CMS-1429-P-3900

Submitter : **Ms. Robin Swanigan** **Date & Time:** **09/24/2004 05:09:06**

Organization : **Regis University**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dr. McClellan,
My name is Robin Swanigan and I am currently a student of the Doctor of Physical Therapy program at Regis University in Denver, CO. I will be graduating and beginning practice in May of 2005. My experience has been as a student both in outpatient and inpatient settings where I have participated in the rehabilitation of various patient populations.
I am writing in regards to the August 5 proposed rule on ?Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.? I strongly support the CMS?s proposed requirement that any person delivering therapy services should be a graduate of an accredited professional physical therapy program. Physical Therapy is a profession and a service like any other area of medicine, such as Cardiologist, General Practioners, Internists, as well as many others. This profession requires licensure in order to practice as well as an extensive education. This education emphasizes anatomy and physiology, biomechanics, musculoskeletal, neurology and evaluation of all of these areas. Physical therapists have completed comprehensive patient care experience, which along with the education received enables physical therapists to achieve positive outcomes for individuals with disabilities and other conditions needing rehabilitation. This education is particularly important when treating Medicare beneficiaries. Physical therapists must be licensed in the states where they practice. As a licensed health care provider, physical therapists are fully accountable for their professional actions. Licensure is imperative to this profession, as well as any other healthcare profession, in order to attain a level of standard of service that is above what any other person is able to provide. Accredited physical therapists and physical therapy assistants, under the supervision of a physical therapist, are experts in the area of rehabilitation and therapy services and so should be the only profession able to bill for these services.
The delivery of so-called ?physical therapy services? by unqualified personnel is harmful to the patient. Without the appropriate education and knowledge of rehabilitation a person would be delivering healthcare outside their scope of practice. One would not seek a cardiologist for a middle cerebral artery aneurysm, in the same respect; one should not seek any other profession than physical therapy for their therapy and rehabilitation needs. A cardiologist specializes in ailments of the cardiovascular system, a neurologist specializes in ailments of the nervous system and a physical therapist specializes in ailments of the musculoskeletal and neuromuscular systems. It is a form of malpractice to practice anywhere outside the scope of your profession.
A financial limitation on the provision of therapy services 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 due to the fact that their ?therapy? services were rendered by an individual who is not accredited or educated in the profession of physical therapy.
I will close with this; 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 program.

I would like to thank you for your time and consideration of my comments. I hope that you will be able to understand my position on this matter. Again, thank you.

Sincerely,

Robin Swanigan, SPT
Regis University
Rueckert-Hartman School for Health Professions
Dept. of Physical Therapy
Mail Code G-4

CMS-1429-P-3901

Submitter : **jeff schmidt** **Date & Time:** **09/24/2004 05:09:36**

Organization : **jeff schmidt**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 23, 2004

Mark B. McClelland, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1429
PO Box 8012
Baltimore, MD 21244-8012

RE: Medicare Program: Revision to Payment Policies under the Physician Fee Schedule of Calendar Year 2005 ? Therapy Incident ? To.

Dear Mr. McClellan:

As a physical therapist, I am writing in regard to the proposed rules of Revisions to Payment Policies under the Physician Fee Schedule of Calendar Year 2004 and in particular the section related to Therapy Incident ? To. I have practiced as a physical therapist in North Dakota for nearly 14 years in a variety of settings. I currently work in a hospital outpatient setting. My case load here includes a large number of Medicare Beneficiaries.

I strongly support CMS establishing the requirement that individuals providing physical therapy services within physician offices be qualified. Physical therapists and physical therapy assistants under a physical therapist?s direction, are the only practitioners who are educated and trained to provide such services.

Physical therapists receive their education at colleges and universities. Physical therapy programs must be accredited by the Commission on Accrediation of Physical Therapy (CAPT). All of these programs offer a master?s degree in physical and by 2005, the majority will offer a doctor of physical therapy (DPT). Physical therapists must be licensed within their practicing state.

Physical therapists are trained to evaluate and treat individuals with a variety of movement impairments. They are able to recognize how various medical conditions may affect an individual?s rehabilitation program and are able to adjust and progress their program appropriately. This education and training is particularly important when treating Medicare beneficiaries who are most likely to have a complicated medical history.

When physical therapy is delivered by unqualified personnel there is a much greater potential for harm to the patient. Treatment will be less cost effective because these personnel would lack the assessment skills necessary to make treatment individualized, functional and progressive.

Requirements for outpatient physical thearpy services should be consistent in every setting. That is, services must be performed by individuals who are graduates of accredited professional physical therapy education programs.

Thank you for considering these comments.

Sincerely,

CMS-1429-P-3902

Submitter : **Mr. William Chapin** **Date & Time:** **09/24/2004 05:09:38**

Organization : **Chapin and Havlicek physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Please forward to:
Mark B. McClellan, MD, PhD
Administrator, Centers for medicare and Medicaid Services
Department of Health and Human Services

Attn: CMS-1429-p

I am in strong support of the CMS proposal that individuals who furnish outpatient physical therapy services in physicians offices must be graduates of an accredited professional physical therapy program. Physical therapists and physical therapist assistants under the supervision of a physical therapist are the only caregivers who have the comprehensive requisite training in pathology , anatomy, physiology, biomechanics, modalities, patient evaluation and specialty techniques to provide physical therapy services to patients.

In particular, the education and training physical therapists vs other unqualified individuals allows for physical therapists (and PT assistants) to treat patients most thoroughly and safely with maximal potential benefit and minimal risk to the patient.

Therefore it is critical that the final ruling on this must contain the language "incident to" such that only qualified Physical Therapists (and PT assistants working under the supervision of a physical therapist) be covered under this ruling for the provision of physical therapy services.

Thank you for your consideration on this extremely important matter.

William Chapin, Physical Therapist
46 Prince Street, suite 402B
New Haven, CT 06519
203-752-7878
chapin.havlicek.pt@snet.net

CMS-1429-P-3903

Submitter : **Mr. Patrick Cummings** **Date & Time:** **09/24/2004 05:09:26**

Organization : **Ohio City Orthopaedics**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Patrick Cummings

280 Brookside Blvd.

Hinckley, Ohio 44233

9/23/04

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

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

Patrick Cummings

280 Brookside Blvd.

Hinckley, Ohio 44233

9/23/04

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. 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,

Patrick Cummings ATC/PTA

280 Brookside blvd.

Hinckley, Ohio 44233

CMS-1429-P-3904

Submitter : **Joseph M. Savoia** **Date & Time:** **09/24/2004 05:09:33**

Organization : **Joseph M. Savoia**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See attachment

CMS-1429-P-3904-Attach-1.doc

Joseph M. Savoia
331 Hillside Ave
Atlantic Highlands, NJ 07716

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,

Joseph M. Savoia, ATC

331 Hillside Ave

Atlantic Highlands, NJ 07716

CMS-1429-P-3905

Submitter : **Ms. Krista Hilton** **Date & Time:** **09/24/2004 05:09:45**

Organization : **Ms. Krista Hilton**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Krista Hilton
2323 Druid Oaks NE
Atlanta, GA 30329

Dear CSM:

I am submitting a letter regarding the proposal 1429-P. I do not support this proposal.

Sincerely,

Krista Hilton, M.Ed.

CMS-1429-P-3905-Attach-1.wpd

Krista Hilton
2323 Druid Oaks NE
Atlanta, GA 30329

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

Sincerely,

Krista Hilton, M.Ed.

CMS-1429-P-3906

Submitter : **Dr. Thomas Bensinger** **Date & Time:** **09/24/2004 05:09:53**

Organization : **Hematology Oncology Consultants**

Category : **Physician**

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

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

RE: CMS-1429-P

Dear Dr. McClellan:

As a hematologist who treats patients with chemotherapy and other pharmaceutical treatments in my office, I write to comment on the proposed revisions to the physician fee schedule for 2005. I am particularly concerned that in the proposed rule, CMS fails to provide hematologists and other physicians affected by the Average Sales Price (ASP) methodology with clear and reliable information upon which to make decisions about our practices for 2005 and beyond.

Section 303-Outpatient Drugs and Biologicals

I am seriously concerned that CMS has not provided affected physicians with the opportunity to comment on the proposed payment allowances for drugs in 2005. CMS has identified tentative payment allowances for only a handful of drugs omitting many of the drugs commonly used by hematologists. Why has CMS not at least provided tentative prices for all of the covered Part B drugs. If, in fact, the complexity of the calculation of ASP is the reason why data was provided only for a few drug products, it is all the more reason why comments from affected physicians are necessary. Moreover, for the limited number of drugs provided, the prices do not reflect the data for the actual period that will be used to calculate the ASP rate; i.e., the 3rd quarter of 2004 but reflects data for an earlier period.

As CMS notes in the rule, drugs constitute a very significant portion of the revenues received by oncologists, in the range of 70 percent. This would include hematologists with large oncology practices. The inability to evaluate and comment on the adequacy of the proposed payment level prior to implementation of the changes January 1, 2005, is a major deficiency of the rule. What business can possibly operate in that kind of environment? Not knowing what will be paid for the majority of our services makes it virtually impossible for a practice to plan ahead. Physicians will not truly know (1) if they can afford to continue to provide chemotherapy to Medicare patients in an office setting, (2) to what extent they will need to reduce staff, close satellite offices, etc., and (3) whether they will need to change their purchasing practices, including possibly referring patients to hospitals for these services or buy the drugs on their own and bring them to the office.

Based on a review of the hematology-related drugs for which estimated ASP prices were provided, I am concerned about my practice?s ability to continue to provide all needed drugs to patients. Although I use a group purchasing organization to buy drugs, there are several drugs for which I am currently paying more than the estimated ASP. It appears that CMS is basing the ASP rate on the sales data reported by manufacturers without regard to whether the product was sold to a hospital or other large purchasing group. I understand that the Congress believes that the ASP rate should reflect the prices actually paid by practicing physicians and that the 6% increment was adequate to cover the variability in the prices paid plus other costs such as inventory costs and wastage. Unfortunately, based on my review of the ASP prices, the proposed payment rate is clearly inadequate.

I urge CMS to delay the implementation of the ASP system for at least one year. CMS needs to develop ASP data that reflects the amounts

actually paid by physicians for drugs. And, before the system is finally implemented, CMS needs to provide physicians with the opportunity to comment on the proposed payment rates for the drugs that are covered under this system.

Sincerely yours,

Thomas A. Bensinger, M.D., FACP

CMS-1429-P-3907

Submitter : **Ms. Rita Haney** **Date & Time:** **09/24/2004 05:09:01**

Organization : **Massachusetts General Hospital**

Category : **Individual**

Issue Areas/Comments

Issues 1-9

CODING-GLOBAL PERIOD

The MGPO believes that implementation of a ninety-day global period for radiation treatment management is feasible as long as the global period only applies to the services provided by the radiation oncologist and not to any other specialists such as the patient?s oncologist. Both the radiation oncologist and the oncologist are an important part of the care team and are part of the same group practice in large multispecialty groups. Denying the services provided by the patient?s oncologist during the global period is unacceptable as both physicians are appropriately treating separate components of the diagnosis

SECTION 611

The concept of a ?Welcome to Medicare? visit is a good one, but we are concerned that the proposed reimbursement structure for that visit will not support CMS goals.

The goal of improving access for seniors to high quality care and recommended preventive services cannot be met within the confines of a visit that is reimbursed at a level equivalent to a 99203 visit. To accomplish all of the required components of the preventive visit in 30 minutes -- including an informed discussion of the preventive services recommended by the U.S. Preventive Services Task Force -- is unrealistic. America?s seniors deserve a thoughtful review of their preventive care options and the opportunity to make informed decisions. Unfortunately, the short duration of the visit afforded by the proposed reimbursement, and the documentation that must accompany it, could make it more difficult to provide these services rather than improving access.

We also believe that CMS?s approach to implementing the new G code should be cognizant of the healthcare needs of America?s seniors. Although some new Medicare patients are healthy and do not have chronic or acute medical conditions, our experience shows that this tends to be the exception rather than the rule. More often than not, Medicare patients have several medical problems that they want to address at a single physician visit. For many of them, the ?Welcome to Medicare? visit will serve as a valued opportunity not only to address their preventive needs, but their acute and chronic care needs as well. We suggest that this reality should be acknowledged and that there be no limit on the code for problems outside the preventive visit.

The current proposal, which would limit the code to a 99211 or a 99212, fails to cover the level of treatment needed for patients with more complex issues. As a result, it is likely that our seniors will either have their preventive needs addressed or their acute and chronic needs addressed in any given visit rather than achieving the CMS goal of integrating all aspects of care.

After much analysis, the MGPO believes that the proposed RVU calculation of 3.29 for the new G code is inadequate. The amount of face-to-face time spent with a patient would exceed the 30 minutes described in the benefit. We believe that CMS should reconsider the value it has placed on these visits and ensure that expectations and reimbursement are appropriately aligned.

In addition, we believe that the inclusion of the EKG service in the new code is problematic. The RVU calculation does not take into account the amount of time needed with a patient to develop, write and review a plan for appropriate screenings nor does it recognize that some practices do not provide and interpret EKG services in their offices. If a provider does not perform all the required services including the EKG would this now make a practice ineligible to provide treatment to Medicare beneficiaries? That could be one interpretation of the proposed regulation, which does not seem to be consistent with the CMS goals.

If implemented, the proposed regulation also raises several operational issues:

? How will CMS identify the Medicare beneficiaries who are eligible for this new service? Only CMS can accurately determine eligibility. Information about new beneficiaries is not currently shared with providers. CMS needs to work with providers to ensure that all eligible Medicare beneficiaries can take advantage of these new services.
? How will a provider know that a beneficiary has not already received this service from another provider?

? Beneficiaries have six months from the time they become eligible to receive this benefit. If the service is not performed within that time, who is responsible

CMS-1429-P-3908

Submitter : **Paul Rockar** **Date & Time:** **09/24/2004 05:09:38**

Organization : **Paul Rockar**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

My comments are contained in the attached letter.

CMS-1429-P-3908-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: 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 Paul Rockar and I have been a physical therapist for the past 29 years. I am currently the CEO of a certified rehabilitation agency in Pennsylvania. We employ over 180 physical therapists and treat numerous Medicare clients across the continuum of care.

The purpose of this letter is to comment on the "Therapy-Incident To" provision contained in the proposed revisions to payment policies under the Physician Fee Schedule for calendar year 2005. I strongly support the proposed requirement that physical therapists working in physician's offices be graduates of accredited professional physical therapist programs. 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 requirement for outpatient therapy services in all settings. The requirement is straightforward: the physical therapy services must be performed by an individual that is a graduate of an accredited professional physical therapy education program. An "on-the-job" training program or training in other professions is inadequate.

I would like to expand upon the education and training of a physical therapist. Physical therapists are professionally educated at the college or university level in programs accredited by the Commission on Accreditation of Physical Therapy, an independent agency recognized by the U.S. Department of Education. Since January of 2002 the minimum education requirement to become a physical therapist is the post-baccalaureate degree and by 2005 the majority of programs will have moved to the Doctor of Physical Therapy degree. The curriculum includes extensive training in the basic sciences, physical therapy evaluation and intervention techniques, and requires the completion of a comprehensive patient care experience. These individuals have the necessary background to effectively and efficiently provide physical therapy services.

There are additional reasons unqualified personnel should not be providing physical therapy services. Physical therapists must be licensed in the states where they practice. The physical therapy practice act of the jurisdiction defines physical therapy, the scope of practice, and holds the licensee accountable for their professional actions. Practice acts illustrate that it is not appropriate for services provided by unlicensed technicians to be classified as physical therapy. A ruling of the Supreme Court of Pennsylvania provided evidence of this in November of 2000. In this decision the Supreme Court ruled that the Southeastern Pennsylvania Transportation Authority was not responsible for the cost of physical therapy care provided by unlicensed providers since it did not meet the standards established by the Pennsylvania Physical Therapy Practice Act (Kleinberg v. SEPTA).

Although current law prevents CMS from requiring licensure, this would be the best method to insure Medicare beneficiaries are receiving appropriate care. This is especially critical in that the fact the financial limitation on the provision of therapy services (the therapy cap) is scheduled to become effective January 1, 2006. Unless the provision on "incident to" is changed a Medicare beneficiary could exceed the therapy cap without ever receiving services from a physical therapist. The Medicare beneficiary could then be faced with the decision of paying out of pocket for physical therapy services that are provided by unlicensed technicians. In light of this fact CMS has the fiduciary obligation to the Medicare beneficiaries to require that physical therapy services are provided by qualified personnel.

Thank you for the opportunity to provide these comments for your consideration. Please feel free to contact me at (412) 673-6660, ext 215, or at rockarp@upmc.edu

Sincerely,

Paul Rockar, PT, MS

CMS-1429-P-3909

Submitter : **Mr. Timothy Brinker, PT** **Date & Time:** **09/24/2004 05:09:35**

Organization : **Therapeutic Associates Hillsboro Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 10-19

THERAPY ASSISTANTS IN PRIVATE PRACTICE

I wish to comment on the August 5 proposed rule on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. In the proposed rule, CMS discusses establishing requirements for individuals who furnish outpatient physical therapy services in physician's offices. I support CMS's proposal in the rule that establish these standards for personnel providing physical therapy services in physicians'offices.

I have had the expeience treating patients where the care provided at the physician office has been inappropriate for the condition which was presented. In this situation the exercises prescribed were not appropriate for the condition presented. In addition, I have treated patients were the utilization of modalities in the physician office were the only form of treatment. The use of modalities only, in these situations, where there was a mechanical problem will not resovle the problem exclusively. In both situations, the services were provide by support staff whom were unlicensed.

I strongly support that the application of physical therapy services is from licensed personel regardless of the setting.

Thank you for your consideration.

Sincerely,

Timothy Brinker, PT, OCS, COMT
Therapeutic Associates, Hillsboro Physical Therapy
5880 NE Cornell RD Ste C
Hillsboro OR 97124
503-844-9294

CMS-1429-P-3910

Submitter : **Annette Champo** **Date & Time:** **09/24/2004 05:09:21**

Organization : **Annette Champo CLMT/ASH Network**

Category : **Health Care Provider/Association**

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-3911

Submitter : **Dr. Matthew Levy** **Date & Time:** **09/24/2004 05:09:47**

Organization : **Ohio City Orthopaedics**

Category : **Physician**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dr. Mathew Levey

Ohio City Orthopedics

1730 W25th

Cleveland, Ohio 44113-3170

9/23/04

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

CMS-1429-P-3912

Submitter : Mr. **Date & Time:** 09/24/2004 05:09:40

Organization : Mr.

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am an Athletic trainer who works alongside PT's. I am astounded that they do not particpate in CEU which is intergral to the development of knowledge. The people who I work with really know their stuff, but we work in the same clinic, doing the same service, and should have the same opportunity with medicare/medicaid patients. It has to be all about the patient, and how can we offer them care

CMS-1429-P-3913

Submitter : **Dr. William Bohl** **Date & Time:** **09/24/2004 05:09:08**

Organization : **Ohio City Orthopaedics**

Category : **Physician**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dr. Mathew Levey

Ohio City Orthopedics

1730 W25th

Cleveland, Ohio 44113-3170

9/23/04

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

CMS-1429-P-3914

Submitter : **Mrs. Jo-Ann Badar** **Date & Time:** **09/24/2004 05:09:07**

Organization : **Mrs. Jo-Ann Badar**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document

CMS-1429-P-3914-Attach-1.txt

Attachment # 3914

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,

Jo-Ann Badar, M.Ed, ATC
22150 Macbeth Ave
Fairview Park, OH 44126

CMS-1429-P-3915

Submitter : **Mrs. Sally Schepper** **Date & Time:** **09/24/2004 05:09:46**

Organization : **Decatur Memorial Hospital**

Category : **Physical Therapist**

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.

