perspective, CMS has required a CMN for these 13 items for very specific reasons. First, CMS believed that these items require more direct involvement from the physician in the prescribing of these items as well as the provision of more specific medical necessity information. Secondly, some if not all of these items have been items for which there was a history of some abuse. Requiring a face-to-face examination with respect to these items addresses the first concern by insuring more direct involvement and also helps to eliminate possible over-utilization issues.

Consistent with CMS's past approach, we believe that the face-to-face examination requirement should be broadened in many instances to include not only the treating physician but also other qualified professionals as well, such as nurses, dietitians and physical therapists. The involvement of other professionals addresses CMS's concerns without requiring physician supervision in cases where it is medically unnecessary.

II. Appropriate Verification Process

The proposed rule would require that an order for DMEPOS be dated and signed within 30 days after the face-to-face examination by the physician or practitioner and include verification of the examination. *CMS has solicited comments on the appropriate verification process.*

Comment

In connection with our recommendation that only those items currently requiring a DMERC CMN and/or Respiratory Assist Devices have the face-to-face requirement, American HomePatient recommends that the DMERC CMN continue to be used by Medicare for verification. CMNs can be revised as needed to address the face-to-face requirement.

CMS should be aware, however, that our experience indicates that many physicians are routinely slow in completing paperwork, including CMNs. Many physicians have told us that they only process paperwork one day per month or "X" number of hours per month. If the amount of paperwork exceeds the amount the physician can process in the given time, they simply leave it until the following month. The supplier does not have the

positional power to make the physician comply with the documentation requirements imposed by this proposed rule, yet would be the party damaged by the physician's failure to comply.

In developing the Final Rule, should CMS go beyond the 13 items currently requiring CMNs and/or Respiratory Assist Devices, CMS should issue instructions to physicians to note the date of the face-to-face examination on the physician's order.

III. Additional Instructions

In the proposed rule, CMS has asked for comments on whether it should issue policy or "permit contractor discretion."

Comment

Normally, the DMERCs are given the task of issuing a policy. HHS/CMS then revises the Program Integrity Manual via a Program Transmittal, and the DMERCs will then revise their LMRPs to reflect the change. We believe this is a process that works well for suppliers and does not need to be changed.

Having CMS issue guidance can promote uniformity among DMERC regions and simplify the burdens of complying with Medicare rules for national suppliers such as American HomePatient.

SECTION 305

I. Additional Services

In the proposed rule, *CMS specifically requests "data and information on the additional services" provided by pharmacies to Medicare beneficiaries using inhalation drugs.*

CMS states that comments should include information related to:

1. The extent to which inhalation drugs can be furnished without these additional services, and
2. The extent to which such services are covered under Medicare.

American HomePatient has provided this requested information below.

Additional Services Provided by Pharmacies

In addition to the cost of purchasing inhalation drugs, there are many services provided by pharmacies to ensure the proper dispensing of inhalation drugs to Medicare beneficiaries. These services include, but are not limited to, the following:

- Licensed pharmacists and pharmacy technicians, licensed respiratory therapists, customer service representatives, and other specially-trained employees to:
    - Train beneficiaries and caregivers on proper use of drugs with nebulizer for optimum therapeutic benefit
    - Establish/revise a plan of care and care coordination
    - Provide in-home visits
    - Provide 24-hours/7-days a week on-call personnel
    - Contact physicians and beneficiaries as required to ensure safe, accurate and timely dispensing and delivery of inhalation drugs
    - Obtain documentation required for dispensing and billing
    - Compound and dispense drugs
    - Provide follow-up contact with beneficiaries, including compliance monitoring and refill calls
- Expense of complying with Medicare documentation requirements
- Pharmacy licenses
- Activities related to accreditation
- Billing and collections personnel and activities, including co-pay billing, posting cash, data entry, etc.
- Purchasing and inventory control personnel and activities, including storage
- Operations overhead, including rent, utilities and telecommunications
- Shipping personnel and costs to package and ship inhalation drugs to beneficiaries at home
- Supervisory personnel
- Insurance
- Bad debt expense
- Sales personnel and activities
- Administrative overhead
- Depreciation and interest
- Taxes

Comment Regarding the Extent to Which Inhalation Drugs Can Be Furnished Without Additional Services

The 2004 dispensing fee of $5.00 per month per prescription, if left unchanged in 2005 when reimbursement for inhalation drugs drops to the average sales price plus six percent ("ASP+6%"), will be wholly inadequate to cover the costs associated with the additional services needed to provide the drugs to Medicare beneficiaries. As a result, we believe many beneficiaries will be faced with an access problem because few suppliers, if any,

will be able to afford to provide these drugs at what will amount to a substantial financial loss.

Comment Regarding the Extent to Which Such Services Are Covered Under Medicare

Until January 1, 2005, the reimbursement rate for inhalation drugs is based on a percentage of the average wholesale price ("AWP"). This reimbursement rate, which was reduced in 2004 by 15% to 80% of AWP from the 2003 rate of 95% of AWP, allows suppliers to offset some of the costs associated with providing the additional services outline above.

Except for the current, small fee for dispensing the drug, none of the services listed above are covered by Medicare.

II. Dispensing Fee

CMS has requested comments on the appropriate dispensing fee to help offset the reduction in drug reimbursement from the 2004 level of 80% of AWP to ASP+6% in 2005 "that would assure beneficiary access to inhalation medications provided by nebulizers."

Comment

In determining a dispensing fee, CMS has requested that persons providing comments give consideration to five proposed changes/clarifications for pharmacies outlined in the NPRM. American HomePatient comments on three of those as follows:

90-Day Supply of Refills. Allowing a 90-day supply of refills versus the current 30-day supply will provide for a modest savings in variable transactional costs related to dispensing, billing and shipping. It will not reduce fixed costs related to the transactions and will have minimal, if any, impact on the costs of patient care (e.g., education, initial intake, and therapy compliance monitoring).

Relaxation of Supplier Contact with Patient Prior to Refills. Allowing suppliers to contact patients with enough time to allow for ground shipment of drugs versus overnight delivery would reduce shipping costs slightly. **Note that greater savings would be seen with elimination of the proof of delivery requirement.**

Proposed Change in Assignment of Benefits (AOB) Requirements. Eliminating the requirement for suppliers to have a signed AOB form from a beneficiary in order for Medicare to make payment will not result in any significant savings for our pharmacy operations, since the AOB is just one of many required Medicare forms signed during the initial set-up of the patient.

In an effort to comment on the amount of an appropriate dispensing fee, we reviewed the CBO scoring for inhalation drugs in 2005 in the MMA. The scoring appears to suggest a savings of approximately 17.7% from the 2003 reimbursement levels of 95% of AWP. This is comparable to the savings achieved by the 2001 San Antonio competitive bidding demonstration which resulted in a reimbursement rate of 66% to 72% AWP, or four to five times the ASP.

It is difficult to set one dispensing fee and remain budget-neutral to the MMA due to the following:

- The final ASP for the first quarter of 2005 has not yet been established for each inhalation drug
- Cost of drugs are dependent on volume and source (direct vs. wholesale)
- There are geographical differences in labor costs for pharmacy services listed above
- Suppliers' costs vary – both large and small (in 2003, American HomePatient's actual direct and indirect costs before overhead, capital cost, taxes and profits were $76.90 to provide an average 120 doses of albuterol per month at 2.5 mg/dose; in 2004, our costs are projected to be $76.20)

In light of the budget neutral requirements of the MMA, for a 17.7% reduction in reimbursement from the 2003 levels, we believe that a dispensing fee should range between $0.85 per dose (2.5 mg) for albuterol to $0.97 per dose for a blended mix of other inhalation drugs, including ipratropium bromide *(refer to table below)*.

Monthly Shipments
Inhalation Medication
(average 120 doses per month)

Albuterol

	2003 95% AWP	2004 80% AWP	2005 ASP+6% current	2005 ASP+6% (with adj. dispensing fee)	
Reimbursement	141.00	117.00	18.44	18.44	
Dispensing Fee	5.00	5.00	5.00	101.72	(equates to $.85 per dose)
Total	146.00	122.00	23.44	120.16	(17.7% reduction from 2003 level)

Blended Mix

	2003 95% AWP	2004 80% AWP	2005 ASP+6% current	2005 ASP+6% (with adj. dispensing fee)	
Reimbursement	194.18	163.06	46.73	46.73	
Dispensing Fee	5.00	5.00	5.00	117.19	(equates to $.97 per dose)
Total	199.18	168.06	51.73	163.92	(17.7% reduction from 2003 levels)

(Note: ASP+6% based on American HomePatient's current cost for medications)

III. Higher Dispensing Fee for 2005

CMS has requested comments on whether the dispensing fee should be somewhat higher in 2005 until metered dose inhalers ("MDIs") are covered by Medicare in 2006 as a Part D benefit.

Comment

CMS's request implies two things:

1. CMS plans to reduce the 2005 dispensing fee beginning in 2006, and
2. CMS believes Medicare beneficiaries will choose MDIs over nebulizer drugs once MDIs are covered under Part D in 2006.

We disagree with the second premise based on the severity of the illnesses of the Medicare population we serve who require nebulizer drugs in order to obtain maximum therapeutic benefit.

It should be noted that the 2006 nebulizer co-pay for beneficiaries will decrease due to the decrease in reimbursement for the drugs, so that the nebulizer costs illustrated in the chart below for 2004 will be *reduced* for beneficiaries in 2006. In contrast, the cost of MDIs is projected to *increase* beginning in 2006 when the ban on the propellant chlorofluorocarbon (CFC) will become effective. Approximately 90% of the MDIs on the market that currently use CFC are generic. The new propellant is called hydrofluoroalkane (HFA) and the drug manufacturers have patents on HFA until 2010. When HFA replaces CFC in 2006, it is predicted that the price of MDIs will double.

We also believe that shifting patients to MDIs would increase patient out-of-pocket costs, despite CMS's contention that MDIs are "less expensive" than nebulizer drugs. The chart below compares the 2004 yearly nebulizer co-pay and deductible for the average Medicare beneficiary using a nebulizer with out-of-pocket costs for Medicare beneficiaries using MDIs.

Drug	2004 annual nebulizer co-pay and deductible	2004/2005 MDI annual cost	2006 MDI annual Part D premiums, co-pay and deductible
Albuterol	**$380.80** (0.083%, 3 ml unit dose 4 times a day)	**$800.00** (2 puffs 4 times a day-Proventil)	**$807.50** (2 puffs 4 times a day-Proventil)
Ipratropium	**$506.08** (0.2%, 2.5 ml unit dose 4 times a day)	**$1,417.92** (2 puffs 4 times a day-Atrovent)	**$1,129.48** (2 puffs 4 times a day-Atrovent)
Albuterol and Ipratropium taken separately	**$786.88** (same strength/ dose as above)	**$2,174.40** (same dose as above)	**$1,151.10** (Proventil and Atrovent inhalers, 2 puffs 4 times a day, 2 inhalers each per month using 90-day mail order)
Combined formula of albuterol/ipratropium	**$592.48** (albuterol 2.5 mg/ipratropium 0.5-3 ml ,4 times a day)	**$1,348.84** (same dose as above)	**$944.71** (Combivent inhaler, 2 puffs 4 times a day, 2 inhalers per month, using 90-day mail order)

ADDITIONAL COMMENTS ON SECTION 305

I. Ability to Purchase Drugs at Less Than ASP

Comment

With regard to albuterol and ipratropium bromide, CMS stated that, since these two drugs are generics with multiple manufacturers, "a pharmacy might be able to obtain [them] at a price below the average." This is highly speculative, since CMS has not yet received the information from manufacturers necessary to set the average sales price for the first quarter of 2005 and suppliers are unaware of the figure CMS will use as ASP for these two drugs. Therefore, it is impossible to determine the reductions, if any, below average a supplier might be able to obtain from manufacturers.

In the proposed rule, CMS states that "for the first quarter of 2005, the Medicare payment at ASP plus 6 percent is estimated to be $0.04 per milligram for albuterol sulfate…." This amount is 31% less than what American HomePatient pays to purchase the drug at a cost of $.058 per milligram of albuterol sulfate.

II. MDIs v. Nebulizers

Comment from the Perspective of Pulmonologists

In a review of the studies conducted on the therapeutic efficacy of MDIs versus that of nebulizers, pulmonologists we spoke with – including many of the 11,987 physicians who wrote letters directly to their U.S. Senators and Representatives about the MMA reimbursement reductions – believe that the majority of the studies were conducted in the patient population generally known not to require the delivery of inhalation drugs via nebulizer. Pulmonologists believe there is a niche of patients that needs to be treated as exceptions for whom MDIs are not as effective. These patients are the very young, the very old and the very sick.

In addition, the studies have been conducted using equal dosing. This means that a patient usually requires four puffs on an MDI to get a dose equal to that delivered via nebulizer. At this rate, the MDI (containing 200 puffs per inhaler) would last the patient only 12-1/2 days, requiring more than two inhalers each month.

Another factor to consider when comparing MDIs to nebulizer treatments is that MDI treatments do not last as long as nebulizer treatments, requiring more frequent re-dosing and leading to the possible abuse of the MDI medication.

As it relates to a physician's prescribing practice, Dr. George G. Burton, American HomePatient's Medical Director who is a nationally-renowned leader in pulmonary

medicine, stated that physicians determine whether to prescribe an MDI or nebulizer by the severity of the patient's chronic obstructive pulmonary disease ("COPD"), the age and physical limitations of the patient and the patient's lack of compliance or therapeutic success with other methods of delivery of inhalation drug. Further, physicians consider whether the "blast" or spray from the MDI causes the patient to cough – thus inhibiting the patient's ability to inhale the drugs (a "cold freon effect" that the patient feels when the drug is delivered may cause bronchospasms in some patients). Physicians also consider the severity of the patient's blood gas abnormality, as well as whether the patient has obstructions of the airways with secretions that do not respond to an MDI.

Generally, the family physician or internist will initially treat a patient with asthma or mild COPD by prescribing treatment via an MDI. However, by the time a patient is referred to a pulmonologist, it has usually been determined that the treatments that the patient received were *not successful,* and most often the prior, unsuccessful treatment included an MDI. The pulmonologist then prescribes inhalation drugs via nebulizer.

Contributing to the physician's prescribing practice is the patient's exposure to treatment via a nebulizer. This exposure often occurs after the patient is admitted to the ER in distress and receives a rescue treatment via nebulizer. Almost every hospital ER physician will give the patient a rescue dose via nebulizer rather than an MDI, with a "rescue dose" involving three consecutive treatments. If this rescue treatment in the ER is not successful, the patient is then admitted.

Following rescue treatments, patients often determine they have greater success using the nebulizer compared with their previous use of the MDI. As a result, the treating physician will develop an action plan for prevention and control that includes the delivery of the inhalation drugs via the nebulizer.

Further, with respect to physicians' prescribing practices, Dr. Burton stated that doctors and patients have the same goal – effective treatment. If the MDI is effective, then the MDI is the treatment modality that is prescribed. MDIs are often requested by the patient because of their convenience. The MDI is small enough to be carried in a purse or briefcase and treatments of a few puffs can be easily taken anywhere. Conversely, since the standard nebulizer is not portable, the patient usually uses the machine at home because the device requires preparation of the machine, 10 to 20 minutes of treatment time and cleaning of the machine after the treatment.