I have had the privelege of working with many ATC's who are highly skilled with orthopedic injuries.
Sincerely,

Sally Schepper
144 N. Westdale Pl
Decatur, IL 62522

CMS-1429-P-3916

Submitter : **Dr. Nina Antoniotti** **Date & Time:** **09/24/2004 05:09:45**

Organization : **Marshfield Clinic**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Commenting on TeleHealth

CMS-1429-P-3916-Attach-1.doc

MARSHFIELD CLINIC TELEHEALTH NETWORK
Medicare Program; Revision to Payment Policies
Under the Physician Fee Schedule for Calendar Year 2005

File Code: CMS-1429-P : Coding TeleHealth

The following comments are submitted in accordance with the published guidelines in the Federal Register, Vol. 69, No. 150: Thursday, August 5, 2004 – Proposed Rules. All comments are referenced by title, page number, column and paragraph, as there is no issue identifier number preceding the section on which we are commenting.

CMS Review (p. 47511, col 1, para 1 – 3)
CMS has determined that the requested CPT codes are Category 2 services, defined as services that are not similar to an office or other outpatient visit, consultation, or office psychiatry because of the potential acuity of the patient in the hospital setting. The intent of the decision is to ensure that the roles of, and interaction among, the patient, physician, or practitioner at the distant site and telepresenter (if necessary) are similar to the current telehealth services.

We disagree with CMS's interpretation. Consultations provided via telehealth technologies mimic the traditional exam, interpretation of data, assessment criteria, and plan of care provided through an in-person office visit or an in-person hospital visit, or a telehealth office visit. In addition, for the proposed codes, a physician or non-physician practitioner retains control of the patient and is present or available during consultations. In fact, in emergency consultations, the patient is cared for by an on-site physician, nurse practitioner, or physician assistant. The telehealth link is for additional expertise, particularly in the area of trauma care, to ensure optimum clinical outcomes for the patient.

We would request clarification on how dialysis teleconsultations, when a physician is not present with the patient, is considered a Category 1 service, and how other services, specifically those with a physician in charge of the patient at the originating site, are classified as Category 2 services requiring extensive clinical trials before approval by CMS.

We understand CMS to say that the current list of evaluation/management and consultation codes may be used for patients in inpatient and observation status in hospitals and for patients receiving inpatient psychotherapy who receive services via telehealth. We would request that CMS comment specifically on which codes are appropriate to replace each of the requested codes for inpatient hospital, emergency department visits, hospital observation services, and inpatient psychotherapy.

End-Stage Renal Disease – Monthly Management of Patients on Dialysis (p. 47511, col 2, par 3)
Marshfield Clinic TeleHealth Network is in support of the inclusion of monthly management of patients on dialysis in the approved codes for telehealth services and acknowledges and supports the exclusion of the initial complete assessment of ESRD patients. An initiative is underway at present to legislatively include dialysis centers as originating sites.

Case Management and Care Plan Oversight (p.47512, col 3, para 1-2)
CMS has determined that the codes for Case Management and Care Plan oversight cannot be added to the list of approved telehealth services as these services do not require the patient to be present. We would ask for clarification on this point. We understand CMS to say that if the patient is not present, CMS does not have the authority to add these services (codes) to the list of approved telehealth services. We are assuming that the lack of authority to add codes that do not require the patient to be present is legislated in the language of BIPA 1997 (where it is determined that services must be provided to an eligible beneficiary). Please clarify the scope of authority over decisions relating to adding codes when the patient is not present.

A second question relates to the ability of a health care team to conduct case management and care plan oversight at a distance when the patient is not present. The statement by CMS indicates that case management or care plan oversight services that includes the participation of one or more of the care plan team using telecommunications does not fall into the telehealth services category but can be billed as a covered service using normal billing procedures. This appears similar to CMS policy on remote interpretation of radiological images and other services that do not require face-to-face consultations with the patient. We would ask CMS to clarify this issue

CMS Report to Congress (p. 47512, col 2, para 3)
Comments by CMS in the Federal Register refer to the required report to Congress (section 223(b) of BIPA). We request that CMS complete its work on this report with the inclusion in the report of the request to add eligible practitioners of speech pathologists, speech therapists, and audiologists as well as the appropriate CPT codes that have been identified by the American Speech-Language Hearing Association (ASHA). We request that CMS identify dialysis centers as a critical originating site, noting the inclusion of CPT codes, the scientific evidence used to support the inclusion of those codes, and the discrepancy of paying for a service that is delivered in a site not listed as an eligible originating site.

CMS-1429-P-3917

Submitter : **Mr. Vincent Simmarano** **Date & Time:** **09/24/2004 05:09:10**

Organization : **APTA**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Hello. My name is Vincent P. Simmarano, of Worcester, MA, a licensed physical therapist in the Commonwealth of Massachusetts. The purpose of my writing to you is that I wish to comment on the August 5 proposed rule on "Revisions to of your letter Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." In the proposed rule, CMS discusses establishing requirements for individuals who furnish outpatient physical therapy services in physician's offices. CMS proposes 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. This means 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.

I would like to express my strong support for CMS's proposed requirement that physical therapists working in physicians? offices be graduates of accredited professional physical therapist programs. 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.

Physical therapists are professionally educated at the college or university level in programs accredited by the Commission on Accreditation of Physical Therapy, an independent agency recognized by the U.S. Department of Education. As of January 2002, the minimum educational requirement to become a physical therapist is a post-baccalaureate degree from an accredited education program. All programs offer at least a master's degree, and the majority will offer the doctor of physical therapy (DPT) degree by 2005.

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.

Physical therapists must also be licensed in the states where they practice. As licensed health care providers in every jurisdiction in which they practice, physical therapists are fully accountable for their professional actions. Services rendered by unqualified personnel can lead to serious injury to Medicare beneficiaries.

Also, a cap on the provision of therapy services 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. The patient may not receive the same comprehensive level of care that would be provided by a physical therapist. No other medical service offered can provide neurologic, orthopedic, cardiovascular, pediatric, or geriatric expertise and specifically relate these backgrounds to individual improvement in one?s functional status.

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.

In closing, I thank you for your consideration of my comments.

Sincerely,

Vincent P. Simmarano, PT, MS, MA License #13361

Hello. My name is Vincent P. Simmarano, of Worcester, MA, a licensed physical therapist in the Commonwealth of Massachusetts. The purpose of my writing to you is that I wish to comment on the August 5 proposed rule on "Revisions to of your letter Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." In the proposed rule, CMS discusses establishing requirements for individuals who furnish outpatient physical therapy services in physician's offices. CMS proposes 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. This means 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.

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In closing, I thank you for your consideration of my comments.

Sincerely,

Vincent P. Simmarano, PT, MS, MA License #13361

CMS-1429-P-3918

Submitter : **Ms. Debra Morris** **Date & Time:** **09/24/2004 05:09:52**

Organization : **Ms. Debra Morris**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See Attached Document

CMS-1429-P-3918-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

CMS-1429-P-3919

Submitter : **Mr. Jeff Rounds** **Date & Time:** **09/24/2004 05:09:38**

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,

Jeff Rounds
312 S. Woodale
Decatur, IL 62522

CMS-1429-P-3920

Submitter : Mr. Walt Wilkins **Date & Time:** 09/24/2004 06:09:53

Organization : North Mississippi Medical Center

Category : Other Practitioner

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.

This country is experiencing an increasing shortage of credentialed allied heath care professionals, particularly in rural and outlying areas.

To allow only physical therapists,occupational therapists, and speech/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 cone to appease the interest of a single professional grooup who would seek to establish themselves as the sole 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.

Certified 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 competion. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficary 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.

CMS-1429-P-3921

Submitter : **Ms. Julie Olberding** **Date & Time:** **09/24/2004 06:09:00**

Organization : **Douglas County Hospital**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I support that services provided to Medicare patients in physican offices continueto be provided ONLY by the following professions: RPT,PTA, OTR, and OTA. I do not feel the Athletic trainers have either the training or experience to be qualified to provide such rehab services.

CMS-1429-P-3922

Submitter : **Ms. Catherine Martin** **Date & Time:** **09/24/2004 06:09:02**

Organization : **Therapeutic Massage of Sterling**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

I wish to emphasize the importance of massage in the chiropractic office in regards to treat medicaid patients. This form of treatment relieves pain and increases the patient's ability to heal quicker, not to mention increasing range of motion and bringing them out of health services earlier. Please continue to allow massage therapists to provide care in this way. Thank you

CMS-1429-P-3923

Submitter : **Ms. Sheila Bradley** **Date & Time:** **09/24/2004 06:09:29**

Organization : **Ms. Sheila Bradley**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I Oppose Medicare's proposed policy to eliminate any provider except physical therapist from providing "Incident to" medical professional services to physician's patients in home or office.

CMS-1429-P-3924

Submitter : **Ms. Julie Orzechowski** **Date & Time:** **09/24/2004 06:09:29**

Organization : **Ms. Julie Orzechowski**

Category : **Individual**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

To Whom it May Concern:

I am writing to make my opinion known. I oppose the proposed changes to 'Incident to' billing regulations. I am in support of certified athletic trainers as providers of rehabilitation services. I have used the services of athletic trainers as both a student and an athletic coach. They do a wonderful job of making our athletes recover safely. Thank you for your consideration.

CMS-1429-P-3925

Submitter : **Ms. Leslye Meffert** **Date & Time:** **09/24/2004 06:09:15**

Organization : **American Massage Therapy Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Licensed massage therapist provide an invaluable benefit to the patient. As specifically trained and educated professionals we contribute a service other types of therapists are only minimally familir much less trained to perform. Clients comments and doctors expressed approval substanciate that our therapies are a much needed contribution to the care and healing of the patient. Please acknowledge the validity and benefit of our profession.

CMS-1429-P-3926

Submitter : **Margaret Kara** **Date & Time:** **09/24/2004 06:09:57**

Organization : **Margaret Kara**

Category : **Other Health Care Professional**

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-3927

Submitter : Ms. Amy Van Alstyne **Date & Time:** 09/24/2004 06:09:00

Organization : Tender Touch Therapeutic Massage

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 therpists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.
I am an RN, LMT and a client who has received each of these services myself. I feel comfortable in expressing my views from the standpoint of patient, Therapist and tax payer. I think LMT's need to be "included" and not "excluded" for recognition of there medical/Therapeutic value and our fees be reimbursed accordingly. CAM's are becoming more marketable, as client's/taxpayers and the voteing public are "demanding" these essential services be "covered by their insurance providers". It is a narrow view to think that only Physical Therapists who deal manly with exercises can be the "end all be all" treatment modality. I ask you to consider your own backaches or medical concerns and think for yourself if Medical Massage can facilitate healing and promote pain relief faster than Physical Therapy modalities and exercises alone. I do recognize that you must represent the "voice" of the voters in your domain, so this voice sings out loud and clear in recognition and respect of the LICENSED Massage Therapist being "allowed" to treat the patients whom are referred to us by Medical Doctors who obviously feel we are a "Medical Necessity". Thank you for your time.

CMS-1429-P-3928

Submitter : **Jennifer Nickita** **Date & Time:** **09/24/2004 06:09:16**

Organization : **Jennifer Nickita**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See attachment

CMS-1429-P-3928-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
Attn: 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 Dr. McClellan,

I am a physical therapist in the Detroit area. I have been practicing for 17 years and have worked in a variety of settings including outpatient rehabilitation, inpatient acute care, and inpatient rehabilitation. I have treated many patients with either Medicare or Medicaid.

I wish to express my *support* for the proposed personnel standards for Medicare **"Incident To" Physical Therapy services.** I strongly believe that individuals providing physical therapy should be graduates of an accredited professional physical therapy program. I have a Bachelor of Science degree and the newer graduates have either a Master's or Clinical Doctorate. Unqualified personnel should not be providing physical therapy services nor billing for "physical therapy". I know of a young woman, 22 years old, that was hired into a physician's office to provide "physical therapy" and told me she was a physical therapist. I inquired more and corrected her, however, her patients may very well have been misled.

When I worked in outpatient, my patients would often tell me of the treatments they received in "physical therapy" at the doctor's office. It struck me that the treatments were not individualized and did not change from session to session. In addition, the patients would not have learned any exercises, self-management or prevention education. Therefore, they would not get better and then find themselves needing more services and hence come to our clinic.

Lastly, it seems to me, if CMS is paying for physical therapy services for Medicare beneficiaries, then it would be reasonable to expect that a qualified physical therapist was providing that care. I believe that only Physical Therapists and Physical Therapist Assistants (working under the supervision of a Physical Therapist) should be providing and billing for **physical therapy services.** So, I hope the "Revisions to Payment Policies Under the Physician Fee Schedule for calendar year 2005" go into effect.

Respectfully Submitted,

Jennifer Nickita, PT.

CMS-1429-P-3929

Submitter : **Dr. Daniel Lehman** **Date & Time:** **09/24/2004 06:09:10**

Organization : **Michigan Society of Hematology and Oncology**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Issues 1-9

SECTION 303

September 23, 2004

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: CMS-1429-P Section 303

Dear Dr. McClellan:

On behalf of our membership of 296 practicing oncologists in the state of Michigan, the Board of Directors of the Michigan Society of Hematology and Oncology requests that CMS reconsider the reductions in oncology reimbursement set forth in the MEDICARE PROGRAM: REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2005.

The 29% reduction in drug administration reimbursement as well as the change to the ASP + 6% drug reimbursement model will result in significant reductions in access and services to the cancer patients in the state of Michigan.

The Michigan Society of Hematology and Oncology has surveyed our member oncologists. Oncologists treating more than 30,000 cancer patients from a cross section of different size facilities and demographics responded. Based on our survey results, practices universally anticipate:

? Reduction/reassignment of staff ? Most practices will be forced to reduce hours and/or numbers of RNs and significantly reduce nurse time dedicated to services such as telephone triage and patient/family education. Other support staff will be eliminated. Rural practices will be forced to close satellite offices, requiring patients to travel greater distances for their care. Cancer research nurses would be reassigned and community cancer clinical trial participation would be diminished.

? Possibly limiting the number of new Medicare patients accepted in their practice. 80% of practices responding indicated that they would have to limit those with Medicare only coverage. The other 20% were reviewing this policy. No office indicated that they would continue to accept new Medicare patients as in the past.

? Limitations to access for care. The drug reimbursement projections for a number of commonly used chemotherapy and supportive care agents identified in the proposed revisions are below acquisition costs. (Repeatedly Gemzar, Aredia, Procrit and Zometa were listed on our surveys.) Medicare patients in most Michigan metropolitan areas could be sent to the hospital (if the hospitals are willing to accept them) for these treatments, typically at a higher cost to the Medicare program. Many rural practices have indicated that their local hospitals currently do not have the appropriate treatment facilities or could not possibly handle the increased volume.

Our practices continue to provide convenient, compassionate, state of the art care to a vulnerable patient population. Providing chemotherapy in the office is not only efficient and cost effective but provides more personal and better integrated care. We urge CMS to reassess the impact of these severe reductions to cancer care reimbursement. Maintaining the 2004 transitional drug administration fee schedule would allow practices to avoid

drastic cuts in personnel and services while the ASP + 6% formula is being evaluated.

We appreciate the opportunity to submit these comments and would make every effort to provide your staff with further information should you require it.

Sincerely,

Daniel J. Lehman, M.D.
President
Michigan Society of Hematology and Oncology

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MSHO Office
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Southfield, MI 48076
800-456-3413
Fax - 248-569-1270

CMS-1429-P-3929-Attach-1.doc

CMS-1429-P-3929-Attach-2.doc

MSHO

Michigan Society of Hematology and Oncology

Advocacy - Research - Education

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1999-2002

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Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-8018

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- **Possibly limiting the number of new Medicare patients accepted in their practice**. 80% of practices responding indicated that they would have to limit those with Medicare only coverage. The other 20% were reviewing this policy. No office indicated that they would continue to accept new Medicare patients as in the past.

17360 WEST 12 MILE - SUITE 101 - SOUTHFIELD, MI 48076-2117
PHONE (248) 569-0837 - (800) 456-3413 - FAX (248) 569-1270 - WEB SITE: WWW.MSHO.ORG

- **Limitations to access for care**. The drug reimbursement projections for a number of commonly used chemotherapy and supportive care agents identified in the proposed revisions are below acquisition costs. (Repeatedly Gemzar, Aredia, Procrit and Zometa were listed on our surveys.) Medicare patients in most Michigan metropolitan areas could be sent to the hospital (if the hospitals are willing to accept them) for these treatments, typically at a higher cost to the Medicare program. Many rural practices have indicated that their local hospitals currently do not have the appropriate treatment facilities or could not possibly handle the increased volume.

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Daniel J. Lehman, M.D.
President
Michigan Society of Hematology and Oncology

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Michigan Society of Hematology and Oncology

Advocacy - Research - Education

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Baltimore, MD 21244-8018

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We appreciate the opportunity to submit these comments and would make every effort to provide your staff with further information should you require it.

Sincerely,

Daniel J. Lehman, M.D.
President
Michigan Society of Hematology and Oncology

CMS-1429-P-3930

Submitter : Mrs. Leslie Lloyd **Date & Time:** 09/24/2004 06:09:05

Organization : The American Occupational Therapy Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-9

SECTION 611

AOTA supports CMS? proposed definition of the new initial preventative physical examination benefit. In particular, AOTA agrees that a review of the beneficiary?s functional ability and level of safety is a crucial component of quality care that must be covered. CMS proposes to define this benefit as including, ?at a minimum, a review of ?activities of daily living, falls risk and home safety.? 69 Fed. Reg. at 47515. These factors are key indicators of health and independence and fit squarely within the domain of occupational therapy. In fact, scientific research published in the Journal of the American Medical Association (JAMA) has shown the positive effects of preventative occupational therapy in reducing rates of decline and incidence of need for expensive acute or long-term care. See Occupational therapy for independent-living older adults: A randomized controlled trial.? JAMA, Vol. 278, No. 16, p. 1321-1326. 1999. We agree with CMS? decision to not define the term, ?appropriate screening instrument? because the physician will want to use the test of his choice. We would strongly recommend that CMS includes in the guidelines for the initial preventative physical examination information that informs physicians? referrals of the beneficiary to an occupational therapist when a more extensive evaluation of activities of daily living, falls risk, and home safety is warranted and also when the initial screening indicates deficits in these areas in which occupational therapy intervention would be medically appropriate.

Issues 10-19

DEFINING THERAPY SERVICES

The American Occupational Therapy Association (AOTA) represents approximately 40,000 occupational therapy professionals, many of whom provide outpatient services to Medicare beneficiaries. We appreciate the opportunity to comment on the proposed changes affecting payment and policies under the Physician Fee Schedule. This proposed rule was published in the Federal Register on August 5, 2004 (69 Fed. Reg. 47488). AOTA's detailed comments follow.

First, however, we must again request that the Centers for Medicare and Medicaid Services (CMS), when discussing the Physical Medicine and Rehabilitation (PM&R) codes (CPT 97000 series), refer to them as "PM&R" or "Rehabilitation" codes, not as "Physical Therapy" (e.g. 69 Fed. Reg. 47492). It is erroneous to refer to these codes as belonging to a specific profession, when they are equally valid for multiple occupations including occupational therapy.

SECTION 302

CMS has proposed expanding the requirements for clinical conditions of coverage to the medical supplies, appliances and devices commonly referred to as prosthetics, orthotics and supplies (POS). CMS has asserted that these items require the same level of medical intervention and skill as durable medical equipment (DME) and that it is appropriate for beneficiaries requiring DMEPOS to be under the care of a physician and for DMEPOS orders to occur in the context of routine clinical care.

Occupational therapists provide orthotics and supplies to meet patients? needs. They evaluate, recommend, design, measure, fabricate, fit, and train patients in the use of orthotics and train in the use of prosthetics. The Medicare coverage rules permit occupational therapists to fabricate and furnish orthotics, prosthetics, and supplies to beneficiaries in a variety of settings, including independently as Medicare enrolled OTPPs (occupational therapists in private practice), in physician offices, or as employees in a facility. In these instances, the occupational therapist or provider (where required) additionally enrolls in the Medicare program as a DMEPOS supplier. In fact, ? 427 of the Benefits Improvement and Protection Act of 2000 (BIPA) specifically includes qualified occupational therapists as ?qualified practitioners? who are able to furnish prosthetics and custom fabricated orthotics. As with all covered occupational therapy services, occupational therapists provide these items to beneficiaries under an occupational therapy plan of care that is approved by a physician. Consequently, the beneficiaries who receive DMEPOS from occupational therapists are already under the care of a physician, and the provision of these items already occurs in the context of routine clinical care.

AOTA agrees with CMS that it is essential to ensure that POS are provided in the context of clinical care in order to assure quality and reduce

waste. There have been significant fraudulent and abusive practices alleged in the orthotics and prosthetics industry, which has been able to directly supply beneficiaries with POS sans medically appropriate clinical care. Far too often our members treat patients whose medical conditions previously were exacerbated due to a supplier furnishing an ill-fitting or inappropriate orthotics or other items of DMEPOS. Requiring physician involvement in DMEPOS can only improve the quality provided by this otherwise largely unregulated industry. The regulations at 42 C.F.R. ?? 410.59, 410.61 already require extensive physician involvement in occupational therapy care, through the certification and recertification of the plan of care. These regulatory requirements safeguard against occupational therapists furnishing DMEPOS or other interventions that are inconsistent with good clinical care. It would be duplicative, unduly burdensome and administratively confusing to additionally require a face-to-face physician examination of beneficiaries who obtain DMEPOS under an occupational therapy plan of care. Consequently, AOTA urges CMS to exempt DMEPOS furnished under an occupational therapy plan of care from the proposed revisions to ? 410.36 and ? 410.38 related to the face-to face examination by a physician.

Issues 20-29

THERAPY - INCIDENT TO

In the proposed rule, CMS proposes to revise 42 C.F.R. ?? 410.26, 410.59, 410.60 and 410.62 to reflect that occupational therapy services provided incident to a physician?s professional services may only be furnished by individuals who meet the existing qualifications for occupational therapists and appropriately supervised occupational therapy assistants as set forth in 42 C.F.R. ? 484.4. AOTA unequivocally supports this proposal and urges CMS to finalize it.

For a number of years, AOTA has urged CMS to change this regulation to assure that Medicare beneficiaries can expect occupational therapy services to be delivered by qualified personnel under all Medicare benefits. This change is long overdue. Not only is it consistent with the Medicare statute, but also it will better achieve consistency in the Medicare personnel requirements under all benefits. More importantly, it should assure that beneficiaries receive authentic and higher quality services. Recently, research conducted by CMS regarding the impending financial limitations on outpatient therapy services have emphasized the need to define the qualifications of those providing therapy services to help assure that precious therapy dollars are spent on bona fide therapy. AOTA is concerned that therapy services in physicians' offices may have been performed by less skilled personnel (e.g., aides, technicians, or athletic trainers) and agrees with CMS that such practices are inconsistent with the law.

THERAPY STANDARDS AND REQUIREMENTS

In the this rule, CMS proposes to change the occupational therapy assistant (OTA) supervision requirements for the private practice setting from "personal" supervision to "direct" supervision. AOTA unequivocally supports this proposal and urges CMS to finalize this change.

Since 1998, when the current requirement was promulgated, AOTA has pointed out to CMS that the current supervision standard for OTAs in occupational therapy private practices (OTPPs) inappropriately exceeds the standard Medicare requires in every other setting in which OTAs work. AOTA applauds CMS for proposing a clinically correct and workable supervision requirement for OTAs who work in OTPPs that is consistent with professional practice and standards. CMS also should be commended for proposing this change because it promotes consistency in Medicare's policies regarding supervision of OTAs in all settings. AOTA also agrees with the proposal to restore the qualifications of OTAs at 42 ? 410.59, which had been inadvertently removed.

THERAPY TECHNICAL REVISIONS

AOTA urges CMS to expediently update the antiquated qualification standards for occupational therapists and occupational therapy assistants and to incorporate these standards into the regulations at 42 C.F.R. ? 410 et. seq. Since these qualifications are set forth in the home health conditions of participation regulations, updating these rules has been long delayed. In addition, it makes no sense that the therapy personnel qualifications that apply to all Medicare Part B settings only reside in the home health regulations. It takes at least an hour of flipping through the Code of Federal Regulations to trace the connection between the coverage criteria for occupational therapy in ? 410.59 and the personnel standards in ? 484.4, and then it requires a law degree to be confident that those personnel regulations do apply to Medicare Part B services. AOTA suggests that CMS simplify this tangled web of regulations by placing the personnel qualifications for covered services in close proximity to the regulations that outline the scope of the benefits available under Medicare Part B. AOTA recommends that CMS adopt the following updated standards for the qualification of occupational therapists and occupational therapy assistant:

A qualified occupational therapist is a person who is licensed or otherwise regulated as an occupational therapist by the State in which he or she is practicing. In addition, the occupational therapist has graduated from an occupational therapy program accredited by the American Occupational Therapy Association's Accreditation Council for Occupational Therapy Education (ACOTE) and is eligible for a national entry-level certification examination recognized by the American Occupational Therapy Association.

A qualified occupational therapy assistant is a person who is licensed or otherwise regulated (if applicable) to assist in the practice of occupational therapy by the State in which he or she is practicing and who shall work under the supervision of an occupational therapist. In addition, the occupational therapy assistant has graduated from an occupational therapy assistant program accredited by the American Occupational Therapy Association's Accreditation Council for Occupational Therapy Education (ACOTE) and is eligible for a national entry-level certification examination recognized by the American Occupational Therapy Association.

CMS-1429-P-3931

Submitter : **Date & Time:** **09/24/2004 06:09:23**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Mark McClellan, MD,PhD.
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Survices
Attention: CMS-1429-P
PO Box 8012
Baltimore, MD 21244-8012

Re: The proposed August 5 rule on "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005."

Dear Sir:

I have been a practicing physical therapist for 21 years and have worked in a variety of settings: hospitals, nursing homes, physician owned practices and private out-patient practices. I corrently own and operate my own out-patient practice.

I am writing to voice my strong support for CMS' proposed requirement that physical therapists working in physician offices be graduates of accredited professional physical therapist programs. Additionally, I wholly believe that PTs are the only practitioners who have the education and training to provide PT services. Unlicensed personnel should not be providing physical therapy sevices to Medicare recipients or any other individual suffering physical impairment from disease ,injury or degenerative changes.

My experience and distinction as an Orthopedic Clinical Specialist by the American Board of Physical Therapy Specialties has enabled me to participate in the education and trainiing of new therapists via clinical internships as well as in a classroom/lab setting for an accredited PT program. I know the time, effort and dedication required for these students to graduate with advanced degrees and to pass their state board examinations. Conversely, I have known individuals in other fields such as massage therapy, kinesiology, athletic training, and personal training. Their curriculums, training and entry level requirements are far less demanding and lack the depth and comprehensiveness necessary to make physical therapy application to a medically involved population. Simply put, they are not qualified to evluate and treat patients with medical problems. Patient safety, efficient treatment and outcomes, and conservation of resources are all compromised when unlicensed personnel are providing PT services.

Physical therapy provided in a physician's office is for the benefit of the patient. These are individuals with some form of physical impairment, injury or illness. They are not "healthy athletes in a health club." Only qualified physical therapists and physical therapy assistants working under the supervision of a physical therapist are specifically trained to safely and effectively provide PT services for this population.

In my career I have treated numerous patients who hade said, "Wow, when I received physical therapy before in "Dr. Smith's" (not his real name)office they never did this or that." Then in further conversation I would discover that they had received "physical therapy" by someone other than a PT or PTA. Their insurance or Medicare benefits had been used to reimburse ineffective treatment by unlicensed personnel and they hadn't even seen a PT for more than a few minutes at their first visit.

As health professionals, licensed by the state, we are accountable for our own professsional actions. Our training is comprehensive and in-depth to prepare us to effectively and safely treat patients with medical infirmities.

Thank you for considering my comments in favor of the proposed rule on "Revisions to Payment Policies under the Physician Fee Schedule for 2005."

CMS-1429-P-3932

Submitter : **Dr. Robert McNamara** **Date & Time:** **09/24/2004 06:09:54**

Organization : **Individual**

Category : **Physician**

Issue Areas/Comments

Issues 20-29

ASSIGNMENT

Re: 424.80 Prohibition of reassignment of claims by suppliers.
CMS should strongly consider requiring any entity submitting claims on behalf of a physician to provide that physician with a monthly summary of what has been billed and remitted in the physician's name. As the physician will be held jointly liable for improper claims submissions they need direct access to this information to fully participate in program integrity efforts. Merely stating there should be unrestricted access may fall short of the goal of physician involvement in these matters. The entities likely to enroll under the new reassignment provision generally possess the contractual power to terminate physicians 'without cause' (no provision for due process) on short notice. Such power creates a strong disincentive for physicians to seek the information they are entitled to. In my past role as a president of a professional society, the American Academy of Emergency Medicine, I had the great misfortune of having to counsel physicians who were terminated or threatened with such when they requested the information about what was being billed in their name. This risk to one's job security is 'common knowledge' among emergency physicians and unless CMS requires direct distribution of the needed information, the proposed regulation may fall short of its intended mark. Thank you for the opportunity to provide this comment.

CMS-1429-P-3933

Submitter : **Sonja Lee** **Date & Time:** **09/24/2004 06:09:01**

Organization : **AMTA, NCTMB, IAHP**

Category : **Individual**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

All qualified health care providers should be allowed to provide services to patients with a physicians prescription or referral.
We beg you NOT to pass this policy in which a physician can only refer "incident to" services to physcial therapists where by limiting a patients chances for recovery.

CMS-1429-P-3934

Submitter : **Ms. Leslie Fried** **Date & Time:** **09/24/2004 06:09:49**

Organization : **Alzheimer's Association**

Category : **Consumer Group**

Issue Areas/Comments

Issues 1-9

SECTION 611

On behalf of the Alzheimer's Association, I am attaching our comments with regard to the Initial Preventive Physical Examination

CMS-1429-P-3934-Attach-1.doc

www.alz.org

Washington
Public Policy Office
1319 F Street, NW, Suite 710
Washington, DC 20004-1106

202 393 7737 **phone**
202 393 2109 **facsimile**

alzheimer's association

September 24, 2004

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

Re: CMS File Code – 1429-P:
Comments on Revision to Payment Policies Under Physician Fee Schedule for 2005
Comments on Section 611 – Initial Preventative Physical Examination

Dear Sir or Madam:

The Alzheimer's Association appreciates the opportunity to comment on the Initial Preventive Physical Examination pursuant to Section 611 of the Medicare Prescription, Drug, Improvement and Modernization Act of 2003 (MMA), published in the federal register on August 5, 2004. The Alzheimer's Association is the premier source of information and support for the 4.5 million Americans with Alzheimer's disease. Through its national network of chapters, it offers a broad range of programs and services for people with the disease, their families, and caregivers and represents their interests on Alzheimer-related issues before federal, state, and local government and with health and long term care providers. The largest private funder of Alzheimer research, the Association has committed nearly $150 million toward research into the causes, treatment, prevention, and cure of Alzheimer's disease.

In its proposed regulations, the Centers for Medicare and Medicaid Services (CMS) proposes to interpret the term, “Initial Preventive Physical Examination” to include a “review of the individual’s comprehensive medical and social history” and a “review of the individual’s functional ability and level of safety.” The Alzheimer’s Association believes that both of these assessments should include questions that would identify Medicare beneficiaries with possible Alzheimer’s disease or other dementias. Individuals identified through this process would need a follow-up diagnostic evaluation, which is already covered by Medicare.

Specific Recommendations

We recommend the following revisions to the proposed regulations and implementation of this new benefit:

1. In §410.16(a)(1), the provision should be revised as follows:

> "Review of the individual's comprehensive medical and social history, **including memory problems."**

With regard to Section §410.16(a)(1), in the review of the individual's comprehensive medical and social history, beneficiaries should be asked whether they have memory problems severe enough to interfere with their ability to carry out routine daily activities. This question can be asked in-person. Alternatively, many physicians have a printed questionnaire that lists important medical conditions and is presented to the patient (or family member or other proxy informant) at the time of the first visit or mailed to the patient to be completed ahead of time. The condition "severe memory problems" can be easily added to the list. Since 1998, Kaiser Permanente has used a health status questionnaire for its elderly Medicare enrollees that includes the question, "Do you have any of the following health conditions?" and lists "severe memory problems" as one of 18 conditions.[1] Approximately 5% of Kaiser enrollees (or their proxy informant) give a positive response to this question, and these individuals have been shown to be very likely to have cognitive impairment or dementia.[2]

2. With regard to §410.16(a)(3), in the review of the individual's functional ability and level of safety," beneficiaries (or their family member or other proxy informant) should be asked about specific daily activities that are likely to be affected by loss of memory, executive function, and other cognitive abilities and likely to have important safety implications. Two such questions are:

- Do you get lost while walking or driving in familiar places?
- Do you have difficulty (or need help with) taking medications according to instructions?

These questions can be easily added to other questions about functional ability that will be included in the Initial Preventive Physical Examination and will provide important information about cognitive status and safety risks that are highly relevant for physicians and other health care providers.

Reasons for using the approach above rather than screening with a brief mental status questionnaire

Brief mental status tests are frequently used for research and often recommended for use in clinical evaluation of elderly people. These tests generally show acceptable to high accuracy for dementia when they are used in samples that include only people who have previously been determined to have either dementia or normal cognition and exclude people with delirium, mental illness, mental retardation, and other acute and chronic conditions that could affect their cognition. When used in general population samples and general medical settings where these

[1] Brody KK, Johnson RE, Ried LD, Carder PC, Perrin N. A comparison of two methods for identifying frail Medicare-aged persons. *J Am Geriatrics Soc*. 2002;50:562-569.
[2] Crooks VC, Buckwalter JG, Petitti DB. Usefulness of a single question in a self-report questionnaire for identifying persons with possible dementia: comparisons with other screening measures of cognitive impairment and dementia. Presentation at the Annual Meeting of the Gerontological Society of America, Nov. 18, 2001; Chicago, IL.

other conditions have not been excluded, mental status test results are much less accurate and result in many false positives, especially for people who are less educated, foreign born, or for whom English is a second language.

For these reasons, the three consensus groups that have considered the use of brief mental status tests to screen for cognitive impairment or dementia in population samples and general medical settings have not recommended their use for this purpose.[3,4,5] In 2003, the U.S. Preventive Services Task Force concluded that "current evidence does not support routine screening of patients in whom cognitive impairment is not otherwise suspected."[6]

All three consensus groups and the U.S. Preventive Services Task Force recommend that health care providers learn about and follow up on signs of possible dementia and respond to concerns expressed by the patient, family members, and other knowledgeable informants. The U.S Preventive Services Task Force concluded (some of this is also quoted above):

> "Although current evidence does not support routine screening of patients in whom cognitive impairment is not otherwise suspected, clinicians should assess cognitive function whenever cognitive impairment or deterioration is suspected, based on direct observation, patient report, or concerns raised by family members, friends, or caretakers."[7]

Approximately 2% of people who are 65 years old have Alzheimer's disease or other dementias. These individuals are much more likely to have vascular dementia than Alzheimer's disease. The Alzheimer's Association believes that the approach we propose will provide a more accurate identification of individuals with potential Alzheimer's disease or other dementias. Beneficiaries identified during the initial preventive physical examination would then require a comprehensive diagnostic evaluation for Alzheimer's disease or other dementias.

We appreciate the opportunity to comment on the proposed regulations regarding the initial preventive physical examination. The Alzheimer's Association is ready to work with you, and to assist in identifying appropriate clinical experts, to assure early identification of beneficiaries with possible Alzheimer's disease or dementia. Please feel free to contact Leslie B. Fried, Director of the Association's Medicare Advocacy Project, (202) 662-8684 to further discuss these matters.

Sincerely,

Bonnie Hogue
Director, Federal and State Policy

Leslie B. Fried
Director, Medicare Advocacy Project

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[3] Brodaty H, Clarke J, Ganguli M, et al. Screening for cognitive impairment in general practice: toward a consensus. *Alzheimer Dis Assoc Disord.* 1998;12:1-13.
[4] Costa PT, Williams TF, Somerfield M, et al. Recognition and initial assessment of Alzheimer's disease and related dementias: clinical practice guideline. Rockville, MD: US Dep. of Health and Human Services, Agency for Health Care Policy and Research: 1996.
[5] Patterson JS, Gass DA. Screening for cognitive impairment and dementia in the elderly. *Can J Neurol Sci*. 2001; 28(suppl.):S42-S51.
[6] U.S. Preventive Services Task Force. *Screening for Dementia,Recommendations and Rationale*,p. 2, accessed Sept. 14, 2004 at http://www.ahrq.gov/clinic/3rduspstf/dementia/dementrr.htm.
[7] Id.

CMS-1429-P-3935

Submitter : Mrs. Cindy Brosig **Date & Time:** 09/24/2004 06:09:40

Organization : Midland Memorial Hospital

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I would like to speak in favor of this ruling in general. I am in favor of the restriction of therapy services to Physical and Occupational Therapists as they are the only professionals with adequate medical training to provide the service. In addition I am in favor of allowing PTA's and OTA's to practice without constant on-site supervision. They are licensed professionals who are capable of functioning well independently with periodic supervision. As Director of Rehabilitation Services at Midland Memorial Hospital, I have many years of experience supervising these professionals, and have confidence that periodic guidance and supervision by a PT or OT is the best way to operate. Thank you.

CMS-1429-P-3936

Submitter : **Mr. Micah Holland** **Date & Time:** **09/24/2004 06:09:32**

Organization : **Lewis University**

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

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-1429-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 rights (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

CMS-1429-P-3937

Submitter : **lynne richardson** **Date & Time:** **09/24/2004 06:09:00**

Organization : **douglas county hospital;**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

i currently agree with the apta standard and opinion on the physical therapist profession continuing to treat the geriatric population. i strongly feel that only those people with extensive education on pathophysiology, geriatrics and disease process' should be working with this population. i had an athletic trainging background prior to going into physical therapy, with three years in the athletic training curriculum and did not have near enough education to safely treat this specialized group of patients. i feel that athletic trainers especially do not qualify to teat this patient population in a clinic setting. as the general population continues to age, our profession will have to continue to stay on the "top" side of treating this specialized group.
sincerely,
lynne richardson
physical therapist

CMS-1429-P-3938

Submitter : Mr. Frank Wire **Date & Time:** 09/24/2004 06:09:38

Organization : Mr. Frank Wire

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The policy of making all massage therapy be performed at a physical therapy site is unecessary and wasteful. Having spent a good deal of time in a PT environment the fees associated with PT are far and above what should and is charged by liscensed massage therapists for what would amount to be the same work. Granted massage therapy in conjunction with PT is very often a useful treatment but in cases where massage therapy alone is required it is inappropriate to mandate the PT environment. Aside from being unecessary it is also a waste of medicare monies that could be better spent elsewhere.