Pulmonologists have experienced that patients are more likely to request inhalation drugs via an MDI because of the portability and convenience of the device even when nebulized treatment is indicated. Pulmonologists state that patients do not request inhalation drugs via nebulizer because Medicare covers the drugs. Further, doctors are required to prescribe medication based on its effectiveness and not on its cost.

As it relates to a patient's physical limitations, although some dexterity is required to use the nebulizer, the device is less time sensitive than the MDI. The patient can spread out

the use of the nebulizer over a period of time – "use" includes filling the machine, taking the treatment and cleaning the machine. A patient with a physical limitation who is using an MDI does not have the luxury of spreading out the use over a period of time.

With respect to CMS's suggestion that increased education and retraining may be necessary to improve results with MDIs, American HomePatient acknowledges that some patients can improve effectiveness with such education. However, there remains a significant portion of patient population – somewhere between 47% and 89%* – who will not be able to use the MDI successfully due to unacceptable inhaler technique (*source: ICSI *Health Care Guideline: Chronic Obstructive Pulmonary Disease,* Third Edition, December 2003). Even with increased compliance on the use of the MDI after training, the compliance rate for the nebulizer will tend to be much higher since the patient only needs to be able to turn on the machine and breathe in the medication.

With respect to CMS's suggestion that the physician or physician's staff train the patient on the use of the nebulizer to eliminate the costs associated with supplier education and training, physicians we spoke with stated that (a) many physicians do not have a nebulizer on which to train the patient and, (b) it would take their staff about 45 minutes to train the patient at a cost that exceeds the proposed Medicare payment of $13.44. Merely shifting this training from one party to another party will not eliminate the time and cost involved in training.

Another factor to consider when comparing nebulizers with MDIs is that there is no reliable method for testing whether an MDI has emptied itself of its therapeutic ingredients and contains only the propellant – this, according to information presented at the 2003 annual meeting of the American College of Allergy, Asthma, and Immunology. Inhaler package inserts typically contain a warning to discard the inhaler upon using the labeled number of doses, even though contents apparently remain in the canister. Therefore, patient training by physicians and pharmacists includes how to accurately track inhaler doses by recording each time the inhaler is used.

Investigators at the annual meeting provided results of a survey of 500 families using MDIs. Among all the respondents, 25% said they had ever found their inhaler empty when it was needed for rescue, and 8% had to call 911 in those cases. Among those who have ever needed a rescue inhaler and found it empty, 82% of respondents who were asked answered, incorrectly, that they believe the inhaler is empty "when nothing more comes out." In addition, nearly one-fourth of all patients using an inhaler with a dose counter could not tell how many doses were left.

If nebulized drugs become unavailable due to the low reimbursement rates that do not cover the costs to provide the drugs, pulmonologists have told us they will prescribe MDIs for their patients. However, they believe patients will become sicker because of their inability to obtain the maximum therapeutic benefit from the drugs. In addition, because of the cost, Medicare patients may choose to reduce their use of MDIs, thus reducing compliance and compromising their health.

Comment Related to Available Research

Our research of the clinical studies involving MDIs and nebulizers shows the following:

- The majority of the studies are for the patient population with asthma (mostly youth) and not the sickest of the sick or elderly COPD patients.
- Most studies acknowledge that there is conflicting evidence about whether there is an advantage in delivering the same doses of drugs via an MDI or nebulizer.
- Most studies admit that the efficacy of the MDI is technique dependent – depending on coordination, breathing pattern, and the level of inspiratory hold.
- **Most studies footnote that there are indications for nebulized therapy, including persistent symptoms despite adequate bronchodilator therapy from MDIs, the patient's inability to use an MDI, and exacerbations.**
- In a letter to the editor of *Chest* (Vol. 103, February 1993, Page 655), Warren C. Miller, M.D., F.C.C.P., and John W. Mason, R.R.T., of the Humana Pulmonary Center in Webster, TX, state that, when viewed critically, studies do not support the conclusion that "economy and quality assurance demand switching from small-volume nebulizers to metered-dose inhalers."

Submitter : Ms. Virginia Gentile **Date & Time:** 09/24/2004 04:09:34

Organization : Massage Therapy

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

It is everyone's right to practice their therapy especially when we have the training and the education to help clients at a cheaper cost and shorter term care providing less cost to the insurance companies and to the client. It is unconstitutional to prevent massage therapists from receiving referrals from DR's and Chiropractors

CMS-1429-P-3834

Submitter : Ms. Kathy Roberts **Date & Time:** 09/24/2004 04:09:35

Organization : NVCC

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

I am writing to support CMS's proposal (42 CFS 484.4 with the exception of licensure in the rule that establishes these standards for personnel providing physical therapy services in physicians' offices.

CMS-1429-P-3834-Attach-1.doc

September 24, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: DMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Subject: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Dear Doctor:

I am a first year student physical therapist assistant attending Northern Virginia Community College.

I wish to comment on the August 5 proposed rule on the above mentioned subject.

I strongly support your position that qualifications of individuals providing physical therapy services "incident to" a physician should meet personnel qualifications for physical therapy in 42 CFR §484.4, with the exception of licensure. I concur that individuals providing physical therapy must be graduates of an accredited professional physical therapist program or must meet certain grandfathering clauses or educational requirements for foreign trained physical therapists.

The value of licensure ensures consistent and reliable treatment delivery to the patient which is who we need to keep in mind is at stake here.

Physical therapists and physical therapist assistants under the supervision of physical therapists are the only practitioners who have the education and training to furnish physical therapy services. Unqualified personnel should NOT be providing physical therapy services.

We receive significant training in anatomy and physiology, have a broad understanding of the body and its functions, and have completed comprehensive patient care experience. This background and training enables physical therapists to obtain positive outcomes for individuals with disabilities and other conditions needing rehabilitations. This education and training is particularly important when treating Medicare beneficiaries.

The delivery of so-called "physical therapy services" by unqualified personnel is harmful to the patient. There is a difference between being educated and trained.

A financial limitation on the provision of therapy services (referred to as the therapy cap) is scheduled to become effective Janaury 1, 2006. Under the current Medicare policy, a

patient could exceed his/her cap on therapy without ever receiving services from a physical therapist. This will negatively impact patient's outcomes.
Section 1862(a)(20) of the Social Security Act clearly requires that in order for a physician bill "incident to" for physical therapy services, those services must meet the same requirements for outpatient therapy services in all settings. Thus, the services must be performed by individuals, who are graduates of accredited professional physical therapist education programs.

Thank you for your consideration of these comments.

Sincerely,

Kathy Roberts
SPTA
703-327-3463
43026 Golf View Drive
South Riding, VA 20152

CMS-1429-P-3835

Submitter : Mr. Wilson Chu **Date & Time:** 09/24/2004 04:09:53

Organization : Quintiles, Inc.

Category : Other

Issue Areas/Comments

Issues 1-9

SECTION 303

VIA DHL AND ELECTRONIC SUBMISSION

Thank you for the opportunity to submit comments on proposed rule CMS-1429-P. Quintiles is a health care consulting firm providing reimbursement strategy and support services for a number of pharmaceutical manufacturers. On behalf of our clients, we are asking for clarification in the ASP reporting requirements and would like to share our concerns on the effect of the implementation of the ASP methodology on physician offices.

Calculation of ASP

With the increasing number of different transaction fees among manufacturers, physicians, and wholesalers, manufacturers have expressed their confusion over what specific elements are included in the ASP calculation. For example, manufacturers are questioning whether any specialty distributor fees or other administrative fees should be included in the calculation. As a result, we are requesting a comprehensive and precise list of all components (fees, discounts, rebates, etc.) included in the calculation of ASP.

Computation of rebates and discounts in the ASP calculation

The Medicare Modernization Act requires that in calculating the ASP, manufacturers are required to include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program).

Neither the April 6th interim final rule on ASP submission nor proposed rule CMS-1429-P detail how manufacturers should calculate discounts (volume, prompt pay, cash). Therefore, we are asking for CMS? guidance to determine how a manufacturer should calculate discounts in the ASP calculation.

In addition, we are asking CMS whether a manufacturer must include rebates to a wholesaler in the ASP calculation. To illustrate this scenario, a manufacturer sells a drug for $10 to a wholesaler, who in turns sells the product for $8 to the physician. The manufacturer provides a $2 rebate to the wholesaler for the product. We are asking whether manufacturers must report this $2 rebate in their calculation.

Providers who are reluctant to join large purchasing groups will be forced to stop providing physician-administered drugs in-office

During the April 20th Special Open Door Forum on ASP submission, a number of physician practices expressed concern about their ability to purchase drugs at 106% of ASP because they are low volume purchasers and do not qualify for discounts enjoyed by large purchasing groups. In the proposed rule, CMS encourages physicians to participate in these large purchasing groups to take advantage of discounted rates. However, physicians may be reluctant to join such groups due to a number of issues, including geography and feasibility. Additionally, some physicians were just made aware of the drug payment changes and may not have sufficient time to enter into a contract with a large purchasing group.

If these physicians purchase drugs at rates higher than the anticipated Medicare allowables, they may no longer be able to provide drugs in their offices and forced to send their patients to hospital outpatient facilities for drug administration. We are asking CMS to consider ways to address this likely scenario.

Thank you for your consideration of our comments. We look forward to your response.

Sincerely,

Wilson Chu

Submitter : Mrs. Amy Jo Larry **Date & Time:** 09/24/2004 04:09:03

Organization : Decatur Memorial Hospital

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

9/25/04

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy ? Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of ?incident to? services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

As a healthcare professional with an athletic training certification and physical therapy license, I have seen first hand the similarities in education. I feel that athletic trainers are qualified to treat orthopeadic patients of all ages. I have also work with several highly skilled athletic trainers in the clinic and feel that their contributions to our staff are invaluable.

Sincerely,
Amy Jo Larry, PT, ATC
1613 Burning Tree Drive
Decatur, IL 62521

Submitter : Mr. Jeffrey Moore **Date & Time:** 09/24/2004 04:09:00

Organization : University of Mississippi

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

This will patient access to qualified healthcare providers.

Submitter : Mrs. Beth Peel **Date & Time:** 09/24/2004 04:09:19

Organization : Mrs. Beth Peel

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer
"incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Why is medicare determining what is best for it's patients???? Let the patient and provider (Doctor) decide.

CMS-1429-P-3839

Submitter : Mrs. Natalie Turney **Date & Time:** 09/24/2004 04:09:36

Organization : Robinson's Chiropractic and Massage

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am requesting the right to treat Medicare patients with massage therapy/ bodywork. As a LICENSED PROFESSIONAL, trained to treat soft tissue, I am offended at the suggestion that physical therapists would suffice in tending to your patients who have a need for massage therapy. Massage therapists are dedicated to providing skilled TOUCH to their clients whereas physical therapists are more familiar with using devices to assist in their treatments with patients. This key difference in technique should not be minimized. Please allow licensed massage therapists the opportunity to do the work we are trained to do... Thank you for your time

Submitter : Ms. Aulesha Harris **Date & Time:** 09/24/2004 04:09:11

Organization : Ms. Aulesha Harris

Category : Other Technician

Issue Areas/Comments

Issues 20-29

DIAGNOSTIC PSYCHOLOGICAL TESTS

This comment is in support of the proposal brought forth by CMS to allow psychologists to supervise diagnostic testing. I feel that the proposed change would allow psychologist's the opportunity to spend more time working with their patients and also give students and/or technicians the opportunity to work with patients as well. Further, according to Sloop & Quarrick, 1974, technicians performance in testing and assessment was highly correlated with psychology doctoral students with regard to reliability and vallidity with regard to test administration. Therefore, technicians have proven to be just as affective in test administration. In addition, Musante, 1974 found that psychology faculty and staff highly rated the performance of technicians. The study indicated that the faculty and staff used the behavioral observations of the technicians extensively to understand patient pathology abd toi write their reports, and that the availability of technicians enabled them to spend more time interviewing each patient. They concluded that the faculty and staff were quite pleased to have psychological technicians added to their work settings. I firmly believe that with the proper educational and field training, it is possible for technicians to complete reliable psychological testing. Technicians can also provide additional information to psychologists in order to provide a more reliable diagnosis and provide additional insight for treatment recommendations.

Musante, G. J., (1974). Staff evaluations of the technician role. Professional Psychology: Research & Practice, 5(2), 214-216.

Sloop, E. W., & Quarrick, E. (1974). Technician Performance: Reliability and validity. Professional Psychology: Research & Practice, 5(2), 216-218.

Submitter : Mrs. Jennifer Close **Date & Time:** 09/24/2004 04:09:25

Organization : Mrs. Jennifer Close

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please See Attached File.

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : Ms. Debra Morris **Date & Time:** 09/24/2004 04:09:14

Organization : Ms. Debra Morris

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached letter.

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

CMS-1429-P-3843

Submitter : Miss. Lisa Feldermann **Date & Time:** 09/24/2004 04:09:49

Organization : NATA

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

see attached letter

CMS-1429-P-3843-Attach-1.doc

My name is Lisa. I am an athletic training student at an accredited university. In the spring of last year I had to observe at a physical therapy clinic as part of the requirements for my Therapeutic Exercise class. After only six hours of being in the clinic they offered me a job. The physical therapist the owned the clinic was interested in having me work in his facility because of all the knowledge that I have about how to rehabilitate athletic related injuries.

Another example of why athletic trainers should be allowed to treat all athletic type injuries in many different settings occurred two years ago. I fell on a sidewalk and broke my leg and suffered a 2 + degree ankle sprain. After my operation, which was preformed by a highly regarded foot and ankle surgeon, he told me to do my own rehabilitation. When I went back to his office two weeks later. I had full strength and full range of motion. The doctor said, “did you go to physical therapy”. I told him that I did all of the rehabilitation myself and he said, “good because they probably would have messed you up”

Based on our studies and clinical work athletic trainers are highly qualified to evaluate and treat athletic injuries. The government should not be able to control where injured people can receive proper rehabilitation. This decision should be made by the physician and his or her patient.

CMS-1429-P-3844

Submitter : **Date & Time:** 09/24/2004 04:09:47

Organization :

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dear Mark B. McClellan, MD, PhD:

I am writing in order to comment on the August 5, 2004 proposed rule on ?Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.? I am currently a physical therapy student working on my entry level Doctor of Physical Therapy degree. I have only one more year of post-baccalaureate work before I graduate.

I strongly support CMS?s proposed requirement regarding physical therapists who work in a physician?s office. As a soon to be new graduate, I believe that anyone who is performing physical therapy services should be a graduate of an accredited professional physical therapy programs. I also believe in the licensure of physical therapists. After graduation I must pass the National Physical Therapy Exam in order to receive my license to practice as a physical therapist. Licensure ensures that I am fully qualified and that I have the knowledge to practice as a physical therapist. Without licensure, there is no way to regulate those providing physical therapy services to ensure that the correct care is being provided.

I am just beginning my third year of graduate school and once I am graduated I will be fully educated to practice as a physical therapist. My education has given me a deep understanding of the human body in regards to the musculoskeletal system and physiology. I have also learned how to properly use modalities to aid in treatment and I understand the science behind how the modalities assist in rehabilitation. I know how to provide the correct rehabilitation for a variety of diagnoses. I do not believe that someone without the same education I have received can competently provide treatment for a patient. It is my education that will allow me to provide patients with the best possible care and subsequently the best outcomes.

Thank you for consideration.

CMS-1429-P-3845

Submitter : Mrs. Diane Ignash **Date & Time:** 09/24/2004 04:09:24

Organization : Mrs. Diane Ignash

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am opposed to the proposed changes to "Incident to" billing regulations which will affect Certified Athletic Trainers. I feel the trainers provide an excellent service to high school athletes.
Having had three sons in high school sports and experienced various injuries, our trainers have provided excellent care at the time of injury as well as any rehab they might require. Do NOT eliminate this very valuable resource to injured students.

Submitter : Mr. Rob Reps **Date & Time:** 09/24/2004 04:09:19

Organization : Hinnant Prosthetics

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Amputees need medical care at the same level as all other Medicare patients. Amputees having problems with their residual limbs, fit, function, suspension, etc. should be able to see their physician with regard to their medical condition even if it involves a prescription for a new prosthesis. The physician should be reimbursed for his services, as he has always been the ?Gatekeeper? with regard to prosthetic services delivered by any prosthetist.

It is difficult to deliver a prosthesis within 30 days especially with an above knee amputee. It takes approximately 5 visits to deliver an above knee prosthesis.

Will physicians be reimbursed for prescriptions for routine supplies such as socks, sheaths, suspension sleeves, suspension belts, silicone liners and other routine maintenance repairs and or replacements? Will a face-to-face visit with the physician be required to obtain such items? Routine maintenance is a large part of any Prosthetic and Orthotic practice. In may cases emergency repairs are needed just to keep patients going until a prescription can be obtained.

What do you hope to accomplish with these new proposed guidelines? Prosthetic and orthotic services are such a small part of the entire Medicare expenditure. Do not be penny wise and pound-foolish. Pay the physician for the new prescription because if you do not? then you will have to pay for the patient to be on disability or to receive care in a patient care facility. This cost far exceeds the price of a new artificial limb.

Rob Reps, CPO
M.Kale Hinnant, PYUAmputees need medical care at the same level as all other Medicare patients. Amputees having problems with their residual limbs, fit, function, suspension, etc. should be able to see their physician with regard to their medical condition even if it involves a prescription for a new prosthesis. The physician should be reimbursed for his services, as he has always been the ?Gatekeeper? with regard to prosthetic services delivered by any prosthetist.

It is difficult to deliver a prosthesis within 30 days especially with an above knee amputee. It takes approximately 5 visits to deliver an above knee prosthesis.

Will physicians be reimbursed for prescriptions for routine supplies such as socks, sheaths, suspension sleeves, suspension belts, silicone liners and other routine maintenance repairs and or replacements? Will a face-to-face visit with the physician be required to obtain such items? Routine maintenance is a large part of any Prosthetic and Orthotic practice. In may cases emergency repairs are needed just to keep patients going until a prescription can be obtained.

What do you hope to accomplish with these new proposed guidelines? Prosthetic and orthotic services are such a small part of the entire Medicare expenditure. Do not be penny wise and pound-foolish. Pay the physician for the new prescription because if you do not? then you will have to pay for the patient to be on disability or to receive care in a patient care facility. This cost far exceeds the price of a new artificial limb.

Rob Reps, CPO
M. Kale Hinnant, CP, FAAOP
Bill Alford, CP

Submitter : Miss. Stefani Voudrie **Date & Time:** 09/24/2004 04:09:18

Organization : Eastern Illinois University

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

9/24/2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012
Re: Therapy ? Incident To
Dear Sir/Madam:
I am writing to express my concern over the recent proposal that would limit providers of ?incident to? services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.
During the decision-making process, please consider the following:
? Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician?s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician?s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
? To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide ?incident to? services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide ?incident to? care in physicians? offices would improperly remove the states? right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
? CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
? CMS does not have the statutory authority to restrict who can and cannot provide services ?incident to? a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
? Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers accompanied the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.
In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.
I do not think that the CMS should be able to pass this statue because it will not only hurt the Athletic Training profession, but also hinder the patient and doctors. The patient will not get the adequate treatment that they deserve and could face many delays that will cost them valuable rehabilitation time and possible require the need of more surgeries to correct the problems that formed because of this. This will ulitimately cost everyone involved much more money in the long run.
Sincerely,
Stefani Voudrie
501 S. Poplar
Pana, IL, 62557

Submitter : Mr. Philip Bonzo **Date & Time:** 09/24/2004 04:09:38

Organization : NovaCare Rehabilitation

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Philip Bonzo
343 Masonglen Ct.
Pataskala, OH 43062

9/24/04

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012
Re: Therapy ? Incident To
Dear Sir/Madam:
I am writing to express my concern over the recent proposal that would limit providers of ?incident to? services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.
During the decision-making process, please consider the following:
? Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician?s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician?s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
? There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.
? In many cases, the change to ?incident to? services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
? This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working ?incident to? the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.
? Patients who would now be referred outside of the physician?s office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient?s recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
? Curtailing to whom the physician can delegate ?incident to? procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician?s ability to provide the best possible patient care.
? To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide ?incident to? services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide ?incident to? care in physicians? offices would improperly remove the states? right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
? CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing.

Submitter : Ms. Debra Morris **Date & Time:** 09/24/2004 04:09:22

Organization : Ms. Debra Morris

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached letter.

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Offices of Strategic Operations and Regulatory Affairs

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter : **Date & Time:** 09/24/2004 04:09:05

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

September 21, 2004

Department of Kinesiology
Greensboro College
815 West Market St.
Greensboro, NC 27401

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy- Incident To

Dear Sir/ Madam:

As a future Certified Athletic Trainer (ATC) and possible future patient, I feel compelled to write this letter in opposition of proposal CMS-149-P. I am concerned that this proposal would limit patient access to qualified health care providers of ?incident to? services, such as ATCs, in physician offices and clinics; thereby, reducing the quality of health care for physically active patients. Furthermore, limiting access to qualified health care providers will cause delays in the delivery of health care, which in turn will increase health care costs and tax an already heavily burdened health care system.

Athletic training is the health care profession that specializes in the prevention, assessment, treatment and rehabilitation of injuries to athletes and others who are engaged in everyday physical activities. Athletic trainers are multi-skilled health care professionals who can, and are, making significant contributions to health care. Athletic trainers are highly educated and fully qualified health care providers, evident in their recognition by the American Medical Association as an allied health care profession. If this proposal would pass, it would threaten the employment of many athletic trainers who are employed as physician extenders in clinics and physician offices. Therefore this proposal threatens my future employment in those settings and the value of my degree in Athletic Training. With this type of limitation artificially placed on the provision of ?incident to? services by qualified (through accredited academic programs in athletic training, a national board examination, and state practice acts) health care providers the CMS will only add to the skyrocketing health care costs, put qualified people out of work, and reduce the overall quality of health care in the United States.

In conclusion, I believe that the CMS-1429-P proposal must be rejected in order to protect the right (the right to choose and the right for quality care) of our patients and my right as a future health care practitioner.

Sincerely,

Athletic Training Student at Greensboro College in Greensboro, North Carolina

CMS-1429-P-3851

Submitter : Ms. Laura Morton **Date & Time:** 09/24/2004 04:09:58

Organization : Ms. Laura Morton

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I would like to voice my strong support for the proposed requirement that physical therapy services offered in physician's offices by provided by graduates of accredited physical therapy programs.

I am a 'career change' physical therapy student in California. One reason I chose this field over other health-fitness related fields is because of the evidenced-based approach that has been increasinly emphasized over the past 10 years in physical therapy programs. This approach is an intregal part of our training, and is crucial to positive outcomes and cost effective Medicare expenditures.

I believe that physical therapy program graduates can best incorporate ongoing research and clinical skills to positively effect patients' ability to return to full function. Physical therapy programs currently require substantial post-baccalaureate education in basic sciences, rehab procedures, and how to access and evaluate relevant research. Physical therapy services should not be provided by unqualified practitioners. Requiring licensure would help ensure quality, but requiring graduation from accredited phyiscal therapy programs is a step in the right direction.

Thank you for the opportunity to comment.

Submitter : Mr. Daniel Lipka **Date & Time:** 09/24/2004 04:09:16

Organization : National registry of rehab Tech Supploers

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The National Registry of Rehabilitation Technology Suppliers (NRRTS) would like to offer the following comments on Section 320 regarding clinical provisions for coverage of DME.

NRRTS is a voluntary organization of almost 900 registered and certified rehabilitation technology suppliers (RTS). NRRTS was conceived and developed over 10 years ago as a grass roots effort by reputable DME and RTS?s within the industry. The primary mission of NRRTS is to establish professional qualifications, standard operating procedures and ethical practice requirements of it?s registrants in order to insure high quality service delivery of a variety of rehabilitation products and assistive technologies. These products usually include durable medical equipment (DME) of a highly complex and technologically advanced nature (power wheelchairs with advanced control features, custom seating systems, advanced ambulation equipment and other specialized technologies) that is individualized for people with catastrophic conditions.

General Comments

? NRRTS agrees with CMS that beneficiaries of DMEPOS should be under the care of a physician, and that it is good clinical practice for the beneficiary to be seen by the physician for their medical condition as it relates to DME and other assistive or rehabilitation technologies, but we have serious reservations about the `face to face? requirements as proposed.

NRRTS believes that a detailed evaluation of the beneficiary?s medical condition, functional and environmental needs and desired outcomes is essential to determine the most appropriate DMEPOS for that individual. The physician has the most primary role in this process, but in many cases, the physician defers this responsibility to other clinical professionals with more detailed knowledge and training. In the area of mobility (i.e. manual and powered wheelchairs and ambulation devices) specialized seating systems and other more advanced rehabilitation technologies, a physician routinely refers this duty to a occupational or physical therapist.

Recommendation: The face to face requirement by the treating physician should include provisions to permit the beneficiary to be evaluated by an occupational or physical therapist or other qualified professional at the physicians discretion.

? NRRTS agrees with the CMS goal of insuring good quality care and the reduction of instances of fraud, but do not believe that the requirement of a face to face visit with the physician will necessarily achieve that outcome.

One of the most notable instances of Medicare fraud for the provision of power wheelchairs involved unscrupulous providers in Harris County Texas. In this instance it was widely reported in the media that a physician was directly involved in this fraud, and that beneficiaries were allegedly transported by hired `head hunters? to visit this unethical physician who prescribed a power wheelchair whether the beneficiary needed it or not. Clearly, the requirement of a face to face visit with a physician would not have prevented this horrible example of fraud and abuse.

Recommendation: CMS should work with industry representatives, professional clinician organizations, beneficiary and other consumer advocacy groups and law enforcement agencies to develop other more effective ways to halt instances of fraud rather than implementing additional bureaucratic regulations and requirements that make it more difficult for honest and legitimate suppliers to provide high quality products and services to disabled beneficiaries.

Issues 10-19

SECTION 302

? NRRTS agrees with CMS that it is desirable for a prescribing physician or other practitioner to maintain appropriate and timely documentation in the medical records that supports the need for DMEPOS ordered, but to require verification of a face to face physician visit by the supplier in order

to process a claim for DMEPOS places an undue burden on that supplier.

Although it is true that the DMEPOS supplier is submitting a claim for payment and has a responsibility to obtain appropriate documentation of medical necessity, NRRTS must point out that suppliers are not in a position to tell physicians how to manage their professional entries into the medical records. When a supplier receives a written order (CMN) from a physician for DMEPOS, they would have very little or no capacity to comply with that order if the physician does not also provide the additional verification requirements of the proposed face to face visit with their patients. As a result, beneficiaries are likely to be denied essential and needed DMEPOS, not because it is unnecessary, but simply because there is insufficient documentation of an overly burdensome bureaucratic requirement. This face to face requirement places an undue obligation on the supplier in the event that the physician does not comply with the requirement, or in the event that they do comply, but do not document well.

Recommendation: CMS must establish a less intrusive method of verifying the medical need for DMEPOS of a beneficiary without placing the entire burden of proof of a physician?s required professional behavior upon the supplier. Requiring the supplier to obtain information from the medical record for each and every order for DMEPOS is unrealistic and difficult at best.

Specific Comments

? NRRTS does not support the face to face requirement for renewal of continually need DMEPOS.

Recommendation: A complete and accurate CMN should be sufficient to renew the need for DMEPOS as long as the physician has seen the beneficiary within the past 12 months, and there has been no significant change in the beneficiary?s medical condition. For example, a person with quadriplegia as a result of a spinal cord injury should not have to have a face to face visit with their physician in order to establish the continued medical need for an electric hospital bed, as long as there has been no change in the beneficiary?s medical condition.

? NRRTS does not support the 30 day requirement between face to face visit and completion of a written order for DMEPOS.

Recommendation: For more extensive technology needs, a 120 day timeframe would be much more appropriate. This is particularly true when another professional clinician, such as an OT or PT, is involved in a more technical and highly detailed rehabilitation technology prescription (i.e. power wheelchair with power tilt in space and alternate drive control systems).

? NRRTS does not support the proposed CMS limitation that the face to face visit with a physician or other professional clinician (OT PT etc.) cannot be the sole purpose for obtaining an order for DMEPOS.

Recommendation: If CMS is going to require that a physician have a face to face meeting with a beneficiary in order to determine that they are in need of DMEPOS, then CMS must also realize that there may be no other reason for the beneficiary to visit the physician. The subsequent time required to perform an evaluation for appropriate for DMEPOS, whether it is by a physician or by another professional clinician such as an OT or PT upon a physicians order, should be billable and appropriate reimbursement be available to the physician or clinician to meet this requirement.

Respectfully Submitted,

Dan Lipka, Med, OTR/L, CRTS
Licensed Occupational Therapist and Certified Rehabilitation Technology Supplier
NRRTS President
ddl@zoominternet.net

Submitter : Mr. Gerard Williams **Date & Time:** 09/24/2004 04:09:02

Organization : Mr. Gerard Williams

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Therapy--Incident to--Dear Sirs, I urge you to adopt the proposed regulations regarding therapy services incident to physician services. It is in the best interest of Medicare patients that these servcies be provided by qualified therapists. Thank you. Gerard Williams 9/24/04

CMS-1429-P-3854

Submitter : Mrs. Melissa Klamm **Date & Time:** 09/24/2004 04:09:25

Organization : National Athletic Trainers' Association

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am a concerned healthcare provider. I have come to understand that this docket, if passed, will limit the amount of work an athletic trainer can perform in a clinical based setting. Certified athletic trainers are highly qualified and trained healthcare professionals. They must receive at least a bachelor's degree from an accrediated program for athletic training, but many athletic trainers also have their master's or even doctorate degrees. In order to practice in the field of athletic training, a person must first pass the exam formed by the National Athletic Trainers' Association Board of Certification. The exam has three rigorous sections: practical, written simulation, and written. A person must pass each section with at least a 80%, which is a higher percentage than a doctor. Only one in three people pass all three sections on their first try. A certified athletic trainer is trained in the theories and application of modalities, such as ultrasound, electrical stimulation, traction, etc. They are also taught specific techniques for injury evaluation and relevant rehabilitation plans. I believe that certified athletic trainers are just as qualified to provide healthcare to patients as physical therapists in clinical, industrial, or sports settings. I understand that physical therapists may be more specialized in rehabilitation techniques for certain populations, but that does not mean that an athletic trainer cannot perform any treatment for a patient covered by medicare. Certified athletic trainers are highly qualified professionals and a viable link in the healthcare profession. I hope that the people responsible for this docket will revise the section affecting the ability of athletic trainers to provide care for patients. Thank you for your time and consideration.