CMS-1429-P-3939

Submitter : **Cate Brennan Lisak** **Date & Time:** **09/24/2004 06:09:51**

Organization : **self**

Category : **Individual**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

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 in response to the recent proposal that would limit providers of ?therapy-incident to? services in physician clinics. As a taxpayer and future Medicare patient, I am greatly concerned about the long-term consequences of this action and urge CMS not to institute the proposed changes.

The United States is experiencing a shortage of qualified health care providers. 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.

Consider the impact of this decision on rural Medicare patients, who would experience delays in receiving care. These delays would hinder the patient?s recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare. In many cases, physicians would be forced to perform 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.

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 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 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,

Cate Brennan Lisak
3534 Ingleside Dr.
Dallas, TX 75229

CMS-1429-P-3940

Submitter : **Dr. Kathleen M. Doyle** **Date & Time:** **09/24/2004 06:09:25**

Organization : **NYState Education Dept-State Bd for Massage Therap**

Category : **State Government**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We are providing this comment for the purpose of consumer protection, as well as ensuring that in the adoption of these changes, there is consideration of the status of the profession of massage therapy as a health care profession in New York State, and in other jurisdictions. We recognize that massage therapy is not included as a service within Section 1862(a)(20), which addresses payment for therapy services furnished incident to a physician?s professional services. Our comment is not intended to seek the inclusion of massage therapy by licensed massage therapists under this section. We are suggesting that the term ?massage therapy services? be removed from the example given in the following sentence, ?This section also does not apply to services that are not covered either as therapy or as evaluation and management services provided incident to a physician or nonphysician practitioner such as recreation therapy, relaxation therapy, athletic training, exercise physiology, kinesiology, or massage therapy services.?

The purpose of our recommendation is that in New York State massage therapists are licensed as independent health care professionals. There are twenty professional education programs located in eighteen colleges or authorized schools leading to either an associate?s degree or to a professional diploma in massage therapy. Currently, there are approximately 15,000 licensed massage therapists, with at least 13,500 licensed and registered massage therapists (registration identifies those in active practice in the State). Some are self-employed, but most are employed by physicians, hospitals, nursing homes, chiropractors, physical therapists, and other health care settings, as well as health clubs and spas. Many insurers do pay for massage therapy services, and the number of these insurers has been growing. The massage therapy statute provides that physicians, nurses, podiatrists, physical therapists and chiropractors may provide massage therapy as a part of their own professional practice, and many employ massage therapists to provide such services.

Our concern is that by including massage therapists within the example used in this section, which identifies providers, who, with the exception of athletic trainers, are not licensed professionals, the impact of this important regulatory statement will cascade to other insurers and lead to a reduction in the number of providers who reimburse for massage therapy. This could have a negative impact on the consumers of the fastest growing health profession in the State.

CMS-1429-P-3941

Submitter : **Mr. Kenneth Robinson** **Date & Time:** **09/24/2004 06:09:04**

Organization : **Brooks**

Category : **Other Health Care Provider**

Issue Areas/Comments

Issues 1-9

SECTION 303

Average Sales Price methodology as outlined in Section 303 is not an appropriate reimbursement model for the following reasons:

? ASP is based on manufacturers sales revenue, which is not a reflection of the actual prices paid by community pharmacies that purchase these drugs. Reimbursement at ASP plus six percent (6%) does not reflect wholesale markups or normal business costs for inventorying and dispensing these drugs. In addition, ASP plus a six percent markup for inexpensive generic drugs will not offset these business costs, which could encourage the use of more expensive brand name drugs ? an outcome that public and private payers attempt to avoid.

? ASP should not be based on a weighted average across all purchasers because pharmaceutical prices differ significantly based on ?purchasing power?. Community pharmacies generally pay higher prices than larger pharmaceutical purchasers, which means ASP may be below acquisition costs. This will force community pharmacies, as the one-stop-shop for healthcare, to provide these products at a loss, thereby creating widespread access problems for Medicare beneficiaries.

? ASP is measured ?retrospectively? based on manufacturer?s quarterly revenues starting six months previously. Pharmaceutical costs changes daily; community pharmacies should not be reimbursed based on drug prices that are out-of-date. Pricing must be updated on a regular basis to ensure that pharmacy is reimbursed properly.

? ASP ignores variability of discounting and could eliminate prudent purchasing. The interim final rule contemplates reducing ASP by the value of certain purchasing incentives that are frankly more appropriately retained by the purchaser. The Medicare program through a reduction in ASP should not capture these. These purchasing incentives, such as prompt pay discounts and volume discounts, are earned by the purchaser, not the Medicare program, and reflect business decisions by the purchaser regarding the use of their money. ASP will reduce incentive for prudent buying if the Medicare program is signaling to providers that it will pay the costs of drugs, rather than allowing some purchasing incentive to remain in the system.

? Unlike AWP, MAC and WAC, ASP is not a publicly available, knowable, and auditable amount. The other pricing metrics are available in publicly available pricing sources, and are regularly updated. In contrast, providers will not know how the ASP was determined or whether and how it will change. Providers cannot be expected to make decisions about participation in health care programs without at least some knowledge of current and future reimbursement rates.

In summary, Average Sales Price does not cover routine business expenses including the costs of inventorying, dispensing and providing professional services to patients.

CMS-1429-P-3942

Submitter : **Ms. Pamela A. Duffy** **Date & Time:** **09/24/2004 06:09:03**

Organization : **Pamela A. Duffy, P.C.**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

As a physical therapist in office practice, I am writing in support of the proposed regulations that require individuals furnishing physical therapy services to be graduates of accredited physical therapy education programs. This is critically important so that patients receive the most appropriate and safest health care for their condition. Physical therapist's education prepares them to appropriately assess the patient's condition and impairments so that services are only given when they are going to facilitate restoration of function and reduce disability. The graduate level education that physical therapists receive differentiates them from others who may wish to provide and bill for services "incident to" the physician. Section 1862 (a)(20) of the Social Security Act those services must meet the standards for outpatient services in all settings. Therefore, this proposed regulation ensures that patients will receive services from a physical therapist.

Thank you for your consideration of these comments.
Sincerely,

Pamela A. Duffy, PT, MEd, OCS

CMS-1429-P-3943

Submitter : **Dr. William Bohl** **Date & Time:** **09/24/2004 06:09:27**

Organization : **Ohio City Orthopaedics**

Category : **Physician**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dr. Mathew Levey

Ohio City Orthopedics

1730 W25th

Cleveland, Ohio 44113-3170

9/23/04

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

CMS-1429-P-3943-Attach-1.doc

Dr. William Bohl

Ohio City Orthopedics

1730 W25th

Cleveland, Ohio 44113-3170

9/23/04

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. 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,

William Bohl, MD

Ohio City Orthopedics

1730 W25th st.

Cleveland, Ohio 44113

CMS-1429-P-3944

Submitter : Ms. Lisa Getson **Date & Time:** 09/24/2004 06:09:14

Organization : Apria Healthcare

Category : Home Health Facility

Issue Areas/Comments

Issues 10-19

SECTION 302

CMS-1429-P-3945

Submitter : **Mr. David Ruffin** **Date & Time:** **09/24/2004 06:09:19**

Organization : **National Athletic Trainers Association**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

This is comment addressing the limiting of physicians ability to bill as incident to. As you may know there is a shortage of allied health care professionals in rural areas and this bill would hurt patients. I am a Certified Athletic Trainer in Mississippi and we are definatly rural. Athletic Trainers are highly educated and licensed in most states. Along with passing a national certification test we are also required to obtain 80 hours of continuing education every 3 years. Our service is valuable to everyone from high school athletes to professional athletes. Every college in America has a certified athletic trainer on staff.
If professional teams trust us to provide services to their multi million dollar athletes that shows or value to physicians. To imply that we are not qualified is absurd.I trust you will make the right descion to let physicians to make their own judgements on who to call incident to. Thank you

CMS-1429-P-3946

Submitter : **Dr. Rick Mishler** **Date & Time:** **09/24/2004 06:09:14**

Organization : **AKDHC**

Category : **Physician**

Issue Areas/Comments

Issues 20-29

MANAGING PATIENTS ON DIALYSIS

File code: CMS-1429-P
Section:
6. Venous Mapping for Hemodialysis

RESPONDENTS: Rick Mishler, MD, Jeffrey Packer, DO, Donald Schon, MD

RE: Proposed rule related to Venous mapping for hemodialysis

We are replying from the perspective of Interventional Nephrologists who are actively involved in the creation and maintenance of vascular access for hemodialysis patients.

Our corporation Arizona Kidney Disease and Hypertension Center (AKDHC) is a large nephrology practice that takes a proactive approach in the management and treatment of End Stage Renal Disease (ERSD) patients. The recommendations established by the widely-recognized National Kidney Foundation-Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI) emphasize that vein mapping is critical in the process of identifying patients who are candidates for an autologous arterio-venous fistula (AVF). In accordance with the K/DOQI guidelines all AKDHC?s Chronic Kidney Disease (CKD) and ESRD patients are encouraged to obtain early vein mapping as part of their treamtment plan. The goal is to educate and initiate early fistula placement in the CKD population with the goal of having a mature, usable vascular access prior to starting hemodialysis. Since the inception of AKDHCs aggressive early screening and educational approach our fistula prevalence has risen from less than 25% AVF to greater than 50% AVF in less than 7 years.

The current draft rule as written would limit reimbursement to only the operating surgeon. This would not only exclude AKDHC from its current practice of early vascular access planning but would dramatically decrease the rate of creating successful AVF due to limited numbers of surgeons that vein map as part of their surgical routine. It has been the exception and not the rule when a patient preoperatively has been vein mapped by the operating surgeon. In our experience the common sequence of events is as follows- the nephrologists provides and reviews the vein mapping prior to making a surgical referral with access recommendation. Many of our vascular surgeons request that the patient have venous mapping performed by an outside center prior to their first encounter with the patient. Collaborative planning between the nephrologists and surgeons is imperitive because of the vast knowledge the nephrologists can provides as the result of seeing the patient in the dialysis unit. In many nephrology practices vein mapping is performed by a licensed provider i.e. an independent diagnostic imaging company, radiologists, or interventional nephrologists. Creating a practitioner-specific restriction would be detrimental to the patient. It would create unnecessary delays in the surgical process. It would limit the number of fistula creation due to limited surgeon mapping availability. In addition, it would prevent many patients from being evaluated for AVF at all in areas that could not provide a surgeon to vein map them.

On behalf of all the current and future CKD/ESRD patients we ask that CMS allow reimbursement of vein mapping to continue for any qualified provider including the operative surgeon. It is imperative that sharing of knowledge and communication between the surgeon and the nephrologists continues to grow with the common goal of creating the best vascular access for this patient population.

CMS-1429-P-3947

Submitter : **Dr. MATTHEW LEVEY** **Date & Time:** **09/24/2004 06:09:45**

Organization : **Ohio City Orthopaedics**

Category : **Physician**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dr. Mathew Levey

Ohio City Orthopedics

1730 W25th

Cleveland, Ohio 44113-3170

9/23/04

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

CMS-1429-P-3948

Submitter : **Mrs. Angela Styers-Gordon** **Date & Time:** **09/24/2004 06:09:46**

Organization : **Central Washington University**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

CMS-1429-P-3948-Attach-1.doc

Angela Styers-Gordon
2211 N. Spar Lane
Ellensburg, WA 98926

September 20, 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,

Angela Styers-Gordon, MS, ATC
2211 N. Spar Lane
Ellensburg, WA 98926

CMS-1429-P-3949

Submitter : Dr. Tye Ouzounian **Date & Time:** 09/24/2004 06:09:47

Organization : American Academy of Orthopaedic Surgeons

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-9

MALPRACTICE RVUs

The AAOS believes CMS' proposed methodology for revising malpractice RVUs is counter intuitive and does not reflect an accurate resource-based methodology. Orthopaedic surgery is often cited as a specialty experiencing a malpractice insurance crisis. Yet, according to the impact table, orthopaedic surgery will see a -0.4% decrease in total malpractice RVUs. This represents one of the largest decreases in RVUs for any specialty. This decrease does not reflect the true malpractice costs for orthopaedic surgery.

The AAOS believes CMS should have conducted a more rigorous analysis of the methodology and data used in revising the malpractice RVUs, and should have sought the input of the medical community. The AAOS believes the disconnect between the proposed malpractice RVU methodology and reality is the result of significant shortcomings in the methodology and data used by CMS. For example, CMS might have erred in adopting the specialty-weighted approach because it does not appropriately capture the malpractice costs for high-risk specialists. Additionally, the utilization data used by CMS' contractor appears to be flawed. In particular, it appears that assistant-at-surgery claims were not excluded from the dataset, which creates a problem for many surgical procedures. Finally, the risk factors used by CMS are questionable. For example, the risk factor for orthopaedic surgery, including spine surgery (7.46), is lower than the risk factor for orthopaedic surgery, excluding spine surgery (8.06).

The AAOS also believes that CMS' proposal to retain current charge based malpractice RVUs for all services with zero work RVUs is flawed. While we understand there are malpractice costs associated with these codes, the AAOS believes this methodology is not consistent with the current concept of resource-based reimbursement. The AAOS believes an appropriate methodology should be developed to assign resource-based malpractice RVUs for these services.

In sum, the AAOS believes that CMS has not conducted an appropriate revision of the malpractice component. The AAOS believes that any malpractice RVUs should be considered 'interim' until a mechanism to allow physician organizations to review the data and have meaningful input is established.

PRACTICE EXPENSE

The AAOS appreciates the opportunity to work with CMS in the refinement of direct practice expense inputs for musculoskeletal codes through the Practice Expense Advisory Committee (PEAC). Although most of the physician fee schedule has gone through the PEAC refinement process, the AAOS believes it is important for the medical community to continue to be involved in the development and refinement of practice expense inputs for services and procedures on the Medicare fee schedule through the AMA/Specialty Society RVS Update Committee (RUC) process.

When developing future practice expense recommendations, the AAOS believes that any review and/or changes of practice expense inputs should take into account the standard times, supply, and equipment packages that have been developed by the PEAC. The members of the PEAC have made remarkable progress in the refinement of direct practice expense inputs through the use of these standards. The AAOS believes future practice expense recommendation should take the PEAC's standards into consideration so that all codes have inputs that are consistent and fair.

The AAOS believes that some practice expense recommendations proposed by CMS for 2005 are problematic. For instance, CMS is proposing adjustments to unrefined 10 and 90 day global codes or codes that were refined early in the PEAC process. Additionally, CMS is proposing to eliminate discharge management from all but the 10 and 90 day global codes, and substituting one phone call for this discharge management. CMS is also proposing to eliminate staff time for phone calls in the post-service period. The AAOS does not believe these concepts are necessarily correct, and errors may inadvertently result from the adoption of these policies. The AAOS agrees that rank order anomalies should be avoided, and incorrect inputs should be corrected; however, CMS' approach may produce additional errors. For example:

1. Some 0 day global should have discharge management when performed in a facility setting. Eliminating this and substituting one phone call would not properly reflect clinical practice and direct expenses.

2. Some codes may appropriately involve additional staff time for phone calls not captured by the post service EM visits. Across the board elimination of this cost may not be consistent with the PEAC process.

The AAOS agrees that errors should be corrected and the refinement process should continue, but we are not comfortable with CMS' proposed recommendations. The AAOS believes CMS should submit a list of affected codes to the RUC, and allow the ad hoc PEAC committee to make appropriate recommendations.

In addition to these concerns, it appears that some CMS recommendations are being proposed that circumvent the PEAC process. For example, CMS is proposing to change the clinical staff time of hyperbaric therapy (99183) from a PEAC recommended time of 42 minutes to 90 minutes. Additional codes (56853 and 36522) have in-office clinical staff inputs that may not reflect PEAC accepted standards. The AAOS believes that CMS should refer these codes back to the RUC and allow the ad hoc PEAC committee to review the proposed changes. This will ensure these codes receive the same amount of scrutiny as all other PEAC reviewed codes.

The AAOS appreciates that CMS has adopted recommendations to use standardized surgical packs and trays that were developed and refined through the PEAC process. The AAOS believes the use of these standards will make the calculation of practice expense values across all specialties more equitable.

The AAOS has reviewed CMS' proposal to classify equipment into six categories and agrees that this will be helpful to both CMS and the medical community in identifying specific equipment listed in CMS' practice expense database.

Finally, the AAOS believes that CMS must address the fiscal impact of newly created non-facility practice expense relative values.

SECTION 303

The AAOS is deeply concerned about the lack of information in the proposed rule on Medicare drug payments that are scheduled to go into effect in 2005. The proposed rule does not provide a complete list of estimated 2005 drug payments, meaning that there is no opportunity to comment formally on many of the drugs. Furthermore, there are doubts about the accuracy of the drug payments that are listed in the rule, as well as the accuracy of the drug payment changes impact analysis. Even though CMS is four months from implementing a new payment system, there is still missing and incomplete payment data that makes it impossible for specialty societies to assess the new payment system.

CMS has been urged to provide 2005 drug payments as soon as possible so that physicians can decide on the best course of action for their patients and their business. In this time of uncertainty, physicians are worried that they may not be able to maintain enough inventory, or may not be able to afford to purchase drugs at ASP, and patients may suffer serious access problems. Thus, the AAOS urges CMS to provide a complete list of estimated 2005 drug payments based on manufacturer-reported 2004 first quarter and second quarter average sales price (ASP) data as soon as possible. The AAOS also believes that CMS should provide an opportunity for public comment on previously unpublished ASPs.

First quarter drug payments for 2005 will be based on 2004 third quarter ASP data, which is not due to CMS until October 30. By the time this data is validated by CMS and published for public viewing, there will be little time left in the year for physicians to incorporate this information and make any necessary adjustments in their practices. Therefore, it is vital that physicians have access to any and all information that will help them to make informed decisions for 2005. It is important for CMS to release estimated payments based on all quarterly data that is currently available so that problems or trends can be identified before the new payments are implemented.

The Medicare Modernization Act provided an unreasonably short transition time to the new drug payment system, giving physicians only one year to reevaluate and restructure their business and patient care plans in light of practically unknown payment changes. Congress required CMS to begin collecting ASP data after the first quarter of 2004, giving CMS and drug manufacturers two ?dry-runs? to iron out problems and questions about ASP reporting before submission of third quarter data, which will be used to calculate the January 1, 2005 ASPs. However, the AAOS urges CMS to seriously consider whether the payment system based on ASP will truly be ready for implementation on January 1, 2005 and to delay implementing the new payment system if necessary to avoid patient access problems and confusion. At the very least, CMS should phase in the more dramatic cuts by establishing a floor over the next few years. Most major changes to the Medicare fee schedule have been phased in to mitigate impacts on physicians, 95 percent of which are small business owners according to CMS.

The AAOS is disappointed that Medicare-covered outpatient drugs continue to be included in the expenditure target. The cost of these drugs are not controlled by physicians, and yet each year they account for a greater portion of the actual costs incurred by the Medicare program. In fact, the cost of drugs has risen at a rate of close to 30 percent annually over the past five years, which has greatly accelerated the SGR target and resulted in physician payment cuts. Much of the increase in drug spending can be traced to government policies that encourage the rapid development of new drugs and cancer therapies.

SECTION 611

The AAOS supports the creation of a "Welcome to Medicare" physical for new beneficiaries. However, the AAOS believes CMS should provide more information on the assumptions used in the impact calculations, especially in light of the fact that any cost increases not accounted for could have a significant impact on the annual physician fee schedule update calculations. The proposed rule states that new payments for the physicals will be made to physicians and other practitioners who provide these examinations and for any medically necessary follow-up tests, counseling, or treatment that may be required as a result of the coverage of these examinations. In the proposed rule, CMS estimates that this new benefit will cost $65 million next year. The AAOS believes CMS should publish all of its assumptions used to derive this estimate.

As in the case with the shift in site-of-service for practice expense and the cost of outpatient drugs, the AAOS believes the initial preventive screening examination could impact expenditures included in the Sustainable Growth Rate (SGR) formula. As such, the AAOS believes CMS must account for these additional costs in the SGR expenditure target to ensure that physicians do not bear the entire burden of funding these changes and additional mandates.

Issues 10-19

SECTION 302

The AAOS supports and encourages CMS' efforts to control the unnecessary proliferation and use of certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The AAOS agrees it is appropriate and necessary for CMS to develop standards and guidelines that outline the conditions for coverage of DMEPOS. As such, the AAOS believes the guidelines on physician evaluation and prescription of DMEPOS are appropriate.

The AAOS also believes that one of the proposed provisions related to payment of covered items of DMEPOS poses a significant problem for physicians. In particular, the provision that requires, 'the prescribing physician or practitioner be independent from the DMEPOS supplier and may not be a contractor or an employee of the supplier,' creates significant problems for physicians or physician offices that have obtained their own supplier number from CMS. The regulation as written would preclude these physicians and physician offices from prescribing and dispensing DMEPOS to Medicare beneficiaries in their own office because they cannot be 'independent' from the supplier since they are the supplier.

It is common for orthopaedic offices to obtain a DME supplier number. An office that has its own supplier number makes it possible for an orthopaedic surgeon to see a patient, write a prescription, and then actually fit the DMEPOS for the patient in their own office. This arrangement is convenient for Medicare beneficiaries because the patient is fitted with the DMEPOS immediately, rather than having to go to another site to get the DMEPOS. Furthermore, the treating orthopaedist can choose the specific DMEPOS best suited for the patient. Both of these factors greatly enhance the quality of care received by the patient. In light of these benefits to the patient, the AAOS believes CMS should reconsider the language of the DMEPOS regulation to make it clear that it is permissible for physicians with supplier numbers to dispense DMEPOS in their own office.

CMS-1429-P-3949-Attach-1.doc

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American Academy of Orthopaedic Surgeons | AAOS American Association of Orthopaedic Surgeons

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September 24, 2005

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

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

Dear Administrator McClellan:

The American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on *Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005*, 69 *Fed. Reg.* 150 (August 5, 2004). The AAOS' comments relate to issues on practice expense, malpractice RVUs, durable medical equipment, payment reform for covered outpatient drugs and biologicals, and Medicare's initial preventive physical examination.

PRACTICE EXPENSE

The AAOS appreciates the opportunity to work with CMS in the refinement of direct practice expense inputs for musculoskeletal codes through the Practice Expense Advisory Committee (PEAC). Although most of the physician fee schedule has gone through the PEAC refinement process, the AAOS believes it is important for the medical community to continue to be involved in the development and refinement of practice expense inputs for services and procedures on the Medicare fee schedule through the AMA/Specialty Society RVS Update Committee (RUC) process.

When developing future practice expense recommendations, the AAOS believes that any review and/or changes of practice expense inputs should take into account the standard times, supply, and equipment packages that have been developed by the PEAC. The members of the PEAC have made remarkable progress in the refinement of direct

practice expense inputs through the use of these standards. The AAOS believes future practice expense recommendation should take the PEAC's standards into consideration so that all codes have inputs that are consistent and fair.

The AAOS believes that some practice expense recommendations proposed by CMS for 2005 are problematic. For instance, CMS is proposing adjustments to unrefined 10 and 90 day global codes or codes that were refined early in the PEAC process. Additionally, CMS is proposing to eliminate discharge management from all but the 10 and 90 day global codes, and substituting one phone call for this discharge management. CMS is also proposing to eliminate staff time for phone calls in the post-service period. The AAOS does not believe these concepts are necessarily correct, and errors may inadvertently result from the adoption of these policies. The AAOS agrees that rank order anomalies should be avoided, and incorrect inputs should be corrected; however, CMS' approach may produce additional errors. For example:

1. Some 0 day global should have discharge management when performed in a facility setting. Eliminating this and substituting one phone call would not properly reflect clinical practice and direct expenses.

2. Some codes may appropriately involve additional staff time for phone calls not captured by the post service EM visits. Across the board elimination of this cost may not be consistent with the PEAC process.

The AAOS agrees that errors should be corrected and the refinement process should continue, but we are not comfortable with CMS' proposed recommendations. The AAOS believes CMS should submit a list of affected codes to the RUC, and allow the ad hoc PEAC committee to make appropriate recommendations.

In addition to these concerns, it appears that some CMS recommendations are being proposed that circumvent the PEAC process. For example, CMS is proposing to change the clinical staff time of hyperbaric therapy (99183) from a PEAC recommended time of 42 minutes to 90 minutes. Additional codes (56853 and 36522) have in-office clinical staff inputs that may not reflect PEAC accepted standards. The AAOS believes that CMS should refer these codes back to the RUC and allow the ad hoc PEAC committee to review the proposed changes. This will ensure these codes receive the same amount of scrutiny as all other PEAC reviewed codes.

The AAOS appreciates that CMS has adopted recommendations to use standardized surgical packs and trays that were developed and refined through the PEAC process. The AAOS believes the use of these standards will make the calculation of practice expense values across all specialties more equitable.

The AAOS has reviewed CMS' proposal to classify equipment into six categories and agrees that this will be helpful to both CMS and the medical community in identifying specific equipment listed in CMS' practice expense database.

Finally, the AAOS believes that CMS must address the fiscal impact of newly created non-facility practice expense relative values. For the first time, dozens of procedures and services have been costed in the non-facility setting because advances in medical technology have made it possible to safely perform these procedures in the office when they were only previously performed in the facility setting. The AAOS believes the assignment of new practice expense relative values in the non-facility setting will have an impact on expenditures included in the Sustainable Growth Rate (SGR) formula. As such, the AAOS believes that these new costs must be accounted for in the SGR expenditure target to ensure that physicians are not penalized for performing these services and procedures in the office setting.

MALPRACTICE RVUs

The AAOS believes CMS' proposed methodology for revising malpractice RVUs is counter intuitive and does not reflect an accurate resource-based methodology. Orthopaedic surgery is often cited as a specialty experiencing a malpractice insurance crisis. Yet, according to the impact table, orthopaedic surgery will see a –0.4% decrease in total malpractice RVUs. This represents one of the largest decreases in RVUs for any specialty. This decrease does not reflect the true malpractice costs for orthopaedic surgery.

The AAOS believes CMS should have conducted a more rigorous analysis of the methodology and data used in revising the malpractice RVUs, and should have sought the input of the medical community. The AAOS believes the disconnect between the proposed malpractice RVU methodology and reality is the result of significant shortcomings in the methodology and data used by CMS. For example, CMS might have erred in adopting the specialty-weighted approach because it does not appropriately capture the malpractice costs for high-risk specialists. Additionally, the utilization data used by CMS' contractor appears to be flawed. In particular, it appears that assistant-at-surgery claims were not excluded from the dataset, which creates a problem for many surgical procedures. Finally, the risk factors used by CMS are questionable. For example, the risk factor for orthopaedic surgery, including spine surgery (7.46), is lower than the risk factor for orthopaedic surgery, excluding spine surgery (8.06).

The AAOS also believes that CMS' proposal to retain current charge based malpractice RVUs for all services with zero work RVUs is flawed. While we understand there are malpractice costs associated with these codes, the AAOS believes this methodology is not consistent with the current concept of resource-based reimbursement. The AAOS believes an appropriate methodology should be developed to assign resource-based malpractice RVUs for these services.

In sum, the AAOS believes that CMS has not conducted an appropriate revision of the malpractice component. The AAOS believes that any malpractice RVUs should be considered "interim" until a mechanism to allow physician organizations to review the data and have meaningful input is established.

SECTION 302 – DURABLE MEDICAL EQUIPMENT

The AAOS supports and encourages CMS' efforts to control the unnecessary proliferation and use of certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The AAOS agrees it is appropriate and necessary for CMS to develop standards and guidelines that outline the conditions for coverage of DMEPOS. As such, the AAOS believes the guidelines on physician evaluation and prescription of DMEPOS are appropriate.

The AAOS also believes that one of the proposed provisions related to payment of covered items of DMEPOS poses a significant problem for physicians. In particular, the provision that requires, "the prescribing physician or practitioner be independent from the DMEPOS supplier and may not be a contractor or an employee of the supplier," creates significant problems for physicians or physician offices that have obtained their own supplier number from CMS. The regulation as written would preclude these physicians and physician offices from prescribing and dispensing DMEPOS to Medicare beneficiaries in their own office because they cannot be "independent" from the supplier since they *are* the supplier.

It is common for orthopaedic offices to obtain a DME supplier number. An office that has its own supplier number makes it possible for an orthopaedic surgeon to see a patient, write a prescription, and then actually fit the DMEPOS for the patient in their own office. This arrangement is convenient for Medicare beneficiaries because the patient is fitted with the DMEPOS immediately, rather than having to go to another site to get the DMEPOS. Furthermore, the treating orthopaedist can choose the specific DMEPOS best suited for the patient. Both of these factors greatly enhance the quality of care received by the patient. In light of these benefits to the patient, the AAOS believes CMS should reconsider the language of the DMEPOS regulation to make it clear that it is permissible for physicians with supplier numbers to dispense DMEPOS in their own office.

SECTION 303 – PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS

The AAOS is deeply concerned about the lack of information in the proposed rule on Medicare drug payments that are scheduled to go into effect in 2005. The proposed rule does not provide a complete list of estimated 2005 drug payments, meaning that there is no opportunity to comment formally on many of the drugs. Furthermore, there are doubts about the accuracy of the drug payments that are listed in the rule, as well as the accuracy of the drug payment changes impact analysis. Even though CMS is four months from implementing a new payment system, there is still missing and incomplete payment data that makes it impossible for specialty societies to assess the new payment system.

CMS has been urged to provide 2005 drug payments as soon as possible so that physicians can decide on the best course of action for their patients and their business. In this time of uncertainty, physicians are worried that they may not be able to maintain enough inventory, or may not be able to afford to purchase drugs at ASP, and patients

may suffer serious access problems. Thus, the AAOS urges CMS to provide a complete list of estimated 2005 drug payments based on manufacturer-reported 2004 first quarter and second quarter average sales price (ASP) data as soon as possible. The AAOS also believes that CMS should provide an opportunity for public comment on previously unpublished ASPs.

First quarter drug payments for 2005 will be based on 2004 third quarter ASP data, which is not due to CMS until October 30. By the time this data is validated by CMS and published for public viewing, there will be little time left in the year for physicians to incorporate this information and make any necessary adjustments in their practices. Therefore, it is vital that physicians have access to any and all information that will help them to make informed decisions for 2005. It is important for CMS to release estimated payments based on all quarterly data that is currently available so that problems or trends can be identified before the new payments are implemented.

The Medicare Modernization Act provided an unreasonably short transition time to the new drug payment system, giving physicians only one year to reevaluate and restructure their business and patient care plans in light of practically unknown payment changes. Congress required CMS to begin collecting ASP data after the first quarter of 2004, giving CMS and drug manufacturers two “dry-runs” to iron out problems and questions about ASP reporting before submission of third quarter data, which will be used to calculate the January 1, 2005 ASPs. However, the AAOS urges CMS to seriously consider whether the payment system based on ASP will truly be ready for implementation on January 1, 2005 and to delay implementing the new payment system if necessary to avoid patient access problems and confusion. At the very least, CMS should phase in the more dramatic cuts by establishing a floor over the next few years. Most major changes to the Medicare fee schedule have been phased in to mitigate impacts on physicians, 95 percent of which are small business owners according to CMS.

The AAOS is disappointed that Medicare-covered outpatient drugs continue to be included in the expenditure target. The cost of these drugs are not controlled by physicians, and yet each year they account for a greater portion of the actual costs incurred by the Medicare program. In fact, the cost of drugs has risen at a rate of close to 30 percent annually over the past five years, which has greatly accelerated the SGR target and resulted in physician payment cuts. Much of the increase in drug spending can be traced to government policies that encourage the rapid development of new drugs and cancer therapies.

Drug expenditures have grown not because of misuse, but because of innovations in the treatment of cancer and arthritis, along with improvements in pain management, enhanced use of screening benefits, rising incidence for some cancers and modifications in clinical practice. Between 1996 and 2000, some 40 new drugs were introduced. Eight of the 15-most frequently used drugs in 2000 were either brought to market or received FDA approval for expanded use after 1996. Three others saw expanded use because they countered the side effects of new combined cancer therapies.

The AAOS believes that if drugs remain in the spending pool, spending growth will consistently exceed the target and payment updates will be significantly reduced each year. The AAOS believes that continued reductions in physician payments will jeopardize Medicare patients' continued access to medical care, and we strongly urge the CMS to exercise its authority to remove drugs from the SGR pool, rather than attempt to finance their cost through reduced payments to physicians.

SECTION 611 – INITIAL PREVENTIVE PHYSICAL EXAMINATION

The AAOS supports the creation of a "Welcome to Medicare" physical for new beneficiaries. However, the AAOS believes CMS should provide more information on the assumptions used in the impact calculations, especially in light of the fact that any cost increases not accounted for could have a significant impact on the annual physician fee schedule update calculations. The proposed rule states that new payments for the physicals will be made to physicians and other practitioners who provide these examinations and for any medically necessary follow-up tests, counseling, or treatment that may be required as a result of the coverage of these examinations. In the proposed rule, CMS estimates that this new benefit will cost $65 million next year. The AAOS believes CMS should publish all of its assumptions used to derive this estimate.

As in the case with the shift in site-of-service for practice expense and the cost of outpatient drugs, the AAOS believes the initial preventive screening examination could impact expenditures included in the Sustainable Growth Rate (SGR) formula. As such, the AAOS believes CMS must account for these additional costs in the SGR expenditure target to ensure that physicians do not bear the entire burden of funding these changes and additional mandates.

The AAOS appreciates the opportunity to comment on these important issues impacting Medicare beneficiaries and the physician community. The AAOS believes it is important for CMS to consider comments from medical specialty societies, like the AAOS, and from other groups within the medical community, such as the AMA/Specialty Society RVS Update Committee (RUC). These organizations provide CMS with valuable advice on how to improve the Medicare physician fee schedule.

Sincerely,

Tye Ouzounian, M.D.
Chair, Health Care Financing Committee
American Association of Orthopaedic Surgeons

CMS-1429-P-3950

Submitter : **Date & Time:** **09/24/2004 06:09:54**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am currently a student in the Master's Physical Therapy program at the University of North Carolina at Chapel Hill. As a student and future physical therapist, I want to express my support for the August 5 proposed rule on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.
I believe it is important that personnel providing physical therapy meet the qualifications for physical therapy. As of January 2002, the minimum educational requirement to become a physical therapist is a post-baccalaureate degree from an accredited education program. Physical therapists must also be licensed in the states where they practice and are fully accountable for their professional actions.
Our physical therapy educational background and training enables us to obtain positive outcomes for individuals with disabilities and other conditions needing rehabilitation. This education and training is particularly important when treating Medicare beneficiaries who may have other health problems that should be considered when choosing a treatment course. Unqualified personnel cannot make necessary decisions during treatment sessions to provide patients the best care. This puts patients at unnecessary risk. I believe every patient has the right to be treated by qualified personnel and as a future healthcare provider I have the responsibility to help assure their rights.
I would like to thank you for your consideration of my comments.

CMS-1429-P-3951

Submitter : **Dr. MATTHEW LEVEY** **Date & Time:** **09/24/2004 06:09:42**

Organization : **Ohio City Orthopaedics**

Category : **Physician**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dr. Mathew Levey

Ohio City Orthopedics

1730 W25th

Cleveland, Ohio 44113-3170

9/23/04

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

CMS-1429-P-3951-Attach-1.doc

Dr. Mathew Levey

Ohio City Orthopedics

1730 W25th

Cleveland, Ohio 44113-3170

9/23/04

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. 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,

Mathew Levy MD

Ohio City Orthopedics

1730 W25th st.

Cleveland, Ohio 44113

CMS-1429-P-3952

Submitter : **Dr. Brian Pereira** **Date & Time:** **09/24/2004 06:09:33**

Organization : **National Kidney Foundation**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

September 24, 2004

The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS-1429-P, Proposed Rule: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005

Dear Dr. McClellan:

The National Kidney Foundation (NKF), America?s oldest and largest voluntary health organization serving the needs of kidney patients and the health care professionals who care for those patients, is pleased to respond to the Notice of Proposed Rule Making (NPRM) that was published in the Federal Register on Thursday, August 5, 2004. Our comments, presented in the order that the issues appear in the NPRM, are motivated by the desire to assure that Medicare beneficiaries with chronic kidney disease will benefit to the fullest extent from the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The National Kidney Foundation offers its expertise and the expertise of its volunteer leadership to help CMS fulfill the statutory mandates in a manner that will foster continuous improvement in quality of care for and by our constituents.

Please let me know if I can provide any additional information to substantiate our recommendations or to assist your agency in implementing them.

Sincerely,

Brian J. G. Pereira, MD
President

cc: Brady Augustine

CMS-1429-P-3952-Attach-1.doc

Attachment #3952
A. CODING-TELEHEALTH

The proposed change recognizes the important and practical role that telemedicine can play in the assessment of dialysis patients who receive treatment in ESRD facilities located in rural or relatively inaccessible areas. It is an important step forward that will directly benefit patient care, especially when geography makes routine, face-to-face, visits with nephrologists challenging for both the patient and the nephrology practitioner.

RECOMMENDATION: The National Kidney Foundation recommends that CMS retain this provision in the Final Rule.

B. CODING: VENOUS MAPPING FOR HEMODIALYSIS

The proposed rule is very restrictive. It will not immediately improve patient care and may not increase the successful placement of arteriovenous fistulas, as intended. According to the Notice of Proposed Rule Making, pre-operative venous mapping can be billed if performed by the operating surgeon, presumably at the time of the placement of a vascular access. Furthermore, it appears that such billing will only be allowed if an arteriovenous fistula is constructed.

The proposed rule does not support the current standard of care. First of all, the great majority of pre-operative venous mapping procedures are carried out by ultrasonagraphers who are radiologists or nephrologists. The procedures are often completed in dialysis facilities. Therefore, reimbursement should not be limited to operating surgeons. Secondly, this procedure is ideally performed days or weeks before the actual operation so that the results can be carefully analyzed and the best operational strategy developed by the nephrologist and the surgeon. Therefore, Medicare reimbursement should not be dependent upon the timing of the procedure. Third, while the National Kidney Foundation's Clinical Practice Guidelines recommend the increased utilization of arteriovenous fistulas, there are instances when venous mapping shows that a patient's vessels are not adequate and a fistula would not be successful. This is an important finding and will save a surgical procedure that would not be successful. It seems counter-intuitive that venous mapping would not then be reimbursed because a fistula was not constructed.

> **RECOMMENDATION: The National Kidney Foundation recommends that the Final Rule authorize payment for vein mapping to nephrologists and radiologists, as well as surgeons, whenever performed, and whether or not a native access is created.**

The National Kidney Foundation is extremely troubled by the reduction in total relative value units for CPT code 36870, percutaneous thrombectomy, by nearly 28 percent, as outlined in the proposed rule. Not only does this reduction run counter to national efforts to improve renal patient outcomes in the area of vascular access, such as the National Vascular Access Improvement initiative and the Fistula First program, but the proposed

rule contains no explanation for the reduction, nor is this code included in Addendum C, providing the PEAC recommendations on practice expense direct cost inputs.