CMS-1429-P-3855

Submitter : **Date & Time:** 09/24/2004 04:09:36

Organization :

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Individuals providing physical therapy should be graduates of an accredited professional physical therapist program. The delivery of so-called "physical therapy services" by unqualified personnel is harmful to the patient. An untrained eye doesn't know what to look for in terms of body mechanics and positioning.

Thank you for your consideration
Sincerely
Christina Dinh, SPTA

CMS-1429-P-3856

Submitter : Ms. Debra Morris **Date & Time:** 09/24/2004 04:09:18

Organization : Ms. Debra Morris

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached letter.

CMS-1429-P-3856-Attach-1.doc

Debra L. Morris
820 Bobbin Mill Road
Athens, Georgia 30606
706.543.6076
morr1227@bellsouth.net

Via Electronic Mail – http://www.cms.hhs.gov/regulations/ecomments

September 22, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy – Incident To; CMS-1429-P

Dear Sir/Madam:

This comment is regarding that part of "Therapy – Incident To" as it applies to limiting services allowed in physician offices and clinics. It appears that the physician's choice of qualified therapy providers will be restricted and therefore, he will not be free to designate the proper therapy provider for his individual patients. As a result, the physician is unable to determine who is best for providing a particular service, in his professional judgment, which should be in the best interest of the patient.

CMS's proposed regulation cuts out one therapy provider on the physical medicine and rehabilitation team, that being the athletic trainer. Athletic trainers are educated and trained similarly to physical therapists and occupational therapists. Generally, core curriculums are essentially identical between therapy providers. Where they diverge is in their respective specialties. Except for the athletic trainer, no other therapy providers' curriculum includes in depth management and treatment of sports and recreation injuries as part of their required educational studies. This is critically important because many rehabilitation patients suffer from a physical injury as a result of physical participation in activities, and, if not, then many of those injured have a desire to return to an activity after suffering from a non activity-related injury or surgery. The athletic trainer is the ONLY therapy provider trained specifically for recognizing, managing, preventing, treating, and rehabilitating physically active individuals and athletes.

Their national professional organization, the National Athletic Trainers' Association, was established in 1950 and has grown to over 26,000 members who practice as health care providers in a variety of settings including clinics, hospitals, colleges and universities, school systems, industries and factories, fitness facilities, return-to-work centers (workers' compensation facilities), Olympic venues and training centers, cardiac rehabilitation offices, and professional sports athletic training facilities (managing the health care of athletes and teams like the

Washington Redskins, Atlanta Braves, Baltimore Orioles and Chicago Bulls). The active hail from all walks of life, not to exclude bicyclists, ice skaters, tennis players, golfers, bowlers, runners, walkers, marathoners, fishers, archers, hunters, little leaguers, skateboarders, childhood players, and more. Athletic trainer abilities are encompass the comprehensive care as they apply to physically active patients at home, at work, and on the field.

Notwithstanding their daily responsibilities for which they are trained and educated in coordinating treatment and recovery of injured patients, a large and overlooked aspect of their daily routine is literally being responsible for matters of life and death of those for whom they serve. An athletic trainer is the ONLY therapy rehabilitation provider who is trained to recognize and manage emergency situations absent the presence of a supervising physician. Examples of situations for which they are trained include head, neck and spinal injuries, cardiac events requiring CPR and use of AED's, administration of first aid techniques, recognition and management of concussions and serious spine injuries, and use of splinting and taping techniques to minimize trauma. In fact, it is not uncommon for an athletic trainer to spend his/her day without medical supervision when any of the emergency or traumatic events above occur. Physician presence is often a luxury to the athletic trainer, so he/she is formally trained to function without that luxury.

In addition, he/she is the one therapy provider whose credentials and certifications provide for him/her to function without the direct supervision of any medical professional. After the passing of the acute stage of an injury ("acute" being the first 24 to 48 hours) an individual is referred to a physician for evaluations, x-rays, tests and diagnoses. Afterwards the athletic trainer renders treatment. The above description of their routine daily tasks are just that, "routine". Athletic trainers are not mere aides or assistants; they are health care providers who design plans of care, provide unsupervised treatment, monitor patient progress, set functional goals, monitor outcomes, hold peer reviews, maintain quality of care standards, and solicit patient and physician input for satisfaction. These abilities and practices are part of the trade and have been in existence nationwide for over fifty years.

The athletic trainer is well-prepared for functioning without direct supervision by a physician because his/her credentials have prepared him/her to function in the absence of that supervision. Physical therapy and occupational therapy, which are both very valuable in their respective settings, were initially started for management of diagnoses such as world war injuries to veterans, polio, cerebral palsy, and CVA's (i.e. strokes) where learning basics such as activities of daily living are essential. In contrast, management of sports injuries is not a part of the physical therapy or occupational therapy curriculum, and to argue that returning one to sports and recreational activities is similar to returning one to activities of daily living would be a gross under statement of the desires and abilities of those who strive to be more active than, say, one whose limitations provide for a more sedentary hobby or lifestyle.

To that end, baby boomers are currently entering their stride and more individuals are active and interested in exercise and disease prevention than ever before. Those beneficiaries deserve the expertise best suited for them – the athletic trainer – just as another patient may be better served by the services of an occupational therapist. Therefore, how can we permit only one or two

providers to join the therapy team when it is not only possible, but also necessary for providing more comprehensive care for those who wish to lead a healthful and active way of life?

Qualifications and educational curriculums are not the obstacles for this specialty group, rather, it is time to be futuristic by examining your patient mix of beneficiaries and how you can improve upon their benefits and meet their needs. Educationally, the athletic trainer graduates from academic programs which are accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) via the Joint Review Committee on Educational Programs in Athletic Training.

In Georgia, athletic trainers have been state licensed since 1978 (OCGA 43-5-1). That license was designed to safeguard health and promote public welfare (See Chapter 5 of Title 43, which I have found, is not current on the internet.) and was endorsed by then Lt. Governor Zell Miller who later became Governor of Georgia. His legal counsel wrote the initial Bill forming the Georgia Board of Athletic Trainers for the purpose protecting the public and licensing athletic trainers. If 1429-P is established as a final rule in its present form, it will be in direct conflict with Georgia's provisions whereby athletic trainers are benefit eligible and reimbursed by insurance carriers as are their fellow speech, occupational and physical therapists. A law was passed in Georgia to address the same inequities that 1429-P presents, in which one therapy provider was favored for payment over another, creating confusion for both the patient AND the insurance carrier. Patients were unfairly restricted from access to the most appropriate therapy clinician for his/her diagnosis. In Georgia we learned that the athletic trainer was actually providing the clinical services to sports and active individuals, while the physical therapists were reaping the rewards of payment, as though they were actually providing the service. As a result, legislation was passed to rectify the inequity and confusion by requiring reimbursement for a covered service so long as it is provided by a specialist who is acting within their scope of practice. Athletic trainer services were not new, and they were not a new mandated benefit by the legislature. The services had been provided by the athletic trainer for years; but someone else was posing as the provider. Therefore, a new "covered benefit" was not created and importantly, carriers did not have to bear the added expense of a new benefit.

Also, in Georgia, O.C.G.A. 33-20A-3(3) provides for an athletic trainer to be inclusive on the list of "health care provider(s)" in Georgia. This Chapter is cited as an addendum to the "Patient Protection Act of 1996." The athletic trainer is also subject to Georgia law as it applies to the waiver of deductibles or co-payments in health insurance plans, which is part of the Georgia Administrative Procedure Act (O.C.G.A. 43-1-19(1)). And finally, any health care insurance policy providing coverage for athletic injuries, (or injuries preventing athletic participation, or any injury comparable thereof as defined in O.C.G.A. sec. 43-5-1) to individuals in the State of Georgia must reimburse such individuals when they receive treatment by an athletic trainer if a doctor of medicine would receive reimbursement for providing the same service. Indeed, if an insurance policy in Georgia covers services within the lawful scope of practice of athletic trainers, insurance carriers are prohibited from excluding patients from receiving reimbursement for services rendered by athletic trainers.

Here an insurance policy does not have to state that it specifically includes coverage for services rendered by an athletic trainer, but rather so long as the policy covers services typically and

legally provided by athletic trainers, then the athletic trainer will receive reimbursement if a doctor or other provider would receive such reimbursement.

O.C.G.A. 43-5-1(1) defines an athletic injury as "[a]ny injury sustained by a person as a result of such person's participation in exercises, sports, games, or recreation requiring physical strength, agility, flexibility, range of motion, speed, or stamina or any comparable injury which prevents such person from participating in such activities." O.C.G.A. 43-5-1(2) defines an athletic trainer as "[a] person with specific qualifications as set forth in Code Section 43-5-8 (which has been amended in 2004) who, upon the advice and consent of a physician, carries out the practice of prevention, recognition, evaluation, management, disposition, treatment, or rehabilitation of athletic injuries; and, in carrying out these functions, the athletic trainer is authorized to use physical modalities, such as heat, light, sound, cold, electricity, or mechanical devices related to prevention, recognition, evaluation, management, disposition, rehabilitation, and treatment. The term 'athletic trainer' shall not include any student, teacher or other person who serves as an athletic trainer for an elementary school or high school, either public or private within this state." (Be aware that the Georgia Attorney General's Opinion is very old and out-dated, and several amendments have been made since 1978.)

If 1429-P becomes a final rule, then Georgia's Code for Professions and Businesses will be in conflict with 1429-P to the detriment of a valuable team member of the therapy profession. As a result, the patient will be denied access to the entire team while given access to just part of the team…a part that is not specifically educated to effectively treat a patient population in need of and deserving of the skills of an athletic trainer. The result? A skill unwisely paired with a patient's needs or diagnosis, resulting conceivably in a less than optimal functional outcome, a risk to the patient, or perhaps additional medical consultation and even more therapy visits.

On the CMS web page, CMS states the following, "On January 11, 1944, President Roosevelt outlined in his State of the Union Message, an 'economic Bill of rights,' which included 'the right to adequate medical care and the opportunity to achieve and enjoy good health.'" Medicare is the nation's largest health insurance program; the latest CMS statistic shows coverage for nearly 40 million Americans. Many of those Americans suffer from injuries sustained during physical activity, recreation, or ordinary activities preventing them from returning to physical activity. The Balanced Budget Act of 1997 extended Medicare Part A by reducing Medicare spending, increasing health care options available to America's seniors, improving Medicare preventive benefits, . . . and providing new demonstrations to help Medicare in the future. By placing limitations on the make up of the therapy team, CMS is in direct conflict with the Act. In doing so, CMS would be decreasing health care options, limiting preventive benefits which are achieved through exercise and physical activity by subscribers. In fact, your decision may deter individuals from being active if they believe that proper medical care and referral follow-up will be limited to them (and therefore jeopardizing their health and safety). In short, your potential rule will contradict CMS's open-mindedness to "work well in the future", by impeding progress. And whenever you restrict how many providers are eligible for benefits, you are in essence negatively impacting the supply and demand curve whereby cost of delivery will increase by limiting your available providers. Although CMS establishes the fee schedule via controlled reimbursement, the cost to the provider will increase and negatively impact the volume of those willing to become providers. Medicare needs willing providers and athletic trainers are not only

willing, but they are adequately trained and specialized for treating your active beneficiaries, young and old alike. This theory would contribute to the fiscal soundness of CMS programs.

Furthermore, by placing the athletic trainer on the therapy team, you are acting in concert with the Relationship Building component of the CMS operational objectives. Additionally, under Quality Improvement, the care that an athletic trainer provides meets professionally recognized standards of health care, is provided in an economical setting by matching the patient with the appropriate clinican/therapy provider with the objective of resulting functional outcomes, tracks quality improvement along with fellow rehabilitation team members, and strives specifically to prevent injuries through research and counseling of the beneficiary personally. These quality improvement principles are consistent with the National Athletic Trainers' Association and are practiced at outpatient clinics across the country.

When HCFA was restructured into CMS, it was described as "more than just a new name . . . it was an increased emphasis on responsiveness to beneficiaries and providers, and quality improvement." Tommy Thompson was quoted saying, "We're going to encourage innovation, better educate consumers about their options, and be more responsive to the health care needs of Americans." To that end, Americans are more active than ever; they are more informed regarding their healthcare; they want skilled providers for their diagnoses; and they don't want to wait a long time to get their care. They know good quality when they get it, and they don't forget bad quality especially when they are denied access to a provider better suited for their diagnosis at the time they need help. As Secretary Thompson has stated, "fine tune" your department so Americans can receive the highest quality care possible by including all members of the rehabilitation team as providers for your beneficiaries. That effect is a better result for your beneficiaries, is safer for the public, is innovative by eliminating the tired argument that only physical therapists can provide therapy when we have progressed to a new age of using not generalists, but specialists for our health care. While seniors are more active (and certainly more particular regarding the skill set of their provider), cost-effectiveness is a priority (when one's skill is appropriately matched to the patient) and education, training and credentials must be top notch, now is the time to recognize that the athletic trainer is an excellent source for meeting all of those needs.

CMS's vision, in serving beneficiaries, is to "open our programs to full partnership with the entire health community to improve quality and efficiency in an evolving health care system." In furtherance of this vision you have published Program Objectives to include Access to Quality Care. Four objectives are listed which are compatible with my recommendation for allowing the athletic trainer to remain a member of the therapy team who will be respected and treated identically the same as their associate team members. They are:

1. Expand health care choices and further strengthen programs and services to adapt to beneficiary needs.

2. Improve quality of care and health outcomes for the beneficiaries of CMS programs.

3. Improve access to services for underserved and vulnerable beneficiary

populations, including eliminating health disparities.

4. Protect beneficiaries from substandard or unnecessary care.

Additionally, CMS would be acting consistent with the four Relationship Building goals of its Operational Objectives, which are:

1. Enhance responsiveness by improving communications with and service for physicians, other health care professionals, providers, health plans, states, territories, tribal governments, the Congress, and other stakeholders.

2. Continually improve CMS programs and operations by actively seeking and responding to the input of beneficiaries and the health care community.

3. Provide enhanced flexibility to states to design and administer their Medicaid and SCHIP programs in ways that improve service, coverage, and quality.

4. Increase public knowledge of the financing and delivery of health care services in CMS programs and in the broader health care system, health care services in CMS programs and in the broader health care system.

In conclusion, the proposed 1429-P provision would allow only physical therapists, occupational therapists, and speech and language pathologists to provide "incident to" outpatient therapy services and would improperly provide exclusive rights to Medicare reimbursement for these groups. Athletic trainers, along with the above-mentioned therapy providers, have a CPT code assigned to them for "Evaluation". Thereafter all groups bill for their services utilizing standard CPT codes. This is consistent for all medical and physical medicine providers. To exclude the athletic trainer as an "incident-to" therapy provider for the benefit of your beneficiaries would be viewed as discriminatory and unjustified, inconsistent with CMS's published goals and objectives, and quite frankly, stifling to your deserving beneficiaries.

Sincerely,

Debra L. Morris
Attorney at Law, Georgia
Athletic Trainer, Certified
Georgia Licensed Athletic Trainer

cc: Warren G. Morris, Chair, Georgia Athletic Trainers Board
Charles Kimmel, President, National Athletic Trainers' Association

Submitter : Mrs. Susan Banner **Date & Time:** 09/24/2004 04:09:41

Organization : Mrs. Susan Banner

Category : Occupational Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Therapy--Incident to
Dear Sirs or Madames,
I support the proposed change in regulations requiring that therapy services provided incident to physicians' services be provided by licensed therapists. I urge you to adopt them.
Thank you,
Susan Banner OT

Submitter : Mr. Dustin Fink **Date & Time:** 09/24/2004 04:09:25

Organization : National Athletic Trainers Association

Category : Other Health Care Provider

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

9/24/2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012
Re: Therapy ? Incident To
Dear Sir/Madam:
I am writing to express my concern over the recent proposal that would limit providers of ?incident to? services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

The Athletic Training profession has endured many hard times, but this should not be one of them. Many men and women have devoted a lot of hours to training and service to become important to the health care field, and this proposal would eliminte a great majority from their professions. Give this some serious thought before you do something that will definitely affect the health care system as we know it.

Sincerely,

Dustin J. Fink, MS, ATC/L
411 W. Washington
Clinton, IL 61727

CMS-1429-P-3859

Submitter : Miss. lina oeij **Date & Time:** 09/24/2004 04:09:01

Organization : NVCC

Category : Other

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I strongly supports the proposed personnel standards for physical therapy services that are provided ?incident to? physician services in the physician?s office. I has argued that interventions should be represented and reimbursed as physical therapy only when performed by a physical therapist or by a physical therapist assistant under the supervision of a physical therapist. I strongly opposes the use of unqualified personnel to provide services described and billed as physical therapy services.

CMS-1429-P-3860

Submitter : Ms. Ruth Cook **Date & Time:** 09/24/2004 04:09:05

Organization : Decatur Memorial Hospital

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

9/24/2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012
Re: Therapy ? Incident To
Dear Sir/Madam:
I am writing to express my concern over the recent proposal that would limit providers of ?incident to? services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.
.
Sincerely,
Ruth E. Cook, MA, ATC/L
208 Hickory Lane
Lincoln, IL 62656

CMS-1429-P-3861

Submitter : **Date & Time:** 09/24/2004 04:09:24

Organization :

Category : Physician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 24,2004

Centers for Medicare & Human Medicaid Services
Department of Health and Human Services
ATT: CMS-1429-P
P.0. Box 8012
Baltimore, MD 21244-8012

RE: Therapy-Incident to

Dear Sirs:

I am writing to express concern over the recent proposal to limit providers of "incident to" services in physician offices and clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it could reduce the quality fo health care to our Medicare patients and increase the costs associated with these services.

I believe the decisions about health care to our patients should be based on quality of care and not on the political or financial concerns of any entity, unless tht financial needs are so the entity can survive to provide the care. I believe there are other qualified personnel, such as licensed athletic trainers, that can provide these services to our patiients in a cost effective and medically sound way.

On reviewing the proposal information I had access to, I found it interesting that the licensed therapists that want exclusive right to provide these services also will be given the right to have assistants provide these services when they are not in attendance. These assistants, from what I have seen personally, have had no formalized schooling in this area other than on the job training. I have found them to be able to provide these services adequately. But, from what I have read, one of the concerns of the licensed therapists is that doctors use just the same type of personnel and should not be allowed to so.

I would hope that the decisions made in this matter, and all matters concerning patient care, would be made as to what is best for patient care. This will include access to care and quality of care. In rural areas of our country access is a very large factor. I do not propose to compromise care, but let us make our decisions on who is able to provide quality care, based on scientific inquiry, and allow all qualified entities to provide this care.

Sincerely,

Richard M. Ingle, M.D.
130 E. Haskell St. Suite A
Winnemucca, NV 89445

CMS-1429-P-3862

Submitter : Mr. Phillip Krause **Date & Time:** 09/24/2004 04:09:48

Organization : HealthQuest Physical Therapy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

I am writing to you regarding the proposed rule published by the Centers for Medicare and Medicaid Services (CMS) that included the ?Revisions to Payment Policies Under the Physician Fee Schedule for calendar year 2005.? More specifically, I would like to comment on the provisions governing ?incident to? services and express my strong support that it be included in the final rule.

I would like to strongly support the CMS proposal that individuals who provide physical therapy services in physicians? offices must be graduates of an accredited program. As a therapist with 25 years experience I have seen the growth in knowledge base of recent graduates. Today`s graduates have earned the opportunity to practice therapy. If physicians are allowed to hire non graduates for a lesser price: why not? The person who suffers the most is the patient who many times dosen`t even realize their being treated by an athletic trainer, exercise physiologist or other sub standard personal. Unfortunatly in many cases it`s a poor outcome, a lengthy rehab or reinjury.

In order to assure that all patients who are insured under CMS get safe, effective, high quality physical therapy , it is extremely important that the provision governing ? incident
To ? services be included in the final rule. Thanks for your time and consideration regarding this manner.

Sincerely,

Philip C. Krause PT, OCS

Submitter : Mr. Darin Buttz **Date & Time:** 09/24/2004 04:09:31

Organization : NATA

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

9/24/2004
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012
Re: Therapy ? Incident To
Dear Sir/Madam:
I am writing to express my concern over the recent proposal that would limit providers of ?incident to? services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.
.
Sincerely,
Darin Buttz, MS, ATC/L
166 N. Westlawn Ave.
Decatur, IL 62522

CMS-1429-P-3864

Submitter : Ms. Marjorie Weigel **Date & Time:** 09/24/2004 04:09:38

Organization : Associated Physical Therapists, Inc

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

RE: Therapy - Incident To
I have been practicing as a licensed physical therapist for the past 30 years and wish to comment on the August 5 proposed rule on "revisions to payment policies under the physician fee schedule for calender year 2005." I strongly support CMS's proposed requirement that physical therapists working in physician offices must be graduates of accredited physical therapist programs. Physical therapists and physical therapist assistants, working under the supervision of a licensed physical therapist, are the only practitioners who have the education and training to furnish physical therapy services. To ensure that all people are provided the best quality care, it is important to ensure the high standards set out by our profession.

Submitter : Mrs. D. Derera **Date & Time:** 09/24/2004 04:09:58

Organization : Mrs. D. Derera

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Therapy--Incident to
Dear Sirs, I support the proposed changes in regulations that would require that qualified therapists provide therapy services incident to physician services and I strongly urge you adopt the proposed regulation.
Thank you very much,
D. Derera, PTA

CMS-1429-P-3866

Submitter : Gary Bartoo **Date & Time:** 09/24/2004 05:09:07

Organization : Coeur d'Alene Physical Therapy & Sports Medicine

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing physical therapist, licensed in the state of Idaho for 30 years. I am in support of CMS' proposal that individuals who furnish physical therapy services in physician's offices must be graduates of an accredited professional physical therapy program or meet certain grandfathering clauses or special rules.

I am further in support of physical therapy services being only offered out of physician offices so as to avoid any confilct of interest or restraint-of-trade issues related to self-referral.

Thank you,
Gary Bartoo, P.T. (208)667-3583
Idaho PT License RPT-105

CMS-1429-P-3867

Submitter : Mr. Ira Gorman **Date & Time:** 09/24/2004 05:09:00

Organization : Regis University

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

My name is Ira Gorman, PT, MSPH and I am an Assistant Professor of Physical Therapy at Regis University in Denver. I wish to express my strong support for CMS?s proposed requirement that physical therapists working in physician?s offices be graduates of accredited professional physical therapist programs. Even though current law prevents the agency from requiring licensure, it would be the most appropriate standard to achieve its objective. Every state requires that physical therapists be licensed in order to protect the public. PT education has grown over the last 8 years and now is an entry level doctorate at over 100 institutions across the country and by 2005 will be the degree granted by over half of the accredited institutions.

Physical therapists receive significant training in anatomy and physiology, have a broad understanding of the body and its functions, and have completed comprehensive patient care experience. This background and training enables physical therapists to obtain positive outcomes for individuals with disabilities and other conditions needing rehabilitation. This education and training is particularly important when treating Medicare beneficiaries.

The delivery of so-called ?physical therapy services? by unqualified personnel is harmful to the patient. An unqualified practitioner may not be able to recognize problems that are outside the scope of physical therapy and therefore unable to make the appropriate and timely referral. This is especially important in the Medicare population which has more complex medical problems that the majority of the population.

In addition a financial limitation on the provision of therapy services (referred to as the therapy cap) is scheduled to become effective January 1, 2006. Under the current Medicare policy, a patient could exceed his/her cap on therapy without ever receiving services from a physical therapist. This will negatively impact patient?s outcomes and affect a patient's ability to receive qualified physical therapy services later during that calendar year for a different problem such as a stroke or hip replacement.

Finally Section 1862(a)(20) of the Social Security Act clearly requires that in order for a physician to bill ?incident to? for physical therapy services, those services must meet the same requirements for outpatient therapy services in all settings. Thus, the services must be performed by individuals, who are graduates of accredited professional physical therapist education programs.

Thank you for your time and attention to these comments.

Sincerely,

Ira Gorman, PT, MSPH

CMS-1429-P-3868

Submitter : Mrs. Beverly Bates **Date & Time:** 09/24/2004 05:09:07

Organization : Holistic Butterfly Studio

Category : Other Health Care Provider

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I OPPOSE MEDICARE's proposed policy to eliminate any provider except PT's from providing "incident to" medical professional's services to patients.

Massage Therapists should have the right to work with or for medical doctors or chiropractors. Patients should be allowed to receive professional health care in physician's offices from those other than physical therapists only. PTs should not be the only health care professionals allowed to provide medically related care to
physician's patients. We know treatments that PTs do not. We provide the essential human touch that PTs do not. The client/patient should have the right to choose what type of care they want to receive. Education and affordable options are in the best interest of the patient. Physical therapy along with Massage therapy can lead to faster results and reduced medical expenses. Before passing this bill, please do some research on the benefits of clinical massage (also called neuromuscular massage or trigger point therapy). This techinque really works; it allows the body to heal itself in a way that helps to prevent reinjury to the area. Preventing reinjury will save on medical claims and expenses. Massage therapy provides a WIN-WIN situation for both the client and the Medicare system.

CMS-1429-P-3869

Submitter : **Dr. Sarode Pundaleeka** **Date & Time:** **09/24/2004 05:09:43**

Organization : **Joliet Oncology-Hematology Associates, Ltd.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS-1429-P

CMS-1429-P-3869-Attach-1.doc

Cancer Care with Compassion

Joliet Oncology-Hematology Associates, Ltd.
2420 Glenwood Avenue
Joliet, IL 60435

September 23, 2004

Mark McClellan, M.D., Ph.D.
Office of the Administrator
Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1429-P

Dear Dr. McClellan:

Thank you for this opportunity to comment on Proposed Rule CMS-1429-P, "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." I would like to take this time to address the following issues: non-Medicare reimbursement impact on the cancer care community, CMS's impact analysis, proposed changes in reimbursement for drug services, and proposed changes for drugs and biologicals.

First, there is a significant risk that the impact on practices may be greater than projected if private payers react to MMA by adopting changes that are similar to those being implemented for Medicare or continue in unrelated attempts to lower reimbursement. A large number of payers, which include Humana and PacifiCare, use Medicare as a benchmark for drug pricing. In addition, many payers use Medicare as benchmark for pricing drugs. As a result, it is possible that the impact of MMA's changes could be compounded by private payer reaction rather than mitigated by private payer reimbursement.

Secondly, I understand that US Oncology analysts have carefully examined CMS's impact analysis of the new ASP +6% reimbursement methodology and have suggested that it may hinge on two important but potentially flawed assumptions. The first assumption is that oncology drug prices will grow by 3.39% between the first and third quarters of this year, thus raising drug reimbursement levels for 2005. However, there is no evidence that suggest such a trend may be continuing. If the inflation rate in its methodology is not realized, CMS will have overstated the drug revenues that oncologists will receive in 2005. US Oncology backed the inflation adjustor out of CMS's assessment of the impact of ASP +6% methodology and determined that 2005 oncology drug

payments would be equivalent to reimbursement level of AWP-27.5%. This is 7.9 percentage points below the AWP-19.6% projected by the CBO. As result, there would be a net $11.5 billion reduction in Medicare reimbursement for cancer care. CMS's estimate of the impact on oncology reimbursement is based on the average payment change for fifteen of the eighteen high-volume oncology drugs. Using only a select group of drugs underestimates the drug revenue reduction that that oncology will experience in 2005. US Oncology estimates that oncology drug payments would be equivalent to reimbursement at AWP-28.8%. This will result in a net 12.6 billion reduction in Medicare reimbursement for cancer care.

Thirdly, I would like to comment on the proposed changes in the reimbursement for drug administration services. CMS estimates the volume-weighted average of the MMA-mandated permanent increases in Medicare payments to oncologists for drug administration services from 2003 to 2005 at 109%. When transitional payments are considered, the volume-weighted increases in Medicare payments for these codes are approximately 170% from 2003 to 2004 and 111% from 2003 to 2005. Since there is a reduction of the transitional payments from 2004 to 2005, Medicare reimbursement for oncology drug administration services will experience a net reduction of 22% next year. These services are nearly one-third of typical oncology revenues in 2004. US Oncology estimates that these reimbursements changes will cover 97% of drug administration services cost in 2004, 73% of costs in 2005, and 67% of costs in 2006.

Finally, I would like to comment on the proposed changes in reimbursement for drugs and biologicals. Medicare payment rates for most drugs and biologicals furnished by oncologists went from 95% AWP to 85% of AWP in 2004. CMS estimates that a switch from AWP-based reimbursements in 2004 to ASP-based reimbursement in 2005 will result in a one year decrease in drug revenues to oncologists of approximately 8%. Drugs are responsible for about 70% of oncologists' revenues in 2004.

In conclusion, I am greatly concerned for the cancer community. With a decrease in the drug reimbursements, which constitutes 70% of oncology revenues, our operation will take a huge loss. Joliet Oncology-Hematology Associates, Ltd. mission is to strive to continually improve the quality of life our of cancer patients and to provide patients with the highest quality of cancer care in an open supportive and compassionate environment. However, with limited resources, our organization will not be able to adapt to the latest technology changes and medical advancements that will ensure patients are receiving the highest quality of care.

Thank you for time and consideration. If you have any questions, please contact our office at 815-725-1355 between the hours of 9:00a.m. to 5:00p.m.