These services can be successfully, efficiently, and safely performed in the outpatient setting, allowing a patient whose vascular access is clotted to be declotted and thus often able to return to their dialysis treatment the same day. Additionally, provision of thrombectomies in the outpatient setting saves the Medicare program overall thousands of dollars in inpatient expenses. As a result, this reduction not only saddles interventional and other nephrologists with a disincentive to provide these services in the outpatient setting, but will likely cause these services to be provided on an inpatient basis and therefore at a substantially greater expense to Medicare.

> **RECOMMENDATION: The National Kidney Foundation therefore strongly urges CMS to restore the total RVUs for CPT code 36870 from the 2005 proposed level of 37.87 to the 2004 level of 52.68, prior to the January 1, 2005 implementation date.**

C. SECTION 303-PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS

1. Average Sales Price (ASP) Methodology

The National Kidney Foundation is concerned that the ASP methodology for drugs provided incident to a visit to a physician's office, even with the minimal administrative fee that CMS is proposing (see below), will make it difficult for nephrologists to deliver anemia therapy for Medicare beneficiaries with reduced kidney function that has not progressed to end-stage kidney failure. In particular, Medicare beneficiaries who do not have Medigap insurance and cannot afford to cover the Part B co-pay may have access to care compromised.

Anemia is present in the majority of patients who have chronic kidney disease (CKD). When untreated, the anemia of CKD is associated with a number of physiologic abnormalities, including decreased tissue oxygen delivery and utilization, increased cardiac output, cardiac enlargement, ventricular hypertrophy, angina, congestive heart failure, decreased cognition and mental acuity and impaired immune responsiveness.

The primary cause of anemia in patients with CKD is insufficient production of erythropoietin (EPO) by diseased kidneys. Medicare authorized payment for recombinant human erythropoietin in 1989. Since then it has been used primarily in the treatment of the anemia experienced by End Stage Renal Disease (ESRD) patients. Recently, however, there has been a growing appreciation of the benefit of anemia therapy for patients in earlier stages of kidney disease. According to the United States Renal Data System (USRDS), a joint project of the Centers for Medicare and Medicaid Services, and the National Institute of Diabetes and Digestive and Kidney Diseases, the percentage of incident patients who had received EPO before the initiation of dialysis jumped from 21.63% to 32.12% between 1995 and 2002 and the mean hemoglobin at initiation of

dialysis increased from 9.2 g/dl to 10 g/dl during the same time period. (USRDS, 2003 *Annual Data Report*, p. 66.) The policies that Medicare is implementing will reverse that positive trend. This would be unfortunate both for Medicare beneficiaries as well as for the Medicare trust funds. Patients who received no or infrequent EPO before the initiation of dialysis have significantly higher rates of hospitalization and overall treatment costs at the time of initial dialysis. (A. J. Collins, "Anaemia Management Prior to Dialysis: Cardiovascular and Cost-Benefit Observations," *Nephrol Dial Transplant* 2003 Jun; 18 Suppl 2:ii2-6.) Among other things, Medicare beneficiaries who did not have access to EPO therapy in the earlier stages of CKD will require larger doses of EPO to achieve target hemoglobin goals once they are on dialysis. This will result in increased expenditures for the Medicare End Stage Renal Disease Program.

As noted in the Notice of Proposed Rule Making, physicians believe that they will not have access to the average discounts that are assumed in the ASP methodology, since they are small purchasers of drugs. Accordingly, the agency requested "comments regarding the extent to which physicians can become members of …buying groups and the possible effects of doing so." Our response is that the proposed level of reimbursement is so low that few nephrologists will have the incentive to join purchasing groups. Moreover, the discounts that might be available through purchasing groups, together with the 2005 administrative fee, may not be adequate to compensate a nephrology practice for the overhead involved in the provision of services to CKD patients.

> **RECOMMENDATION: The National Kidney Foundation recommends that CMS engage the services of an independent agency to determine whether ASP+6% approximates drug acquisition cost in the typical nephrology practice.**

2. Provisions for Appropriate Reporting and Billing for Physicians' Services Associated With the Administration of Covered Outpatient Drugs

We believe that the 2005 administration fee is inadequate to compensate nephrology practices for overhead expenses incurred in providing anemia therapy to Medicare beneficiaries. In the Notice of Proposed Rule Making CMS states: "We also plan to analyze any shift or change in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect." This analysis will be facilitated by comparing data entered on 2728 forms, before and after this policy is implemented. Any evaluation should also include an examination of changes in morbidity and mortality that Medicare beneficiaries with CKD may experience as a result of reduced utilization and impaired access to care attributable to MMA implementation.

> **RECOMMENDATION: The National Kidney Foundation urges CMS to develop plans, as soon as possible, to evaluate the impact of the 2005 changes in drug reimbursement and drug administration fees on access to care for Medicare beneficiaries with CKD who are not yet on dialysis.**

3. Payment for Drugs Furnished During 2005 in Connection with the Furnishing of Renal Dialysis Services if Separately Billed by Renal Dialysis Facilities

The National Kidney Foundation maintains that a system of reimbursement based upon ASP minus 3% is not sustainable and will not cover the costs of providing dialysis services over time. In particular, the NKF is concerned that reimbursement for separately billable drugs at ASP minus 3% may threaten the viability of small and independent dialysis providers, many of which are located in rural communities and are often the sole source of ESRD care in their service areas. The Report from the Office of Inspector General (OIG), Department of Health and Human Services, "Medicare Reimbursement for Existing End-Stage Renal Disease Drugs" (May, 2004), states that independent providers' average acquisition cost for EPO in 2003 was $9.50 per 1,000 units. For Paricalcitol, independent providers paid $4.15 per 1mcg. In contrast, reimbursement in 2005, at the level of ASP minus 3%, will be $9.04 for EPO and $3.99 for Paricalcitol. In fact, Medicare reimbursement to independent dialysis providers next year, at ASP minus 3 percent, would be less than acquisition cost for all injectables except vancomycin.

If ESRD facilities in rural and remote areas are forced to close, dialysis patients, who are often frail and debilitated, will be required to travel long distances, three times a week, in order to receive the treatment they need to survive. Although home hemodialysis or home peritoneal dialysis may be an alternative for some of these patients, many patients may not be candidates for home dialysis, either because of physical or mental impairment or because of problems relating to water and electrical supply. In addition, there are not enough home dialysis training programs, and the reimbursement level for home dialysis training is not high enough ($12 for a CAPD training session or $20 for a home hemodialysis or CCPD training session) to stimulate the development of new programs. One other factor that has and will continue to limit the growth of home dialysis programs is that Medicare and Congress have eliminated the exception request process for accelerated training.

Under another possible scenario, dialysis facilities might refer patients to other providers for the administration of separately billable injectable drugs. That would impose additional hurdles for dialysis patients to secure care, with regard to scheduling and keeping additional appointments, as well as extra transportation demands. Many dialysis patients will not be able to meet this challenge and could experience medical complications because the management of the co-morbidities that accompany ESRD has been compromised.

A third scenario would involve switching patients to oral substitutes for injectable medications, when available. These oral agents may not be as effective as the injectable version and, moreover, efficacy would vary according to patient compliance. Once again, under this scenario, medical complications could ensue because the management of the co-morbidities that accompany ESRD has been compromised. As a result, the advances in care achieved through the CMS Clinical Performance Measures initiative would be eroded.

RECOMMENDATION: The National Kidney Foundation urges CMS to make absolutely certain that the economic viability of independent dialysis providers is protected as these provisions of MMA are implemented.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that payments for separately-billable drugs provided in connection with the furnishing of dialysis services should be set at the "acquisition cost" for each particular drug, as determined by the Inspector General. The currently proposed ASP-3 percent "proxy" for the drug acquisition costs of dialysis facilities is not sustainable over the long term. First, it is based on a methodology that understates the true aggregate costs incurred by independent dialysis facilities associated with acquiring drugs, and it fails to capture many associated routine administrative costs over and above the purchase price of the drugs. Second, the dynamic drug pricing changes that are occurring and will continue to occur under the broader Medicare Part B ASP-based drug payment reforms will not be adequately captured in projections based on an ASP-3% system. There is no basis for assuming that the acquisition cost relationships in the base snapshot taken by the OIG will continue to be reflective of the drug acquisition costs to be faced by facilities in 2005. Although the option was not reflected in the proposed rule, CMS acknowledged this challenge in the preamble to the NPRM, "An alternative approach would be to use the 2003 acquisition prices from the OIG report, calculate the aggregate difference between such prices and payments for drugs under the AWP system, update this difference to 2005 and then apply the budget neutrality adjustment."

Furthermore, CMS should use the OIG's drug-specific acquisition cost data, adjusted for inflation, rather than aggregate data, in setting reimbursement levels for these drugs. Finally, CMS failed to account for certain drugs properly: (1) two forms of Iron Dextran are lumped together in one ASP in the Notice of Proposed Rule Making and (2) whereas the OIG Report stated that the ASP for Carnitor is $10.93, CMS lists it as $7.39.

RECOMMENDATION: The National Kidney Foundation recommends that CMS use the drug-specific acquisition cost data included in Tables 1 and 2 of the OIG report, updated for inflation, to set payment levels for drugs furnished during 2005 in connection with the provision of dialysis services if separately billed by dialysis providers.

Congress decided to change the way Medicare pays for separately billable drugs furnished in connection with the provision of dialysis services for two reasons: (1) to eliminate cross subsidization that obscured the true cost of care, and (2) to remove incentives for inappropriate utilization of drugs and biologicals. In his 2003 Report to Congress, "Towards a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System," Secretary of Health Thompson acknowledged that composite rate payments to dialysis providers do not cover the cost of the services they are required to provide under the composite rate and that separately billable costs make up the shortfall. This cross subsidization arose because of the lack of a system for an annual update to the composite rate, which failure Congress has yet to address. However, the legislature has acted to align incentives for the utilization of drugs and biologicals and the NPRM published on August 5, 2004 outlines the way CMS plans to implement that

Congressional intent. Under the circumstances, there would appear to be little basis for CMS to pursue the parallel revision of the EPO HMA policy that was proposed on July 7, 2004. That proposal was apparently prompted by the perception that there is over-utilization of erythropoietin in the Medicare ESRD program. Furthermore, by instituting two changes in EPO payment policy, more or less simultaneously, there is the danger that any potential negative impact on patient outcomes could be compounded.

> **RECOMMENDATION: The National Kidney Foundation recommends that CMS withdraw the draft revised policy for monitoring claims for EPO for ESRD patients.**

4. Supplying Fee

CMS proposes to pay a $10 supplying fee to pharmacies that dispense immunosuppressive drugs to Medicare beneficiaries who have had a solid organ transplant and need these drugs in order to reduce the risk of rejecting their grafts. While a supplying fee at that level might compensate pharmacies for the cost of stocking many medications, it does not reflect the overhead costs associated with dispensing expensive immunosuppressive pharmaceuticals such as calcineurin inhibitors, TOR Inhibitors and Antiproliferative Agents. These costs include carrying charges, as well as expenses in relation to billing DMERCs and collecting co-payments from secondary payers. Many pharmacies may refuse to fill prescriptions for expensive immunosuppressive drugs, making it difficult for transplant recipients to obtain the drugs they need to preserve their transplants. (A re-transplant or return to dialysis would be much more costly to Medicare.) We suggest that an alternative might be a sliding supplying fee, which would be calculated as a percentage of the cost that the pharmacy incurs in acquiring the drug.

> **RECOMMENDATION: The National Kidney Foundation recommends that the Final Rule authorize the payment of a supplying fee to pharmacies dispensing immunosuppressive drugs that adequately compensates them for providing this service to Medicare beneficiaries who have received a life-saving organ transplant.**

D. SECTION 623 – PAYMENT FOR RENAL DIALYSIS SERVICES

1. Options for Applying the Drug Add-On Adjustment to the Composite Payment Rate

CMS proposes a single drug add-on adjustment to the ESRD composite rate for both hospital-based and independent facilities to account for changes in pricing of separately billable drugs and biologicals. This alternative is proposed even though the two types of providers have been subject to different reimbursement policies for all of these drugs except for EPO. Hospital-based facilities provide high quality care to patients with ESRD and deserve to be adequately reimbursed. However a single adjustment would ignore the different impact that the implementation of MMA will have on the two kinds of providers.

RECOMMENDATION: The National Kidney Foundation recommends that the drug add-on adjustment should be designed to compensate both hospital-based and independent dialysis facilities for the actual loss of revenue they will experience as the result of changes in pricing of separately billable drugs.

A central feature of implementing the add-on adjustment is how CMS will update it, consistent with the statutory requirements. Unfortunately, the Proposed Rule does not address this issue. The proposed system for 2005 is not sustainable and will not cover the costs of providing dialysis services over time. CMS must provide information to the kidney community about how the separately billed drug payments and add-on amounts will be updated before finalizing the rule. Therefore, NKF strongly urges the agency to include a discussion of the update mechanism in the Final Rule and to provide interested parties with an opportunity to comment on it.

To ensure a sustainable system over the long-term, it is imperative that CMS describe more fully how it proposes to account for the changes that will occur in the drug acquisition costs facilities will face. Therefore, we feel very strongly that CMS must comply with the provisions governing acquisition costs and budget neutrality requirements by 1) updating the add-on payment on a regular basis so as to take reasonable account of these market dynamics, as well as the effects of broader Part B payment reform, 2) and do so in a manner consistent with the concepts and objectives evidenced in Section 1847A of the Social Security Act.

RECOMMENDATION: The National Kidney Foundation recommends that the final rule include, for comment, a mechanism that will reflect changes over time in acquisition cost for injectable drugs provided in the dialysis clinic.

2. Proposed Patient Characteristic Adjustments

CMS is proposing to adjust the composite rate for age, gender, AIDS and PVD. The National Kidney Foundation is concerned that these variables are not significant predictors of cost variation and that other patient characteristics, such as BMI and pediatric age, might be more important considerations. Furthermore, it will be difficult to implement adjustments for AIDS and PVD. This information is not captured on the cost report. There is no standard definition of PVD. Medical confidentiality laws prohibit screening patients for HIV status or asking patients to disclose HIV status. CMS should delay implementation of case-mix adjustment until it has developed mechanisms to collect and validate the necessary data upon which to select and weight those patient characteristics that increase the cost of care. This should include an examination of the complexity of care involved in treating pediatric ESRD patients. Case-mix adjustment for pediatric dialysis patients should be pursued because of the difficulty providers experience in securing a pediatric exception. Three applications for pediatric exceptions have been filed since the window was re-opened and two of them have been rejected. Theoretically, the inclusion of a pediatric category would provide an incentive for adult units to dialyze children who live in communities where there are no pediatric units.

RECOMMENDATION: The National Kidney Foundation recommends that CMS delay implementation of case-mix adjustment of the composite rate.

3. Geographic Index

CMS does not propose any revision to the current set of composite rate wage indexes, and the urban and rural definitions used to develop them, even though these have not been adjusted for 20 years. The National Kidney Foundation urges the agency to reconsider this plan. New updated OMB definitions for MSAs, CSAs and "micropolitan" areas have been developed and implemented in other areas of health care. Updating the wage index will address the concerns of dialysis facilities in parts of the country where the cost of living is high and it is difficult to compete, on the basis of salary, with other health care facilities, in the hiring and retention of nurses in an era of nursing shortage. In addition, updating the geographic wage index may provide relief for dialysis providers in areas that were considered rural 20 years ago but would now be characterized as suburban.

RECOMMENDATION: The National Kidney Foundation recommends that CMS develop a plan to update the geographic wage index for the ESRD program.

4. Summary of Composite Rate Revisions and Proposed Implementation

Section 623 (a) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 provides an increase in the ESRD composite rate by 1.6 percent, effective January 1, 2005. However, CMS proposes to adjust this increase to achieve budget neutrality. We question the statutory basis for the agency's plan.

RECOMMENDATION: The National Kidney Foundation recommends that CMS not adjust the 1.6 percent update in the composite rate for budget neutrality.

CMS-1429-P-3953

Submitter : **Date & Time:** **09/24/2004 06:09:36**

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do not pass this policy. ALL health care providers, not just physical therapists, should be able to provide beneficial health care to patients under a doctor's supervsion!

CMS-1429-P-3954

Submitter : **Ms. Jenny Knapp** **Date & Time:** **09/24/2004 06:09:59**

Organization : **Ms. Jenny Knapp**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I oppose proposed changes to Incident to billing regulations.

I support recognition of Certified Athletic Trainers as providers of Rehabilitation Services.

CMS-1429-P-3955

Submitter : **Ms. Colleen Carpenter** **Date & Time:** **09/24/2004 06:09:55**

Organization : **CMS Atlanta**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

Comment CMS 1429-P Q Code for the Set-Up of Portable X-Ray Equipment.
CMS should continue to price this service. Carriers do not have the expertise to evaluate the data sent by portable x-ray suppliers in order to set an equitable payment rate for this service. This is evidenced by the wide variance in payment for the transportation component, HCPCS procedure code R0070. Allowances range from $189 to $60. Some carriers have been able to successfully negotiate the data supplied by the industry while others have merely accepted the industry's data to set a reimbursement rate. CMS should not delegate pricing of this service to carriers until such time as CMS can provide explicit instructions or auditing expertise to the contractors.

CMS-1429-P-3956

Submitter : **Ms. Lucinda Long** **Date & Time:** **09/24/2004 06:09:36**

Organization : **Wyeth Pharmaceuticals**

Category : **Drug Industry**

Issue Areas/Comments

Issues 1-9

SECTION 303

See attachment

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-3957

Submitter : **Ms. Kristin Peters** **Date & Time:** **09/24/2004 06:09:00**

Organization : **MeritCare Health Systems**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

CMS-1429-P-3957-Attach-1.doc

September 23, 2004

Mark B. McClelland, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1429
PO Box 8012
Baltimore, MD 21244-8012

RE: Medicare Program: Revision to Payment Policies under the Physician Fee Schedule of Calendar Year 2005 – Therapy Incident – To.

Dear Mr. McClellan:

As a physical therapist, I am writing in regard to the proposed rules of Revisions to Payment Policies under the Physician Fee Schedule of Calendar Year 2004 and in particular the section related to Therapy Incident – To. I have practiced as a physical therapist in North Dakota and Minnesota for 91/2 years in a variety of settings. I currently work in a hospital outpatient setting. Our case load here includes a large number of Medicare Beneficiaries.

I strongly support CMS establishing the requirement that individuals providing physical therapy services within physician offices be qualified. Physical therapists and physical therapy assistants under a physical therapist's direction, are the only practitioners who are educated and trained to provide such services.

Physical therapists receive their education at colleges and universities. Physical therapy programs must be accredited by the Commission on Accrediation of Physical Therapy (CAPT). All of these programs offer a master's degree in physical and by 2005, the majority will offer a doctor of physical therapy (DPT). Physical therapists must be licensed within their practicing state.

Physical therapists are trained to evaluate and treat individuals with a variety of movement impairments. They are able to recognize how various medical conditions may affect an individual's rehabilitation program and are able to adjust and progress their program appropriately. This education and training is particularly important when treating Medicare beneficiaries who are most likely to have a complicated medical history.

When physical therapy is delivered by unqualified personnel there is a much greater potential for harm to the patient. Treatment will be less cost effective because these personnel would lack the assessment skills necessary to make treatment individualized, functional and progressive.

Requirements for outpatient physical thearpy services should be consistent in every setting. That is, services must be performed by individuals who are graduates of accredited professional physical therapy education programs.

Thank you for considering these comments.