Sincerely,
Sarode Pundaleeka, MD
President
SP

CMS-1429-P-3870

Submitter : Mrs. Jane Winders **Date & Time:** 09/24/2004 05:09:27

Organization : Memorial Medical Center

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I wish to comment on the August 5 proposed rule regarding therapy incident to services. I am a physical therapist who manages a hospital based, outpatient therapy department. I strongly support the recommendation that physical therapists working in physician's offices be graduates of an accredited professional physical therapist program. Physical Therapists possess a professional education by a college or university accredited by the Commission of Accreditation of Physical Therapy. This is an independent agency that is recommended by the U.S. Department of Education. Currently a Physical Therapists graduate with a master's degree or a doctor of physical therapy. Physical Therapy Assistants have an associates degree from a program with the same accreditation. Physical Therapists are also licensed individuals holding them to a high degree of professional accountability in the states in which they practice. We possess a broad understanding of anatomy, physiology, the body and how it works through the nature of our education. This is imperitive when treating the public. Our licensure tells the public that we possess this broad knowledge base. I hear frequent stories from patients who have received services that they perceived were physical therapy when they were not given by a person who graduated from a qualified program. They did not benefit from positive outcomes, and in some cases felt worse than when they started. There are business that advertise physical therapy, but do not have a physical therapist on staff. There are other professionals who are also licensed to perform specific tasks. Their education and training prepare them for those tasks and I would feel comfortable in obtaining those services from them. I would be concerned however, if they functioned beyond that. I am very proud to be part of a profession with strong academic requirements and competenct clinicians. I am concerned that people who are not graduates of accredited professional physical therapist education programs who are attempting to provide these services.
Thank you for consideration of these comments.
Jane Winders P.T.
217-862-0433
winders.jane@mhsil.com

Submitter : Tim Leach **Date & Time:** 09/24/2004 05:09:28

Organization : Tim Leach

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

CMS-1429-P-3872

Submitter : Mr. Bill Wire **Date & Time:** 09/24/2004 05:09:26

Organization : Mr. Bill Wire

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I would like to urge you to NOT adopt this change that limits a physician to refering 'incident to' patients ONLY to physical therapists. I fully believe in allowing both doctors and patients to have the widest range of treatment options available to them. All qualified health care professionals should be permitted to provide prescribed services or work with a physician to provide treatment for a particular condition.

Physical Therapists are not the only people who can render aid. Other forms of treatment work as well, or better for certain cases. I urge you not to discount their value or deny access to them for the patients which they would benefit.

Thank you for taking the time to consider my opinion on this matter.

Submitter : Mrs. Kristina Borg-Ii **Date & Time:** 09/24/2004 05:09:21

Organization : Mrs. Kristina Borg-Ii

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

As a professional Healthcare provider I urge you to not vote to limit the Dr.'s ability to refer to All catigories of providers. It limits the patients and Doctors rights to seek the most benificial treatment for that person. No one field of provider will be able to help all areas that need to be addressed. It needs to be written in that ALL health care fields be allowed under this docket.

Submitter : Mr. Tyler Buege **Date & Time:** 09/24/2004 05:09:13

Organization : Mr. Tyler Buege

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Therapy--Incident To--
Dear Sirs, I support the proposed changes in the Medicare regulations that would require therapy services provided incident to physician's services be delivered by qualified therapists. Thank you very much, Tyler Buege, SPT

Submitter : Ms. Sherry Borcherding **Date & Time:** 09/24/2004 05:09:04

Organization : Ms. Sherry Borcherding

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

Please do not pass a policy under which a physician may only refer "incident to" services to physical therapy. In some situations other helathcare professionals are more appropriate for the treatment needed. The doctor and patient should be able to choose the service needed in a particular situation.

CMS-1429-P-3876

Submitter : Mr. John Carlson **Date & Time:** 09/24/2004 05:09:35

Organization : Gifts of Healing

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to reconcider your policy change where physicians can only refer 'incident to' services to physical therapists. Any professionally trained health care practitioner should be allowed to provide services to clients with a physicians prescription or under their supervision. This will severelly limit the patients/clients choice of the health care practitioner they wish to go to, to be treated.

Submitter : Ms. Susan Dill **Date & Time:** 09/24/2004 05:09:48

Organization : Ms. Susan Dill

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am writing this on behalf of my friends in the hemophilia community. I am urging you to please reconsider the NPRM proposed $0.05 per unit separate add-on payment for items and services related to the furnishing of blood clotting factor. Those individuals with hemophilia who have Medicare coverage should be entitled to the same level of care as others. With this proposed separate add-on payment that level of care will no longer be there for them. There will be increased emergency room visits, which include physician fees, ER fees in addition to the cost of factor and supplies that could have been administered at home. There will be prolonged recovery period not to mention increase in pain. It would be like turning back the clock in an effort to contain cost by eliminating services that have not only improved quality of life but reduced the cost of care of an individual who has hemophilia. The services that are provided by full-service hemophilia homecare companies are essential and necessary to make hemophilia a manageable disorder rather than a devasting, catastrophic, chronic disease. Again, I am urging you to please reconsider the NPRM proposal.

Submitter : Mrs. Danielle Flores **Date & Time:** 09/24/2004 05:09:56

Organization : Mrs. Danielle Flores

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the bleeding disorders community, I urge reconsideration of the proposed changes in blood clotting factor reimbursement by Medicare.

As someone who has been around hemophilia all of my life, it is so reassuring to explain our history to new families hit with this devastating diagnosis. There are no more days of long hospital visits and joint damage from non-treatment. My father, a small business owner 30 years ago, did not have the time to spend hours on end at the hospital waiting for treatment and infusions. He would suffer through bleeding episodes only to make it worse on his body and ultimately his insurer, costing them much more than would have initial treatments. The hemophiliacs of today can infuse at home, on their own schedule and not interfere with their work or their schooling. I am proud to offer new hope to families by telling them this. PLEASE do not make me have to start telling them where we came from, where we were and how we have to go back! It will be IMPOSSIBLE for home health care companies to supply factor to medicare patients under the proposed changes in reimbursement. Why don't medicare patients have the same rights as privately insured patients? If these changes go into effect, medicare patients will no longer have access to home infusion, will have to go to emergency rooms for treatment and wait, where long term damage can take place and drive up the total costs all the while. During this 'waiting period for treatment' they will imediately become unproductive.

In closing, if the day to day welfare AND long term effects on these patients, are of no interest to you, PLEASE just review the bottom dollar costs. Long term, over time, you will ultimtately, without a doubt pay more for these patients' care.

REVIEW YOUR HEARTS AND YOUR LONG TERM BUDGETS!
Thank you!

Submitter : Mr. Eric Oehms **Date & Time:** 09/24/2004 05:09:20

Organization : Encore Rehabilitation, Inc

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 24, 2004
Dear Sir/Madam:

Regarding the issue of incident to billing, as a Certified Athletic Trainer who is licensed by the State Department of Health in Mississippi, I find this provision to be absurd. I attended the University of Southern Mississippi and received a BS in Sports Medicine/Athletic Training, which is a CAAHEP accredited program. This provision, if adopted, would severely affect my ability to utilize the skills I learned in school and throughout my seven years of experience. This will effectively cause my profession to become obsolete. However, more importantly, this provision would completely limit patient's access to healthcare. If this provision is allowed, the patient will suffer the consequences due to delays in care, greater cost, and a lack of immediate care. I do not see how this provision is good for the patient. We, ATC's, are educated healthcare professionals who have been providing excellent health care for over fifty years. I personally view this provision as saying that I am an uneducated, unimportant cog in the healthcare wheel, while physical therapy assistants, who have a two-year degree, can continue to charge incident to. This to me is insulting and forces me to believe that the future of quality healthcare in this country is in jeopardy. I feel that CMS should not institute the proposed changes and that this provision is a health care access deterrent.

Sincerely,
Eric Oehms, MS, ATC/L
Sports Medicine Coordinator
Encore Rehabilitation, Inc.
Bienville Orthopaedic Specialists

CMS-1429-P-3880

Submitter : karen fiske **Date & Time:** 09/24/2004 05:09:47

Organization : karen fiske

Category : Other Health Care Provider

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

please do not discontinue payment for massage therapy by massage therapists under medicare. massage therapy by massage therapists have helped many people live more productive, pain- free satisfying lives.

Submitter : Mr. Daniel Hannah **Date & Time:** 09/24/2004 05:09:03

Organization : Lander University

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file.

CMS-1429-P-3881-Attach-1.doc

September 24, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician offices and clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system. Furthermore, it is an insult to the profession of athletic training to say that we are incapable to provide services to Medicare patients who have sustained orthopaedic injuries that are in need of physical rehabilitation.

During the decision-making process, please consider the following:

- "Incident to" has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY "incident to" service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. ***It is imperative that physicians continue to make decisions in the best interests of the patients.***

- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.

- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.

- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.

- Athletic trainers are highly educated. ALL certified or licensed athletic trainers ***must have a bachelor's or master's degree*** from an accredited college or university. Foundation courses include: human physiology, human anatomy, kinesiology/biomechanics, orthopaedic assessment, therapeutic modalities, therapeutic exercise, nutrition, acute care of injury and illness, statistics and research design, and exercise physiology. Seventy (70) percent of all athletic trainers have a master's degree or higher. This great majority of practitioners who hold advanced degrees is comparable to other health care professionals, including physical therapists, occupational therapists, registered nurses, speech therapists and many other mid-level health care practitioners. Academic programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) via the Joint Review Committee on educational programs in Athletic Training (JRC-AT).

- To allow *only* physical therapists, occupational therapists, and speech and language pathologists to provide "incident to" outpatient therapy services would improperly provide these groups exclusive rights to Medicare reimbursement. To mandate that only these practitioners may provide "incident to" outpatient therapy in physicians' offices would

improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

- CMS, in proposing this change, offers no evidence that there is a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.

- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. ***In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of therapy services.***

- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.

- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to **prevent, assess, treat and rehabilitate** injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of walking in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Daniel Hannah, MA, ATC, SCAT
Lander University
320 Stanley Ave.
Greenwood, SC 29639

Submitter : Mrs. AnnMarie O'Hare **Date & Time:** 09/24/2004 05:09:43

Organization : Mrs. AnnMarie O'Hare

Category : Occupational Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Therapy--Incident to
Dear Sirs, I urge you to adopt the proposed regulations requiring that therapy services provided incident to physicians' services be performed by qualified therapists. It would provide better quality of care to Medicare patients. Thank you.
AnnMarie O'Hare, COTA

Submitter : Dr. William Blaylock **Date & Time:** 09/24/2004 05:09:28

Organization : Mobile Urology Group, P. A.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs/Madames,

The propsed rule changes for drug reimbursement will have a profound impact on our ability to provide care for our patients since we do not have a fee schedule and these incomplete data make running a business extremely difficult. If these massive cuts are implemented, we may find ourselves unable to care for cancer patients in the outpaient setting.

A margin of six percent leaves very little room for patients with no secondary insurance, and will also have a profound effect on our ability to care for other patients, particularly indigents and medicaid patients.

We look forward to continuing to care for cancer patients in our practice, but we must maintain a viable entity in which to provide this care.

Sincerely,
William E. Blaylock, M.D.

CMS-1429-P-3884

Submitter : Mr. Lawrence Fogel **Date & Time:** 09/24/2004 05:09:42

Organization : Mr. Lawrence Fogel

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please, please, please correct the gross injustice of classifying Santa Cruz County, California as a RURAL county in the proposed CMS rules for 2005.

According to federal guidelines Santa Cruz County is even more URBAN that Los Angeles, Sacramento and San Diego counties. To the immediate north, Santa Clara County is designated for the HIGHEST payments in the COUNTRY ! ! ! And yet the costs of housing are HIGHER in Santa Cruz County. And Santa Clara County payments will be TWENTY-FIVE percent higher under the proposed guidelines. We are losing current and prospective medical personnel to Santa Clara County. My wife and I will be on Medicare in five years. We do not want to have to drive half an hour over a windy mountain road to obtain medical attention. Please do the right thing ! ! ! !

Regards,
Lawrence Fogel

Submitter : Dr. Wesley Pittman **Date & Time:** 09/24/2004 05:09:02

Organization : American Optometric Association

Category : Physician

Issue Areas/Comments

GENERAL

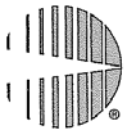
GENERAL

see attached

CMS-1429-P-3885-Attach-1.doc

CMS-1429-P-3885-Attach-2.pdf

Wesley E. Pittman, O.D.
President



American Optometric Association
243 N. Lindbergh Blvd. • St. Louis, MO 63141 • (314) 991-4100
FAX: (314) 991-4101

September 24, 2004

Mark McClellan, M.D.
Centers For Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 1429- P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Doctor McClellan:

The American Optometric Association (AOA) appreciates the opportunity to comment on the proposed Medicare Fee Schedule for 2005. The AOA represents more than 33,000 optometrists in the United States. Doctors of optometry are independent primary care health professionals who examine, diagnose, treat, and manage diseases and disorders of the visual system, the eye and associated structures. They are also the most accessible eye care providers in the United States, both for Medicare beneficiaries and the general population.

Clinical Conditions for Coverage of DME (Section 302)

The regulation proposes to make the face-to-face examination by the physician requirement of Section 302 of the Medicare Modernization Act an explicit requirement for all DMEPOS. For eye care providers this would apply to the very limited coverage of post-cataract eyewear. Medicare pays for only one pair of eyeglasses following each cataract surgery. Carriers have well established protocols and screens in place to reconcile eyewear claims with cataract surgery claims to assure appropriate payment. We are not aware of any data to suggest that there has been a proliferation of use of these products or that patients not entitled to them have received them. A face-to-face exam by the physician to prescribe these devices is always the case - these are post-cataract patients who require a final evaluation before eyewear can be prescribed. We would suggest that including post-cataract eyewear in the requirement is unnecessary because of present standards of care, the coverage limitations and the carrier policies already in place. Should the requirement be maintained for eyewear we believe the requirement that the prescriber be independent from the DME supplier should be clarified to allow beneficiaries to continue to obtain eyewear from the prescribing physician, who in many cases will be a supplier as well. Many patients as a matter of convenience wish to obtain

their post-cataract eyewear from the prescribing physician in his/her office. Again, there is no evidence to suggest that the current system has resulted in inappropriate payments – indeed the coverage policy and carrier protocols make such inappropriate payments virtually impossible.

Medical Malpractice Crosswalk of Specialties to Similar Specialties Assigned an ISO Code

We found it appropriate that CMS has selected a methodology of assigning an ISO code and risk class with similar physician specialties providing the same services. It certainly makes sense that optometry and ophthalmology would be a natural crosswalk.

Our organization agrees with your conclusion that malpractice liability is a product of physician specialty, level of surgical involvement and physician's malpractice history.

Equipment Items Needing Specialty Input

Regarding E71013- Computer VDT and software: Attached please find information from the Bernell Corporation. The cost for this should be $5600. The breakdown is as follows:

VISAGRAPH	$3400 (includes software and goggles)
Printer (HP)	$1200 (from CMS' Equipment List)
Monitor	$ 350
Computer	$ 650

Thank you for the opportunity to comment. If you have any questions, please contact Kelly Hipp at (703) 739-9200 or email at khipp@aoa.org.

Sincerely,

Wesley Pittman
President

Attachments

Bernell Corporation

4016 N. HOME ST. • MISHAWAKA, IN 46545-4308
(800) 348-2225 • (574) 259-2070 • FAX (574) 259-2102 OR 259-2103
www.bernell.com • E-Mail: amartin553@aol.com

The cost of the Visagraph is $3,400.00. The unit consist of the software and the goggles. A computer does not come with the unit.