Sincerely,

Kristin Peters, MPT

CMS-1429-P-3958

Submitter : Ms. Marie-Elizabeth Finamore **Date & Time:** 09/24/2004 06:09:51

Organization : Have Thumbs, Will Travel!

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

The arrogance of those proposing these changes, that physicians are not competent to choose the appropriate healthcare professionals to execute their plans of care, is simply preposterous. Physicians are legally entitled, and liable, to dictate and implement plans of care for all of their patients. They have been permitted to do so, under "incident to", within Medicare, since it's inception in 1965.
Certified athletic trainers, recognized as allied health professionals by the American Medical Association, are a valuable part of the healthcare team. Specialists in prevention, emergency care, and sports conditioning, as well as rehabilitation, we offer care for the most active in the population. Many seniors now live life beyond the "activites of daily living", and wish to continue doing so, even after an injury. For healthcare professionals whose specialties lie in other areas to demand our specific exculsion from working with the Medicare population limits the legal rights of physicians, state regulatory agencies, Certified Athletic Trainers, and diminishes the availability and quality of care available to many patients. There is not now, nor has there ever been, competency issues in regard to Certified Athletic Trainers working with any population. We continue to be the front line of medical care for athletes in the scholastic and team environments, including the Olympic games. I have worked in many settings with athletes of all ages, and they appreciate working with a professional who understands their desire to function beyond being able to get up a flight of stairs or brush their teeth. This is not to diminish the importance of those professionals whose only goal and training is to help patients reach that level of function. However, there is a significant portion of the population that wants, enjoys, and deserves more, and Certified Athletic Trainers are the ones to get them there. Their supervising physician is the one to make the decision, not some self-serving lobbying group evidently interested in being the only available recipients of federal healthcare dollars. As the President of the United States has said, leave healthcare to the physicians and patients! To limit competition among pools of qualified healthcare providers goes against all cost-reduction strategies. Allowing a particular group to become the sole provider for services, simply at their request, creates a monopoly and invites abuse and cost overruns. It is, simply, un-American.

CMS-1429-P-3959

Submitter : **Dr. Sharon Rounds** **Date & Time:** **09/24/2004 07:09:08**

Organization : **American Thoracic Society**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

Practice Expense Relative Value Unites for Methacoline Challenge ? CPT 95070
The ATS notes that CMS is proposing to remove supply costs for methacholine CPT code 94070 and place these costs in CPT code 95070. This change is based on the recommendation of PEAC. Although CMS is proposing to accept this PEAC recommendation, CMS has not increased the practice expense RVUs for CPT code 95070 to reflect the supply cost for adding methacoline.

The ATS strongly recommends CMS add the cost supply cost associated with methacoline to the practice expense relative value for 95070.

SECTION 413

Section 413 ? Physician Scarcity Areas and Health Professional Shortage Areas Incentive Payments
The ATS is pleased that Congress has taken steps to encourage primary care and specialty physicians to practice in physician Scarcity and Health Professional Shortage Areas. The incentive payments offered to physicians who practice in these areas will help ensure appropriate access to physicians for Medicare beneficiaries who reside in these areas.

We strongly encourage CMS to publish a list of areas (by zip code) that will receive Medicare incentive payments. Providing this information as soon as possible will help encourage service in these areas and will increase the usefulness of these incentive payments as a tool to recruit new physicians to serve in these areas.

SECTION 611

Section 611-Initial Preventive Physical Examination
Effective January 1, 2005, the Medicare Modernization Act (MMA) creates coverage for an initial preventive physical examination within the first six months of the beneficiary?s entrance into Medicare Part B. CMS proposes to establish a new HCPCS code, G0XX2, "Initial preventive physical examination," which includes an electrocardiogram (EKG), consistent with the statute. 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 RVU in the office setting, which is equivalent to the relative value units for a 99203 plus a complete EKG, 93000.

CMS further proposes that when a physician otherwise does the work of a problem-oriented E/M service at the same encounter, it will only allow a medically necessary E/M service no greater than a level 2 (i.e., 99202 or 99212) to be reported. In this situation, the problem-oriented E/M service should have a modifier -25 appended to it. CMS makes this proposal on the premise that some of the components for a medically necessary E/M visit are reflected in the new HCPCS code.

The ATS has several concerns with CMS's proposed payment policy for this new benefit. First, we question the necessity of establishing a new "G" code for the service. In the case of diabetes screening tests and cardiovascular screening blood tests, CMS is allowing physicians and others to use existing CPT codes with appropriate "V" diagnosis codes for screening to bill for the services in question. We believe that a covered initial preventive physical examination should likewise have been 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). The preventive medicine visit codes in CPT describe a service that fits the statutory definition of an initial preventive physical examination as well as the elements proposed in 42 CFR 410.16. The ATS strongly believes that existing CPT codes for preventative medicine visits are appropriate and that the creation of a new G-code to describe the service is unnecessary and undermines the integrity of the CPT coding systems.

The ATS believes that CMS has undervalued the non-EKG portion of this service. As noted, we believe the non-EKG portion of this service, as

described in both the statute and the proposed regulations, is captured in the current CPT codes for preventive medicine services. Assuming this to be a new patient, as CMS has done, and assuming the typical Medicare beneficiary is eligible based on age (i.e., 65 years or older), the corresponding CPT code is 99387. Currently, Medicare assigns a total of 4.00 relative values to this non-covered service in the office setting, as compared to 2.58 for a 99203. In several instances in this NPRM, CMS requests the RUC to review an interim proposal.

The ATS also has strong concerns regarding CMS's decision to cap the level of problem-oriented E/M service for which physicians may bill when this work is done in conjunction with an initial preventive physical examination. Such a cap suggests that CMS will only recognize self-limited or minor problems (in the case of established patients) or problems of low to moderate severity (in the case of new patients) in these situations. We see no basis for such a view, especially in light of the multiple chronic conditions suffered by so many Medicare beneficiaries. CPT allows physicians 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. We believe CMS should follow CPT in this regard.

CMS-1429-P-3959-Attach-1.pdf

CMS-1429-P-3959-Attach-1.pdf

CMS-1429-P-3959-Attach-1.pdf

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Molecular Biology ®

Internet: www.atsjournals.org

September 24, 2004

Mark B. McCellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building
Room 443-G
200 Independence Avenue, SW
Washington, D.C. 20201

Dr. McClellan:

On behalf of the members of the American Thoracic Society (ATS), I would like to express our appreciation for the opportunity to comment on the Medicare Revisions to Payment Policies under the Physician Fee Schedule for CY2005 published on August 5, 2004. The ATS represents over 14,000 physicians, researchers, and allied health professionals who are actively engaged in the diagnosis, treatment and research of respiratory disease and critical care medicine. As such, the ATS is very interested in how Medicare policy affects the patients we serve.

The ATS offers the following comments:

Sustainable Growth Rate (SGR) Formula
The ATS continues to be concerned about the flaws in the formula used to calculate the SGR and CMS inflexibility in applying the formula. The 1.5% increase in the 2004 conversion factor required an act of Congress. While we are pleased that Congress chose to intervene to provide temporary relief, the underlying flaws in the SGR remain.

To address these flaws in the SGR, the ATS recommends the following:

Changes in Law and Regulation
Medicare law requires CMS to make adjustments to the SGR calculation to reflect increases (or decreases) in physician spending resulting from changes in law or regulation. The ATS believes that CMS has mistakenly underestimated the impact of new law and of regulation on increased spending on physician services under Medicare.

Preventative Services Benefits
Congress has shown increased interest in making preventative services more available to Medicare beneficiaries. The ATS strongly supports increased awareness of the value of preventative medicine. Adding these benefits to Medicare will mean incurring the direct cost for providing the preventative

services. Adding preventative services will also add ancillary costs – through tests, additional physician visits, laboratory services - when these preventative services lead to the detection of disease. CMS needs to fully account for the direct costs and the ancillary costs that result from providing preventative services in the SGR.

National Coverage Decisions

CMS must also fully account for the increase in physician services driven by National Coverage Decisions (NCDs). The ATS appreciates CMS efforts to provide uniformity and clarity to the Medicare system by issuing NCD, however we remain concerned that CMS is not fully accounting for the increase in physician services caused by these NCDs in the SGR.

For example, ATS supports the CMS decision to cover lung volume reduction surgery (LVRS) for appropriately screened patients with emphysema. Coverage of LVRS for Medicare beneficiaries will add the direct cost of the service to Medicare physician expenditures. It will also add ancillary costs. The ATS notes that there are an estimated 3 million Americans – most of whom are Medicare beneficiaries – who have emphysema. Clearly not all of these patients are appropriate candidates for LVRS. However, by making LVRS available to Medicare beneficiaries, we expect to review and evaluate additional emphysema patients to assess their suitability for LVRS. Even though most of these patients will not be appropriate candidates for LVRS, the evaluation process for assess suitability for surgery alone will drive an increase in physician services.

Remove Medicare-Covered Drugs from the SGR Calculation

The ATS strongly recommends that CMS exercise its discretionary authority to remove the costs of Medicare-covered physician-administered drugs from the SGR calculation. The ATS, and nearly the entire physician community, have commented on this issue previously and are frustrated that CMS has not yet acted on this issue.

The ATS notes that expenditures for Medicare-covered physician-administered drugs have increased from $3.3 billion in 1998 to $8.4 billion in 2002. Inclusion of this tremendous increase in costs for Medicare-covered physician-administered drugs in the SGR adversely effects Medicare payments to physicians.

Respiratory Therapy

The ATS is concerned that CMS has significantly undervalued three G-codes that have been established for providing respiratory therapy. The code G0237 (therapeutic procedures to increase strength of respiratory muscles, one-on-one) was valued at 0.49 RVU with the codes G0238 (therapeutic procedures to improve respiratory function other than the ones described in G0237, one-on-one) and G0239 (therapeutic procedures to improve respiratory function or increased strength, two or more patients) were carrier-priced.

In the proposed rule, CMS has assigned values to G0238 for 0.49 RVU and G0239 of 0.34 RVU. The ATS believes the values for these codes are still low and fail to recognize the intensity of services, monitoring and equipment costs associated with providing these services. The ATS would appreciate the opportunity to provide CMS with more complete data to assist in establishing a more appropriate RVU value for these codes.

Section 305 – Payment for Inhalation Drugs
The ATS is very concerned that precipitous cuts in Medicare reimbursement for inhalation therapy drugs will create patient access problems to this valuable therapy. We urge CMS to move cautiously in changing the reimbursement policy for nebulized medicines.

Inhalation Drug Spread
The ATS concurs with the Congressional finding, supported by several GAO and IG studies, that current Medicare policy reimburses DME suppliers for inhalation albuterol sulfate and ipratropium bromide are significantly more than the DME suppliers acquisition costs. The Medicare payment at average sales price (ASP) plus 6% is estimated to be $0.04 per milligram for albuterol sulfate and $0.30 per milligram for ipratropium bromide. This represents a 90% cut in reimbursement from current payments levels.

The ATS also concurs with the contention of DME suppliers that the reimbursement for albuterol sulfate and ipratropium bromide allows DME companies to supply other valuable services to Medicare beneficiaries, including:

- Access to respiratory therapists
- On call pharmacists
- 24-hour support lines
- Continuing patient education

These added services are not explicitly covered by other components (nebulizer equipment, drug costs, dispensing fee) in the Medicare reimbursement for DME provided nebulizers.

AAHomecare, an organization that represents home health care industry, has contracted MUSE Associations to conduct a study on the actual costs of these additional services provided by suppliers of nebulizer services to Medicare beneficiaries. The study estimates that in order to maintain 2004 levels of service to Medicare beneficiaries and provider and operating margin of 7%, an additional payment of $68.10 per service encounter should be made.

Nebulizers vs. MDIs
The ATS believes that a portion of the Medicare beneficiaries using nebulized albuterol and/or ipratropium bromide could safely switch to the MDI formulation of these drugs. However, many patients will be unable to use MDIs. Further, the ATS believes that a significant portion of Medicare beneficiaries currently using nebulized albuterol and/or ipratropium bromide do so to avoid out-of-pocket costs associated with MDI formulations.

When the Medicare prescription drug benefit begins in 2006, the ATS expects reductions in the cost differential - to the Medicare beneficiary – between nebulized albuterol and ipratropium bromide versus MDI formulations. The reduction of the price differential will likely mean that more patients will switch to MDIs for convenience and the potential increased efficacy offered by MDIs. The magnitude of patient migration from nebulizer to MDI formulations will be highly dependent on both the willingness of DME providers to continue to provide inhalation drugs at the proposed price reduction implemented in 2005 and the costs of MDIs under the Medicare prescription drug benefit offered in 2006.

The ATS is concerned that during 2005 there may be significant disruptions of access to care of patients who require albuterol and ipratropium bromide to manage their respiratory diseases. The

level of cuts legislated by Congress for 2005 will result in significant changes in how DME companies supply inhalation drugs and in their willingness to supply inhalation drugs and related services. The Medicare prescription benefit is not scheduled to begin until 2006. If the cuts in reimbursement for inhalation drugs force DME providers to reduce or discontinue providing nebulizers/inhalation drugs, many Medicare beneficiaries with respiratory disease will not be able to switch to MDI formulations until 2006. This year-long gap in access to these drugs may cause significant problems for Medicare beneficiaries with respiratory diseases. The ATS is concerned that the Medicare-sanctioned discount drug card may not offer any palpable relief in 2005 to patients using inhalation drugs.

Dispensing Fee

CMS proposes to make several changes to current policy regarding the dispensing requirements for inhalation drugs, including:

- Allow for 90-day prescriptions of inhalation drugs
- Allow prescription refills to be shipped approximately 5 business days prior to the end of the previous prescription
- Clarification of policy regarding signed original orders before a prescription is filled
- Changes in proof of delivery requirement
- Changes in requirements regarding the assignment of benefits form

The ATS supports the proposal to change the length of prescriptions for nebulized medicine from a 30-day limit to a 90-limit. Most of the patients who receive nebulized medications are suffering from chronic lung diseases – COPD and asthma being the two most common – and will require medication to manage their disease for prolonged periods. The extension of the prescription duration to 90-days will reduce paperwork and redundant effort on the part of patients, physicians, and DME suppliers.

The other changes deal mostly with shipping, proof of delivery, billing and documentation requirement of the DME supplier. In the proposed rule, these changes are described as having the potential to reduce pharmacy costs for distributing covered inhalation drugs to Medicare beneficiaries.

In general, the changes listed in the proposed rule appear to allow the DME providers to move from a model of service that utilizes technically trained staff to a model that is primarily based on mail order delivery of equipment, drugs and supplies. While this model change may reduce the costs associated with delivering inhalation drugs, the ATS is concerned that the quality of service offered to Medicare beneficiaries may decline.

Additionally, many Medicare beneficiaries will migrate to MDIs for albuterol sulfate and ipratropium bromide. This migration will be caused by changes in caused by cuts in inhalation drug reimbursement and the advent of MDI coverage in 2006. However, those patients who are not able to use MDIs will likely be more frail and require the level of personal service the DME providers currently provide. The ATS is concerned that reduction in services caused by the cuts in reimbursement for inhalation drugs and the evolution of the DME service model to a mail order system will reduce the respiratory services offered by DME providers needed by these vulnerable Medicare beneficiaries.

The ATS recommends the following:

CMS should consider delaying the implementation of cuts in Medicare reimbursement for inhalation drugs until 2006. This delay will ensure that physicians and Medicare beneficiaries will have a range of delivery options for managing respiratory diseases.

CMS should recognize service components provided by DME providers in the dispensing fee. The ATS encourages CMS to review the study conducted by MUSE Association to estimate the value of services offered by DME suppliers to Medicare beneficiaries.

Section 413 – Physician Scarcity Areas and Health Professional Shortage Areas Incentive Payments

The ATS is pleased that Congress has taken steps to encourage primary care and specialty physicians to practice in physician Scarcity and Health Professional Shortage Areas. The incentive payments offered to physicians who practice in these areas will help ensure appropriate access to physicians for Medicare beneficiaries who reside in these areas.

We strongly encourage CMS to publish a list of areas (by zip code) that will receive Medicare incentive payments. Providing this information as soon as possible will help encourage service in these areas and will increase the usefulness of these incentive payments as a tool to recruit new physicians to serve in these areas.

Section 611-Initial Preventive Physical Examination

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CMS further proposes that when a physician otherwise does the work of a problem-oriented E/M service at the same encounter, it will only allow a medically necessary E/M service no greater than a level 2 (i.e., 99202 or 99212) to be reported. In this situation, the problem-oriented E/M service should have a modifier -25 appended to it. CMS makes this proposal on the premise that some of the components for a medically necessary E/M visit are reflected in the new HCPCS code.

The ATS has several concerns with CMS's proposed payment policy for this new benefit. First, we question the necessity of establishing a new "G" code for the service. In the case of diabetes screening tests and cardiovascular screening blood tests, CMS is allowing physicians and others to use existing CPT codes with appropriate "V" diagnosis codes for screening to bill for the services in question. We believe that a covered initial preventive physical examination should likewise have been 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). The preventive medicine visit codes in CPT describe a service that fits the statutory definition of an initial preventive physical examination as well as the elements proposed in 42 CFR 410.16. The ATS strongly believes that existing CPT codes for preventative medicine visits are appropriate and that the creation of a new G-code to describe the service is unnecessary and undermines the integrity of the CPT coding systems.

The ATS believes that CMS has undervalued the non-EKG portion of this service. As noted, we believe the non-EKG portion of this service, as described in both the statute and the proposed regulations, is captured in the current CPT codes for preventive medicine services. Assuming this to be a new patient, as CMS has done, and assuming the typical Medicare beneficiary is eligible based on age (i.e., 65 years or older), the corresponding CPT code is 99387. Currently, Medicare assigns a total of 4.00 relative values to this non-covered service in the office setting, as compared to 2.58 for a 99203. In several instances in this NPRM, CMS requests the RUC to review an interim proposal.

The ATS also has strong concerns regarding CMS's decision to cap the level of problem-oriented E/M service for which physicians may bill when this work is done in conjunction with an initial preventive physical examination. Such a cap suggests that CMS will only recognize self-limited or minor problems (in the case of established patients) or problems of low to moderate severity (in the case of new patients) in these situations. We see no basis for such a view, especially in light of the multiple chronic conditions suffered by so many Medicare beneficiaries. CPT allows physicians 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. We believe CMS should follow CPT in this regard.

Practice Expense Relative Value Unites for Methacoline Challenge – CPT 95070

The ATS notes that CMS is proposing to remove supply costs for methacoline CPT code 94070 and place these costs in CPT code 95070. This change is based on the recommendation of PEAC. Although CMS is proposing to accept this PEAC recommendation, CMS has not increased the practice expense RVUs for CPT code 95070 to reflect the supply cost for adding methacoline.

The ATS strongly recommends CMS add the cost supply cost associated with methacoline to the practice expense relative value for 95070.

The ATS appreciates the opportunity to comment on the revisions policies under the Medicare Physician Fee Schedule. We encourage CMS to keep our recommendations in mind when finalizing these proposed policy changes.

Sincerely,

Sharon I.S. Rounds MD

American Thoracic Society

CMS-1429-P-3960

Submitter : **Mrs. Jo Sauder** **Date & Time:** **09/24/2004 06:09:23**

Organization : **American Massage Therapy Association**

Category : **Other Practitioner**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am contacting you to voice my opposition to the policy where a physician can only refer "incedent to" services to Physical Therapists. I believe that patients should be able to receive quality care with a physicians prescription to all qualified health care providers, such as Athletic Trainers, Chiropractors and Massage Therapists. Thank you for you concern in this matter.