Regards,
Tanisha
Bernell Customer Representative

Visagraph® III

All Reading Levels

Introducing the Visagraph® III:

The Visagraph® III is the culmination of over 70 years of eye-movement recording and reading research. The Visagraph® is the only objective measurement tool for evaluating reading efficiency (fluency). The reading characteristics that determine fluency are visual/functional proficiency, perceptual accuracy and information processing competence. These characteristics directly affect the ease and comfort with which we read and comprehend and are termed the *Fundamental Reading Process*.

Through the use of infra-red sensors, an individual's oculo-motor activity is recorded while he or she silently reads an appropriate text selection with the Visagraph® goggles. Following the reading, a brief series of questions determines whether or not the subject read with reasonable comprehension. Eye-movement characteristics are automatically analyzed, and detailed reports that provide insight as to "how" the individual reads are then generated.

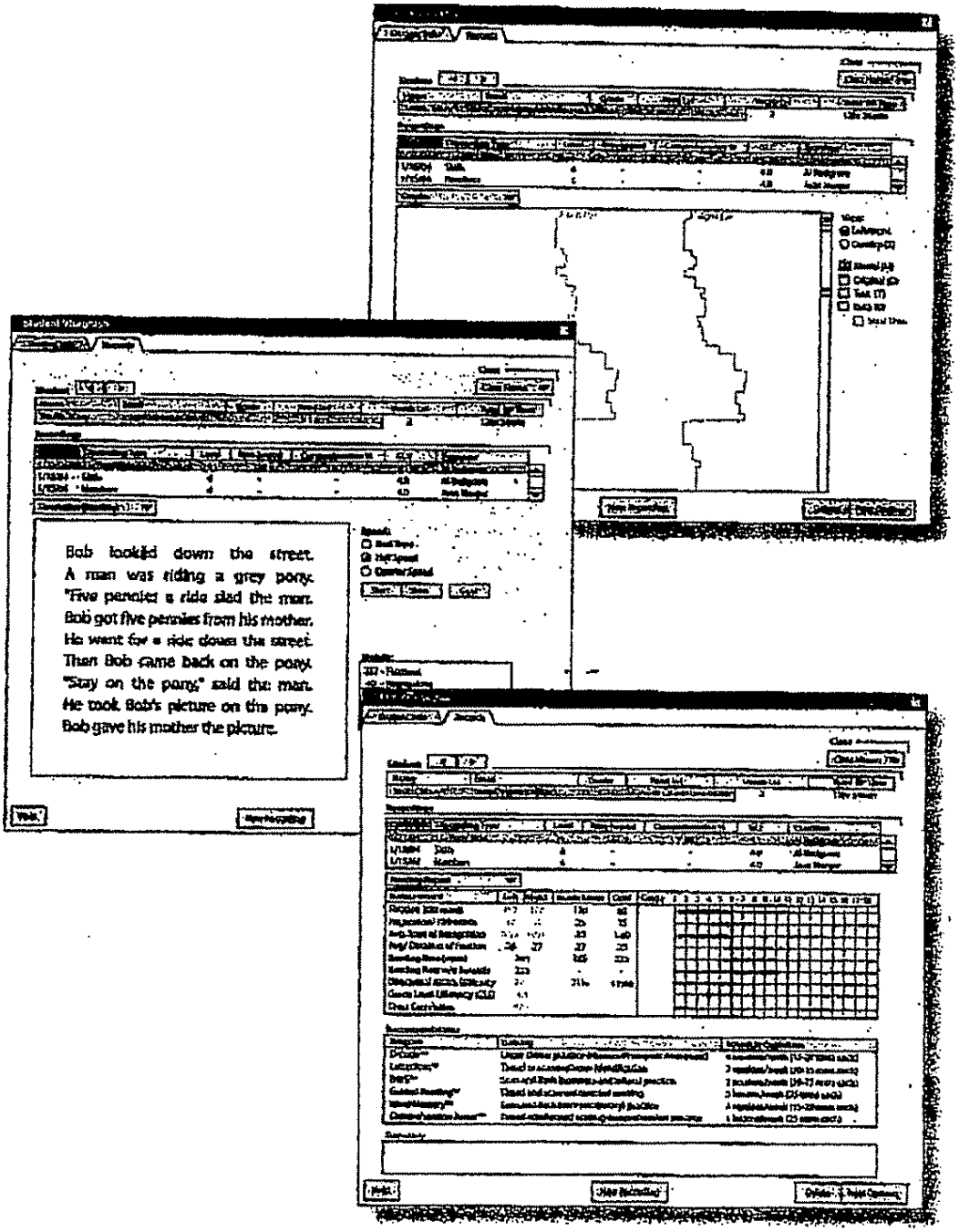
What's New?

- Refined Reporting & Management System
- Browser-Based Stand-Alone, Network and Online Delivery
- Online Data Comparison of Regional and National Norms
- Increased Signal Strength Resulting in Improved Discrimination
- Adjustable for Younger Students
- Automatic Inter-Pupilary Distance Adjustment
- Enhanced Reading and Non-Reading Simulations

Taylor Associates/Communications, Inc.
200-2 E. Second St, Huntington Station, N.Y. 11746 • (800) READ PLUS (732-3758) • Fax (631) 549-3156 • www.readingplus.com • info@readingplus.com

The Visagraph Answers the Following:

Ease and Comfort - Is reading visually coordinated and effortless?
Energy - Is reading expeditious with appropriate visual activity?
Time - Are reading tasks completed rapidly?
Comprehension - Does reading facilitate realization of syntax?
Enjoyment - Does the reading process encourage recreational reading?



CMS-1429-P-3886

Submitter : Mr. Peter Alrutz **Date & Time:** 09/24/2004 05:09:54

Organization : American Massage Therapy Association

Category : Health Care Provider/Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I respectfully request that you NOT pass this policy. That does not allow the patient's access to all qualified health care providers. Thus limiting their ability to achieve optimum health. This is not right. Nor is it cost effective. Thank you for your consideration and the opportunity to be heard.

CMS-1429-P-3887

Submitter : Dr. Jordan Cohen, MD **Date & Time:** 09/24/2004 05:09:44

Organization : Association of American Medical Colleges

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Request confirmation of my electronic comments @ cflowers@aamc.org

CMS-1429-P-3887-Attach-1.doc

September 24, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Hubert Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Attention: CMS-1429-P

Dear Dr. McClellan:

The Association of American Medical Colleges represents approximately 400 of the nation's major teaching hospitals and health systems, all 125 accredited allopathic medical schools, 96 professional and academic societies, nearly 105,000 academic physicians and the nation's medical students and residents. The AAMC appreciates this opportunity to submit comments on the *Revisions to Payment Policies Under The Physician Fee Schedule Rule for Calendar Year 2005.*

Published Changes to the Fee Schedule

The proposed rule indicates that a conversion factor (CF) update of –3.7% would occur under the Sustainable Growth Rate (SGR) if the SGR methodology were to be in place for CY 2005. Instead, a positive update of 1.5% will occur because of provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Although the physician community welcomes the positive updates of 1.5% for CYs 2004 and 2005, the gap between the CF updates and the Medicare Economic Index (MEI), projected at 2.8% for CY 2005, continues to widen. Thus, payment rate increases and medical practice cost increases are not keeping pace and the differential continues to place financial strains on physicians participating in the Medicare program.

The Medicare Trustees project that between 2006 and 2012, when the physician payment update methodology returns to the SGR, the CF will be updated by approximately –5% annually. The MEI is expected to continue to rise and to increase by an additional 19% by 2012. If action is not taken, the result of the cumulative decreases in payment, in light of the steadily increasing practice costs, will erode further the ability of physicians to maintain economic viability while serving Medicare beneficiaries.

Section 303—Covered Outpatient Drugs and Biologicals

Fundamental changes to the SGR system will require additional action from Congress. However, the Administration has the ability to take specific action in the 2005 payment rule to help address issues created by the payment methodology. Specifically, as previously requested by the physician community, CMS can remove expenditures on drugs, biologicals and changes due to law and regulations from the SGR target.

The Centers for Medicare and Medicaid Services (CMS) includes the costs of physician-administered drugs in its determinations of whether or not spending under Part B has exceeded the SGR target. Between the SGRs base year of 1996 and 2002 spending for physician administered drugs rose from $1.8 billion to $6.2 billion, an increase of 244% per beneficiary, compared to an increase of 38% per beneficiary for physician services. Thus, drugs have represented an increasing share of SGR dollars, rising from 3.8% of the total to 10.2%.

It has been argued that including drugs in the SGR was necessary to curtail over-utilization under the drug reimbursement system. However, most of the drug-related increases, in terms of both numbers of drugs and dollar expenditures, arise from use of chemotherapy and other cancer-related drugs. Due to the nature of these drugs, physicians have little discretion regarding their utilization.

Further, the MMA has eliminated such incentives, had they existed, by reducing payment rates for these drugs in an effort to bring reimbursement for actual drug costs and drug administration fees in line with physicians' actual costs.

According to the Congressional Budget Office, the uneven growth in drug-related expenditures and physician related expenditures has resulted in a target for physician services that is about one-half percent lower than it would be if drug and lab tests were not included in the SGR. In light of the advances of medical research and various efforts to support the acceleration of drug development and market readiness, it is anticipated that the number of and costs associated with physician-administered drugs will increase, thus worsening this problem under the current system.

Thus, it is requested that CMS use its administrative authority to remove drugs from the SGR system in the CY 2005 Physician Fee Schedule Rule, retroactive to the SGR base year (April 1, 1996 to March 31, 1997).

Average Sales Price

In accordance with the MMA, effective January 1, 2005, payment for many covered prescription drugs will be based on manufacturers' average sales price (ASP). It has been recommended previously that CMS provide the physician community with ASP data for all impacted drugs as soon as possible. It is recognized that this payment system transition requires considerable data gathering and analysis by CMS. However, physicians are dependent upon the results to make financial planning decisions. The original list of ASPs published by CMS as part of the 2005 proposed fee schedule included data for only 31 covered drugs and did not include drugs administered by some specialties, such as those used to treat infectious diseases.

Thus, it is requested that CMS publish a complete list of covered drugs as soon as possible. Further, drug payment rates published in the final rule should be considered interim so that CMS can update rates if further refinements to the data indicate that updates are warranted.

Section 413--Professional Shortage Areas

The MMA provides a new 5% incentive payment to physicians providing services in physician primary care and specialty care scarcity areas. These payments will be effective from January 1, 2005 to December 31, 2007. The MMA also required CMS to publish the counties identified as primary and specialty shortage areas as part of the proposed and final rules for the applicable years. The counties were not included in the CY 2005 proposed rule.

CMS is urged to publish the list of primary and specialty shortage areas as soon as possible and to make the availability of the list broadly known to the physician community.

Section 952—Revisions to Reassignment Provisions

Section 952 of MMA revises the reassignment provisions with respect to services provided offsite from the entity billing Medicare. Specifically, MMA permits independent contractor physicians or nonphysician practitioners to reassign payment for Medicare-covered services, regardless of site of service, as long as there is a contractual arrangement between the physician and nonphysician practitioner and the entity that submits the bill for those services. Previously, such reassignment arrangements were not

available for services furnished offsite from the facility or health care delivery system that submitted the bill.

Academic medical centers and other physician practices employ contract physicians and nonphysician practitioners who practice in offsite locations, such as those associated with branch campuses or in community outreach locations. This expansion of the provisions will now enable reassignment and create the ability for an academic health center to enter into consistent billing relationships with its entire workforce, regardless of employment status or practice location, thus eliminating the need for differentiated arrangements.

Section 611 – Initial Preventive Physical Examinations

Section 611 of the MMA provides a new Medicare benefit for coverage of an initial preventive physical examination for new beneficiaries. Previously, Medicare law had not allowed for payment for routine physical examinations or checkups. Accordingly, CMS had interpreted services to be excluded from coverage prior to MMA.

The MMA defines an "initial preventive physical exam" to include:

(1) a physical examination (including measurement of height, weight, and blood pressure, and an electrocardiogram, but excluding clinical laboratory tests) with the goal of health promotion and disease detection; and
(2) Education, counseling, and referral with respect to screening and other covered preventive benefits separately authorized under Medicare Part B.

In implementing this new benefit, the proposed rule sets forth additional comprehensive criteria for defining the term "initial preventive physical examination," and CMS is requesting public comment on this definition**.** It is recommended that the specifics of the exam, except as required by and stated in statute, be determined by the examining physician/provider based on the specific patient and within the parameters described under MMA. This recommendation is consistent with the recent deliberations by the Practicing Physicians Advisory Council (PPAC) at its August 30, 2004 meeting.

In billing for the new initial preventive physical exam, physicians will have to separately report the physical exam and any affiliated services provided pursuant to the exam. CMS proposes to establish a new HCPCS code, G0XX2, "Initial preventive physical examination," which includes an electrocardiogram (EKG). Other Medicare-covered preventive services would be separately reportable using the existing codes for those services. CMS proposes to assign this code a total of 3.29 relative value units in the office setting, the equivalent to the relative value units for a level three office visit plus a

complete EKG, 93000. Also as noted by PPAC at its August 2004 meeting, it would seem more appropriate to allow payment for the new visits to be commensurate with the level of service provided. The physician/practitioner will be in the best position to understand the level of service required for each individual patient, based on her/his health status, previous treatment and previous relationship with that patient. Although the proposal to provide payment commensurate with a level 3 office visit was based on review of data for a population of patients, it represents just that—a population based average, and does not necessarily correlate with the services needed by and thus billed for each patient.

Also, CMS should examine whether a new "G" code for the service is necessary, since physicians currently are allowed to use existing CPT codes with appropriate "V' diagnosis codes when billing for other existing screening tests. Covered initial preventive physical exams could be billed with the appropriate existing CPT code for preventive medicine visits (99381-99397) and an EKG code (e.g., 93000) with the appropriate "V" diagnosis code (e.g., V70.0). We encourage CMS to work within current CPT code determination processes to establish the most appropriate codes to be used for these services.

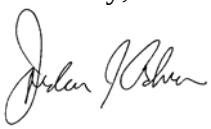
Further, CMS proposes that when the work of a problem-oriented E/M service is provided at the same encounter as the initial preventive physical exam, Medicare will only allow a medically necessary E/M service up to a level 2 (i.e., 99202 or 99212) to be reported. This proposal is based on the fact that some of the components for a medically necessary E/M visit are reflected in the new HCPCS code.

Setting a limit to the level of problem-oriented E/M service that physicians may bill when this work is performed in conjunction with an initial preventive physical examination is problematic. This cap suggests that patient will only present with self-limited or minor problems (established patients) or problems of low to moderate severity (new patients). In light of the multi-system/chronic conditions that afflict many Medicare beneficiaries, it seems unlikely that all beneficiaries will present with such low-levels of severity. Physicians are able to report a problem-oriented E/M service in conjunction with a preventive medicine service without regard to the level of problem-oriented E/M service. It is urged that CMS follow current CPT practice in this regard.

Finally, as discussed above, it is strongly urged that CMS not include expenditures for these new benefits required by law and regulation in future calculations of the SGR.

The AAMC appreciates the opportunity to comment on the proposed rule. Please do not hesitate to contact me or my staff (Robert Dickler or Denise Dodero at 202-828-0490) if we can be of assistance.

Sincerely,



Jordan J. Cohen, M.D.

Cc: Robert Dickler
Senior Vice President

Denise Dodero
Associate Vice President

Submitter : Ms. Elizabeth Osterkamp **Date & Time:** 09/24/2004 05:09:08

Organization : Ms. Elizabeth Osterkamp

Category : Other Health Care Provider

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

All qualified practitioners, including massage therapist, should be allowed as part of a patients healthcare team.

CMS-1429-P-3889

Submitter : Ms. Heidi Baker **Date & Time:** 09/24/2004 05:09:51

Organization : Ms. Heidi Baker

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I OPPOSE Medicare's propsed policy to eliminate any providers except PT's from providing "incident to" medical professional's services to patients. Massage Therapists should have the right to work with or for medical doctors or chiropractors.
Before passing this bill, please so some research on the benifits of massage. Educate yourself about massge therpay and different types of bodywork. Talk to those who have experienced the benifits of these healing techniques.
Massage Therapy can has a wide range of benifits. It can be a good way to relieve the body of stress which can prevent major health issues caused by stress. Massage can also address, heal and prevent specific injury.

CMS-1429-P-3890

Submitter : Mr. Kenneth Robinson **Date & Time:** 09/24/2004 05:09:48

Organization : Mr. Kenneth Robinson

Category : Academic

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

massage therapy from non PTs

Submitter : Carolyn Hottle **Date & Time:** 09/24/2004 05:09:03

Organization : Nlt. Certification Board for Therapeutic Massage

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I think that you are being very short-sighted to limit physician referrals only to Physical Therapists. Licensed Massage Therapists are qualified to treat patients with soft tissue injuries and muscle pain. Please reconsider your change in policy. Thank you.

Submitter : EVelyn Gray **Date & Time:** 09/24/2004 05:09:16

Organization : EVelyn Gray

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do not pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter : Mr. Reed Trettin **Date & Time:** 09/24/2004 05:09:49

Organization : Progressive Rehabilitation Associates, L.L.C.

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Via Electronic Mail -- http://www.cms.hhs.gov/regulations/ecomments

Reed Trettin, LAT
Progressive Rehab. Assoc., L.L.C.
2401 Towncrest Drive
Iowa City, IA 52240

September 24, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012
Re: Therapy ? Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of ?incident to? services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.
During the decision-making process, please consider the following:

? Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician?s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician?s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
? Patients who would now be referred outside of the physician?s office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, cost the patient in time and travel expense. Delays would hinder the patient?s recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
? To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide ?incident to? services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide ?incident to? care in physicians? offices would improperly remove the states? right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
? CMS does not have the statutory authority to restrict who can and cannot provide services ?incident to? a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
? Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
? Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes

injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.
? These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Reed Trettin, LAT

CMS-1429-P-3894

Submitter : Miss. Diana Torres **Date & Time:** 09/24/2004 05:09:26

Organization : Miss. Diana Torres

Category : Academic

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dear CMS,
My name is Diana Torres and I am attending the graduate entry level Doctor of Physical Therapy program at U.M.D.N.J. I am writing this letter to share my sentiments about the ?Therapy-Incident To proposal.? I am in full support of the proposal because we as physical therapists are taught an enormous amount of knowledge in kinesiology and musculoskeletal theory. Where as physicians are taught pathophysiology, and physiology of the organ systems. I am not saying that they do not have any education on muscle and movement theory, I am just saying that we as physical therapy majors are more qualified in education when it comes to those theories because we are specialized in muscle performance and movement function. We are also taught how to correct impairment and functional limitations through therapeutic exercise activities, whereas physicians are not taught therapeutic exercise in their curriculum. If this proposal is put into effect than we as a physical therapy community are guaranteed to have a permanent profession as an autonomous health care provider. I do not know what ramifications against our profession and the patient population await if this proposal is not passed, and that is what most concerns me. I wish you luck on your endeavors to put this proposal into action. If there is any other way I can get involved in this process please let me know.

Sincerely,

Diana Torres, SPT

CMS-1429-P-3895

Submitter : Mr. David Tomkalski **Date & Time:** 09/24/2004 05:09:04

Organization : Elmira College

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician offices and clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

(see attached file)

CMS-1429-P-3895-Attach-1.doc

Via Electronic Mail – http:// www.cms.hhs.gov/regulations/ecomments

David Tomkalski, ATC
Elmira College
One Park Place
Elmira, NY 14901

September 22, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Therapy–Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician offices and clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- For the past 25 years I have been taking care athletes injuries at all levels including professional, college, high school, Olympic class and recreational. While working in a sports medicine/physical therapy clinic I was asked to work with workmen comp cases and elderly patients. I was never questioned on my knowledge or capabilities and I find it appalling that my profession and I am being questioned now.

- "Incident to" has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY "incident to" service. Because the physician accepts legal responsibility for the individual under his or her supervision,

Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. *It is imperative that physicians continue to make decisions in the best interests of the patients.*

- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.

- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.

- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.

- Athletic trainers are highly educated health care professionals as recognized by the AMA. ALL certified or licensed athletic trainers *must have a bachelor's or master's degree* from an accredited college or university. Seventy (70) percent of all athletic trainers have a master's degree or higher. This great majority of practitioners who hold advanced degrees is comparable to other health care professionals, including physical therapists, occupational therapists, registered nurses, speech therapists and many other mid-level health care practitioners. Academic programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) via the Joint Review Committee on educational programs in Athletic Training (JRC–AT). Athletic trainers must also complete a continuing education requirement of 80 hours in a three-year period in order to keep their credentials active.

- To allow *only* physical therapists, occupational therapists, and speech and language pathologists to provide "incident to" outpatient therapy services would improperly

provide these groups exclusive rights to Medicare reimbursement. To mandate that only these practitioners may provide "incident to" outpatient therapy in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

- CMS, in proposing this change, offers no evidence that there is a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.

- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. *In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of therapy services.*

- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.

- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, athletic trainers are hired by the USOC to provide coverage for the athletes that compete in international competition. NASCAR, the rodeo circuit, the PGA, NASA, the auto industry and many other institutions interested in the health of their athletes and employees also hire athletic trainers. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of walking in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

- Before CMS makes this very important decision and succumb to lobbyists for health care professionals interested in monopolizing health care, it should send people out into the field to witness first hand the quality of athletic trainers work. I am positive that after seeing the quality of care provided, you would table this proposal.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

CMS-1429-P-3896

Submitter : Mr. Michael Monteiro **Date & Time:** 09/24/2004 05:09:24

Organization : Rhode Island Athletic Trainer's Association

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Please see attached Word Document.

CMS-1429-P-3896-Attach-1.doc

CMS-1429-P-3896-Attach-2.txt

Attachment # 3896 (1 of 2)

September 24, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Sir or Madam:

I am writing to express my concern over the recent proposal that would limit providers of "Therapy-incident to" services in physician offices and clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service, placing an undue burden on the health care system. During the decision-making process, please consider the following:

"Therapy-incident to" has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including Certified Athletic Trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical sub-specialty and individual patient.

There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY "incident to" service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.

To allow only Physical Therapists, Occupational Therapists, and Speech Pathologists to provide "incident to" outpatient therapy services would improperly provide these groups exclusive rights to Medicare reimbursement. To mandate that only these practitioners may provide "incident to" outpatient therapy in physicians' offices would improperly remove the right of each state to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

CMS, in proposing this change, offers no evidence that there currently exists a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider

of therapy services.

CMS does not have the statutory authority to create any restrictions as to who can and cannot provide services incident to a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of therapy services.

Independent research has demonstrated that the quality of services provided by Certified Athletic Trainers is equal to the quality of services provided by physical therapists.

Athletic Trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. For CMS to even suggest that Athletic Trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured while participating in a local 5K race and solicits their local physician for treatment is outrageous and unjustified.

These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients accepted.

In summary, it is not necessary, or advantageous, for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Michael A. Monteiro, MS, ATC, CSCS
Loss Prevention Ergonomic Consultant
Beacon Mutual Insurance Company
One Beacon Centre
Warwick, RI 02886

Attachment #3896 (2 of 2)

September 24, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Sir or Madam:

I am writing to express my concern over the recent proposal that would limit providers of "Therapy-incident to" services in physician offices and clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service, placing an undue burden on the health care system. During the decision-making process, please consider the following:

"Therapy-incident to" has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including Certified Athletic Trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical sub-specialty and individual patient.

There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY "incident to" service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.

To allow only Physical Therapists, Occupational Therapists, and Speech Pathologists to provide "incident to" outpatient therapy services would improperly provide these groups exclusive rights to Medicare reimbursement. To mandate that only these practitioners may provide "incident to" outpatient therapy in physicians' offices would improperly remove the right of each state to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

CMS, in proposing this change, offers no evidence that there currently exists a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.

CMS does not have the statutory authority to create any restrictions as to who can and cannot provide services incident to a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of therapy services.

Independent research has demonstrated that the quality of services provided by Certified Athletic Trainers is equal to the quality of services provided by physical therapists.

Athletic Trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. For CMS to even suggest that Athletic Trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured while participating in a local 5K race and solicits their local physician for treatment is outrageous and unjustified.

These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients accepted.

In summary, it is not necessary, or advantageous, for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Michael A. Monteiro, MS, ATC, CSCS
Loss Prevention Ergonomic Consultant
Beacon Mutual Insurance Company
One Beacon Centre
Warwick, RI 02886

CMS-1429-P-3897

Submitter : Ms. Carmece Cunningham **Date & Time:** 09/24/2004 05:09:03

Organization : TX State University-San Marcos PT Prg

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see my attachment in that a letter has been written to CMS.

Thanks,
Carmece Cunningham, SPT

CMS-1429-P-3897-Attach-1.doc

September 23, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Therapy-Incident to Mr. McClellan:

My name is Carmece Cunningham, and I am currently a 2nd year physical therapy student at Texas State University-San Marcos. May 2005 I will be graduating from the program. After graduating, I will be practicing in either an orthopedic or acute physical therapy setting in either the Dallas or Houston metroplex.

The proposed rule made on August 3, 2005, "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005," denotes a critical dilemma in providing healthcare services to patients. The assimilation of providing physical therapy services in physician's offices is not an accountable nor ethical trait. Although physicians are quite skilled, these individuals do not undergo the extensive training in joint mobilizations, muscle insufficiencies, neuropathies, and electrical modalities. Physical therapists are trained to specialize in these areas for over 24 months. We are accredited by the Commission on Accreditation of Physical Therapy and the value of a licensure to practice PT is essential. As of 2002, the minimum education requirement to become a physical therapist is obtaining a master's degree, and in 2005 the majority of physical therapy programs will encompass the doctor of physical therapy degree (DPT).

Do you feel it is ethical that the future patients will be undergoing treatment sessions by unskilled personnel? If a physician performs a modality on a patient, ultrasound for example, he or she has not been taught the correct parameters i.e. frequency and duration, to perform a sound wave based modality. It is a risk that the physician could potentially harm the patient. Not knowing when to use thermal versus non-thermal effects for this particular modality can hinder progression of rehabilitation. The impact of healthcare is that all of the guided principles that each physician and practitioner will exhibit can be in summoned to question in the future. On the contrary, physical therapists have undergone at least four months of modality training to know the benefits as well as contraindications of each modality.

Thank you for your time and I hope you consider the moral and ethical impact CMS can make in withstanding this matter.

Sincerely,

Carmece Cunningham, SPT

CMS-1429-P-3898

Submitter : Dr. Matt Booth **Date & Time:** 09/24/2004 05:09:08

Organization : Idaho Physical Therapy Association

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012
Subject: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

Dear Dr. McClellan:

My name is Matt Booth. I am a physical therapist in Boise, Idaho, where I run a private outpatient physical therapy clinic. I have been in practice for over six years as a physical therapist. My education was from the University of Southern California with a bachelor's degree in Exercise Science, and a Doctorate degree in Physical Therapy. Not only am I writing to you as a private practitioner of physical therapy, but also as the legislative chair of the Idaho Physical Therapy Association. I am writing to you about the 'Therapy-Incident To' policies.

I wish to comment on the August 5 proposed rule on 'Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.' I strongly support CMS's proposed requirement that physical therapy services furnished in a physician's office be provided by graduates of accredited professional physical therapy programs. Physical therapists (PT's) and physical therapy assistants (PTA's) are the only practitioners who have the education and training to provide physical therapy services. Unqualified personnel should not be providing physical therapy services. I have treated many patients who have been seen at a physician's office and received what they were told was 'physical therapy' that turned out to be ultrasound or electrical stimulation provided by an office aide. I later treated these patients when they did not reach their functional goals, and they all have expressed that they thought physical therapy only consisted of ultrasound and electrical stimulation. They had no idea that they were missing out on valuable evaluation and assessment of their entire condition, to include range of motion measurements, joint mobility testing, sensation testing, and strength testing, to name a few. Once their treatment plan was put together and implemented, these patients have made dramatic improvement with appropriate manual mobilization of joints, and appropriate strengthening and stretching exercises. I fear that many patients are not receiving the care they need, and are led to believe that physical therapy is an unskilled profession when they receive 'physical therapy' from an unqualified aide in a physician's office.

Physical therapists are highly educated, receiving at minimum a post-baccaulaureate degree as of January, 2002. The majority of physical therapy programs will offer a doctor of physical therapy (DPT) degree by 2005. Physical therapists receive significant training in anatomy, kinesiology, physiology, and are uniquely positioned to analyze body movement patterns to develop and implement plans to improve function in individuals with impairments, disabilities, and handicaps.

Thank you for consideration of my comments. I hope you will maintain the proposed rules as written on August 5, 2004 for Medicare 'Incident To' Physical Therapy Services.

Sincerely,

Matt Booth, DPT, OCS

Submitter : Mrs. Gina Abraham **Date & Time:** 09/24/2004 05:09:41

Organization : Vascular Center of Wichita Nephrology Group

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

RE: RVUS FOR CPT CODE 36870-PERCUTANEOUS THROMBECTOMY

I am greatly concerned that in the newly proposed fee schedule the Non-Facility RVUs for the the abovementioned code have been reduced from 46.98 to 32.39. This is a total reduction of 27.7%. Work RVUs are unchanged and malpractice RVUs increased slightly.

There is nothing that has happened in the past year that reduced the costs associated with performing a declot in an office setting. We are still faced with significant costs associated with equipment and supplies in these technically difficult procedures performed on chronically ill dialysis patients.

Dialysis patients need a dedicated angographic suite with Fluoroscopic unit along with supplies and dedicated, trained staff.

Dialysis patients require a working AV access in order to receive their life saving treatments. Unfortunately, these accesses clot and patients cannot dialyze until a declot is performed. An office dedicated to dialysis patients is able to perform the declot, and have the patient successfully dialyzing the same day. This is much more efficient and economical than any acute setting.

A review of the practice expense files show no major difference between 2004 and 2005 calculations. Therefore, we are requesting a review of the input files and formally request that the RVUs be adjusted prior to the final rule.

We would be happy to provide documentation on the more than 15,000 declots our managed centers have performed over the past few years.