JoAnn Sauder
Physical Therapist Assistant/Nationally Certified Massage Therapist
Lic# TE000775-L Certificate #395799-00
4 Cardiff Ct
Lititz, PA 17543

CMS-1429-P-3961

Submitter : **Dr. Brian Pereira** **Date & Time:** **09/24/2004 06:09:24**

Organization : **National Kidney Foundation**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

This attachment was not included in the prior transmission.

CMS-1429-P-3961-Attach-1.doc

A. CODING-TELEHEALTH

The proposed change recognizes the important and practical role that telemedicine can play in the assessment of dialysis patients who receive treatment in ESRD facilities located in rural or relatively inaccessible areas. It is an important step forward that will directly benefit patient care, especially when geography makes routine, face-to-face, visits with nephrologists challenging for both the patient and the nephrology practitioner.

RECOMMENDATION: The National Kidney Foundation recommends that CMS retain this provision in the Final Rule.

B. CODING: VENOUS MAPPING FOR HEMODIALYSIS

The proposed rule is very restrictive. It will not immediately improve patient care and may not increase the successful placement of arteriovenous fistulas, as intended. According to the Notice of Proposed Rule Making, pre-operative venous mapping can be billed if performed by the operating surgeon, presumably at the time of the placement of a vascular access. Furthermore, it appears that such billing will only be allowed if an arteriovenous fistula is constructed.

The proposed rule does not support the current standard of care. First of all, the great majority of pre-operative venous mapping procedures are carried out by ultrasonagraphers who are radiologists or nephrologists. The procedures are often completed in dialysis facilities. Therefore, reimbursement should not be limited to operating surgeons. Secondly, this procedure is ideally performed days or weeks before the actual operation so that the results can be carefully analyzed and the best operational strategy developed by the nephrologist and the surgeon. Therefore, Medicare reimbursement should not be dependent upon the timing of the procedure. Third, while the National Kidney Foundation's Clinical Practice Guidelines recommend the increased utilization of arteriovenous fistulas, there are instances when venous mapping shows that a patient's vessels are not adequate and a fistula would not be successful. This is an important finding and will save a surgical procedure that would not be successful. It seems counter-intuitive that venous mapping would not then be reimbursed because a fistula was not constructed.

> **RECOMMENDATION: The National Kidney Foundation recommends that the Final Rule authorize payment for vein mapping to nephrologists and radiologists, as well as surgeons, whenever performed, and whether or not a native access is created.**

The National Kidney Foundation is extremely troubled by the reduction in total relative value units for CPT code 36870, percutaneous thrombectomy, by nearly 28 percent, as outlined in the proposed rule. Not only does this reduction run counter to national efforts to improve renal patient outcomes in the area of vascular access, such as the National Vascular Access Improvement initiative and the Fistula First program, but the proposed

rule contains no explanation for the reduction, nor is this code included in Addendum C, providing the PEAC recommendations on practice expense direct cost inputs.

These services can be successfully, efficiently, and safely performed in the outpatient setting, allowing a patient whose vascular access is clotted to be declotted and thus often able to return to their dialysis treatment the same day. Additionally, provision of thrombectomies in the outpatient setting saves the Medicare program overall thousands of dollars in inpatient expenses. As a result, this reduction not only saddles interventional and other nephrologists with a disincentive to provide these services in the outpatient setting, but will likely cause these services to be provided on an inpatient basis and therefore at a substantially greater expense to Medicare.

> **RECOMMENDATION: The National Kidney Foundation therefore strongly urges CMS to restore the total RVUs for CPT code 36870 from the 2005 proposed level of 37.87 to the 2004 level of 52.68, prior to the January 1, 2005 implementation date.**

C. SECTION 303-PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS

1. Average Sales Price (ASP) Methodology

The National Kidney Foundation is concerned that the ASP methodology for drugs provided incident to a visit to a physician's office, even with the minimal administrative fee that CMS is proposing (see below), will make it difficult for nephrologists to deliver anemia therapy for Medicare beneficiaries with reduced kidney function that has not progressed to end-stage kidney failure. In particular, Medicare beneficiaries who do not have Medigap insurance and cannot afford to cover the Part B co-pay may have access to care compromised.

Anemia is present in the majority of patients who have chronic kidney disease (CKD). When untreated, the anemia of CKD is associated with a number of physiologic abnormalities, including decreased tissue oxygen delivery and utilization, increased cardiac output, cardiac enlargement, ventricular hypertrophy, angina, congestive heart failure, decreased cognition and mental acuity and impaired immune responsiveness.

The primary cause of anemia in patients with CKD is insufficient production of erythropoietin (EPO) by diseased kidneys. Medicare authorized payment for recombinant human erythropoietin in 1989. Since then it has been used primarily in the treatment of the anemia experienced by End Stage Renal Disease (ESRD) patients. Recently, however, there has been a growing appreciation of the benefit of anemia therapy for patients in earlier stages of kidney disease. According to the United States Renal Data System (USRDS), a joint project of the Centers for Medicare and Medicaid Services, and the National Institute of Diabetes and Digestive and Kidney Diseases, the percentage of incident patients who had received EPO before the initiation of dialysis jumped from 21.63% to 32.12% between 1995 and 2002 and the mean hemoglobin at initiation of

dialysis increased from 9.2 g/dl to 10 g/dl during the same time period. (USRDS, 2003 *Annual Data Report*, p. 66.) The policies that Medicare is implementing will reverse that positive trend. This would be unfortunate both for Medicare beneficiaries as well as for the Medicare trust funds. Patients who received no or infrequent EPO before the initiation of dialysis have significantly higher rates of hospitalization and overall treatment costs at the time of initial dialysis. (A. J. Collins, "Anaemia Management Prior to Dialysis: Cardiovascular and Cost-Benefit Observations," *Nephrol Dial Transplant* 2003 Jun; 18 Suppl 2:ii2-6.) Among other things, Medicare beneficiaries who did not have access to EPO therapy in the earlier stages of CKD will require larger doses of EPO to achieve target hemoglobin goals once they are on dialysis. This will result in increased expenditures for the Medicare End Stage Renal Disease Program.

As noted in the Notice of Proposed Rule Making, physicians believe that they will not have access to the average discounts that are assumed in the ASP methodology, since they are small purchasers of drugs. Accordingly, the agency requested "comments regarding the extent to which physicians can become members of …buying groups and the possible effects of doing so." Our response is that the proposed level of reimbursement is so low that few nephrologists will have the incentive to join purchasing groups. Moreover, the discounts that might be available through purchasing groups, together with the 2005 administrative fee, may not be adequate to compensate a nephrology practice for the overhead involved in the provision of services to CKD patients.

> **RECOMMENDATION: The National Kidney Foundation recommends that CMS engage the services of an independent agency to determine whether ASP+6% approximates drug acquisition cost in the typical nephrology practice.**

2. Provisions for Appropriate Reporting and Billing for Physicians' Services Associated With the Administration of Covered Outpatient Drugs

We believe that the 2005 administration fee is inadequate to compensate nephrology practices for overhead expenses incurred in providing anemia therapy to Medicare beneficiaries. In the Notice of Proposed Rule Making CMS states: "We also plan to analyze any shift or change in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect." This analysis will be facilitated by comparing data entered on 2728 forms, before and after this policy is implemented. Any evaluation should also include an examination of changes in morbidity and mortality that Medicare beneficiaries with CKD may experience as a result of reduced utilization and impaired access to care attributable to MMA implementation.

> **RECOMMENDATION: The National Kidney Foundation urges CMS to develop plans, as soon as possible, to evaluate the impact of the 2005 changes in drug reimbursement and drug administration fees on access to care for Medicare beneficiaries with CKD who are not yet on dialysis.**

3. Payment for Drugs Furnished During 2005 in Connection with the Furnishing of Renal Dialysis Services if Separately Billed by Renal Dialysis Facilities

The National Kidney Foundation maintains that a system of reimbursement based upon ASP minus 3% is not sustainable and will not cover the costs of providing dialysis services over time. In particular, the NKF is concerned that reimbursement for separately billable drugs at ASP minus 3% may threaten the viability of small and independent dialysis providers, many of which are located in rural communities and are often the sole source of ESRD care in their service areas. The Report from the Office of Inspector General (OIG), Department of Health and Human Services, "Medicare Reimbursement for Existing End-Stage Renal Disease Drugs" (May, 2004), states that independent providers' average acquisition cost for EPO in 2003 was $9.50 per 1,000 units. For Paricalcitol, independent providers paid $4.15 per 1mcg. In contrast, reimbursement in 2005, at the level of ASP minus 3%, will be $9.04 for EPO and $3.99 for Paricalcitol. In fact, Medicare reimbursement to independent dialysis providers next year, at ASP minus 3 percent, would be less than acquisition cost for all injectables except vancomycin.

If ESRD facilities in rural and remote areas are forced to close, dialysis patients, who are often frail and debilitated, will be required to travel long distances, three times a week, in order to receive the treatment they need to survive. Although home hemodialysis or home peritoneal dialysis may be an alternative for some of these patients, many patients may not be candidates for home dialysis, either because of physical or mental impairment or because of problems relating to water and electrical supply. In addition, there are not enough home dialysis training programs, and the reimbursement level for home dialysis training is not high enough ($12 for a CAPD training session or $20 for a home hemodialysis or CCPD training session) to stimulate the development of new programs. One other factor that has and will continue to limit the growth of home dialysis programs is that Medicare and Congress have eliminated the exception request process for accelerated training.

Under another possible scenario, dialysis facilities might refer patients to other providers for the administration of separately billable injectable drugs. That would impose additional hurdles for dialysis patients to secure care, with regard to scheduling and keeping additional appointments, as well as extra transportation demands. Many dialysis patients will not be able to meet this challenge and could experience medical complications because the management of the co-morbidities that accompany ESRD has been compromised.

A third scenario would involve switching patients to oral substitutes for injectable medications, when available. These oral agents may not be as effective as the injectable version and, moreover, efficacy would vary according to patient compliance. Once again, under this scenario, medical complications could ensue because the management of the co-morbidities that accompany ESRD has been compromised. As a result, the advances in care achieved through the CMS Clinical Performance Measures initiative would be eroded.

RECOMMENDATION: The National Kidney Foundation urges CMS to make absolutely certain that the economic viability of independent dialysis providers is protected as these provisions of MMA are implemented.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that payments for separately-billable drugs provided in connection with the furnishing of dialysis services should be set at the "acquisition cost" for each particular drug, as determined by the Inspector General. The currently proposed ASP-3 percent "proxy" for the drug acquisition costs of dialysis facilities is not sustainable over the long term. First, it is based on a methodology that understates the true aggregate costs incurred by independent dialysis facilities associated with acquiring drugs, and it fails to capture many associated routine administrative costs over and above the purchase price of the drugs. Second, the dynamic drug pricing changes that are occurring and will continue to occur under the broader Medicare Part B ASP-based drug payment reforms will not be adequately captured in projections based on an ASP-3% system. There is no basis for assuming that the acquisition cost relationships in the base snapshot taken by the OIG will continue to be reflective of the drug acquisition costs to be faced by facilities in 2005. Although the option was not reflected in the proposed rule, CMS acknowledged this challenge in the preamble to the NPRM, "An alternative approach would be to use the 2003 acquisition prices from the OIG report, calculate the aggregate difference between such prices and payments for drugs under the AWP system, update this difference to 2005 and then apply the budget neutrality adjustment."

Furthermore, CMS should use the OIG's drug-specific acquisition cost data, adjusted for inflation, rather than aggregate data, in setting reimbursement levels for these drugs. Finally, CMS failed to account for certain drugs properly: (1) two forms of Iron Dextran are lumped together in one ASP in the Notice of Proposed Rule Making and (2) whereas the OIG Report stated that the ASP for Carnitor is $10.93, CMS lists it as $7.39.

RECOMMENDATION: The National Kidney Foundation recommends that CMS use the drug-specific acquisition cost data included in Tables 1 and 2 of the OIG report, updated for inflation, to set payment levels for drugs furnished during 2005 in connection with the provision of dialysis services if separately billed by dialysis providers.

Congress decided to change the way Medicare pays for separately billable drugs furnished in connection with the provision of dialysis services for two reasons: (1) to eliminate cross subsidization that obscured the true cost of care, and (2) to remove incentives for inappropriate utilization of drugs and biologicals. In his 2003 Report to Congress, "Towards a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System," Secretary of Health Thompson acknowledged that composite rate payments to dialysis providers do not cover the cost of the services they are required to provide under the composite rate and that separately billable costs make up the shortfall. This cross subsidization arose because of the lack of a system for an annual update to the composite rate, which failure Congress has yet to address. However, the legislature has acted to align incentives for the utilization of drugs and biologicals and the NPRM published on August 5, 2004 outlines the way CMS plans to implement that

Congressional intent. Under the circumstances, there would appear to be little basis for CMS to pursue the parallel revision of the EPO HMA policy that was proposed on July 7, 2004. That proposal was apparently prompted by the perception that there is over-utilization of erythropoietin in the Medicare ESRD program. Furthermore, by instituting two changes in EPO payment policy, more or less simultaneously, there is the danger that any potential negative impact on patient outcomes could be compounded.

> **RECOMMENDATION: The National Kidney Foundation recommends that CMS withdraw the draft revised policy for monitoring claims for EPO for ESRD patients.**

4. Supplying Fee

CMS proposes to pay a $10 supplying fee to pharmacies that dispense immunosuppressive drugs to Medicare beneficiaries who have had a solid organ transplant and need these drugs in order to reduce the risk of rejecting their grafts. While a supplying fee at that level might compensate pharmacies for the cost of stocking many medications, it does not reflect the overhead costs associated with dispensing expensive immunosuppressive pharmaceuticals such as calcineurin inhibitors, TOR Inhibitors and Antiproliferative Agents. These costs include carrying charges, as well as expenses in relation to billing DMERCs and collecting co-payments from secondary payers. Many pharmacies may refuse to fill prescriptions for expensive immunosuppressive drugs, making it difficult for transplant recipients to obtain the drugs they need to preserve their transplants. (A re-transplant or return to dialysis would be much more costly to Medicare.) We suggest that an alternative might be a sliding supplying fee, which would be calculated as a percentage of the cost that the pharmacy incurs in acquiring the drug.

> **RECOMMENDATION: The National Kidney Foundation recommends that the Final Rule authorize the payment of a supplying fee to pharmacies dispensing immunosuppressive drugs that adequately compensates them for providing this service to Medicare beneficiaries who have received a life-saving organ transplant.**

D. SECTION 623 – PAYMENT FOR RENAL DIALYSIS SERVICES

1. Options for Applying the Drug Add-On Adjustment to the Composite Payment Rate

CMS proposes a single drug add-on adjustment to the ESRD composite rate for both hospital-based and independent facilities to account for changes in pricing of separately billable drugs and biologicals. This alternative is proposed even though the two types of providers have been subject to different reimbursement policies for all of these drugs except for EPO. Hospital-based facilities provide high quality care to patients with ESRD and deserve to be adequately reimbursed. However a single adjustment would ignore the different impact that the implementation of MMA will have on the two kinds of providers.

RECOMMENDATION: The National Kidney Foundation recommends that the drug add-on adjustment should be designed to compensate both hospital-based and independent dialysis facilities for the actual loss of revenue they will experience as the result of changes in pricing of separately billable drugs.

A central feature of implementing the add-on adjustment is how CMS will update it, consistent with the statutory requirements. Unfortunately, the Proposed Rule does not address this issue. The proposed system for 2005 is not sustainable and will not cover the costs of providing dialysis services over time. CMS must provide information to the kidney community about how the separately billed drug payments and add-on amounts will be updated before finalizing the rule. Therefore, NKF strongly urges the agency to include a discussion of the update mechanism in the Final Rule and to provide interested parties with an opportunity to comment on it.

To ensure a sustainable system over the long-term, it is imperative that CMS describe more fully how it proposes to account for the changes that will occur in the drug acquisition costs facilities will face. Therefore, we feel very strongly that CMS must comply with the provisions governing acquisition costs and budget neutrality requirements by 1) updating the add-on payment on a regular basis so as to take reasonable account of these market dynamics, as well as the effects of broader Part B payment reform, 2) and do so in a manner consistent with the concepts and objectives evidenced in Section 1847A of the Social Security Act.

RECOMMENDATION: The National Kidney Foundation recommends that the final rule include, for comment, a mechanism that will reflect changes over time in acquisition cost for injectable drugs provided in the dialysis clinic.

2. Proposed Patient Characteristic Adjustments

CMS is proposing to adjust the composite rate for age, gender, AIDS and PVD. The National Kidney Foundation is concerned that these variables are not significant predictors of cost variation and that other patient characteristics, such as BMI and pediatric age, might be more important considerations. Furthermore, it will be difficult to implement adjustments for AIDS and PVD. This information is not captured on the cost report. There is no standard definition of PVD. Medical confidentiality laws prohibit screening patients for HIV status or asking patients to disclose HIV status. CMS should delay implementation of case-mix adjustment until it has developed mechanisms to collect and validate the necessary data upon which to select and weight those patient characteristics that increase the cost of care. This should include an examination of the complexity of care involved in treating pediatric ESRD patients. Case-mix adjustment for pediatric dialysis patients should be pursued because of the difficulty providers experience in securing a pediatric exception. Three applications for pediatric exceptions have been filed since the window was re-opened and two of them have been rejected. Theoretically, the inclusion of a pediatric category would provide an incentive for adult units to dialyze children who live in communities where there are no pediatric units.

RECOMMENDATION: The National Kidney Foundation recommends that CMS delay implementation of case-mix adjustment of the composite rate.

3. Geographic Index

CMS does not propose any revision to the current set of composite rate wage indexes, and the urban and rural definitions used to develop them, even though these have not been adjusted for 20 years. The National Kidney Foundation urges the agency to reconsider this plan. New updated OMB definitions for MSAs, CSAs and "micropolitan" areas have been developed and implemented in other areas of health care. Updating the wage index will address the concerns of dialysis facilities in parts of the country where the cost of living is high and it is difficult to compete, on the basis of salary, with other health care facilities, in the hiring and retention of nurses in an era of nursing shortage. In addition, updating the geographic wage index may provide relief for dialysis providers in areas that were considered rural 20 years ago but would now be characterized as suburban.

RECOMMENDATION: The National Kidney Foundation recommends that CMS develop a plan to update the geographic wage index for the ESRD program.

4. Summary of Composite Rate Revisions and Proposed Implementation

Section 623 (a) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 provides an increase in the ESRD composite rate by 1.6 percent, effective January 1, 2005. However, CMS proposes to adjust this increase to achieve budget neutrality. We question the statutory basis for the agency's plan.

RECOMMENDATION: The National Kidney Foundation recommends that CMS not adjust the 1.6 percent update in the composite rate for budget neutrality.

CMS-1429-P-3962

Submitter : **Ms. Kim Begley-Brauer** **Date & Time:** **09/24/2004 06:09:32**

Organization : **Ms. Kim Begley-Brauer**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Santa Cruz is not a rural county anymore!

My home, that I purchased in Santa Cruz County 15 years ago was $325,000. Today, it is appraised at Silicon Valley rates at $775,000!! My husband was in a motorcycle accident May of this year. Because Santa Cruz County is not properly defined as "urban", there are no head trauma surgeons in Santa Cruz County. He had to be airlifted at a cost of $14,000 to Santa Clara Valley Medical Center in order to save his life. Now San Jose Medical Center is closing and Santa Clara Valley Medical Center is proposing not to take trauma patients from Santa Cruz County because of the overburdon on their system. If you do your research correctly, the cost of living in Santa Cruz County as at the same if not higher as other "urban" bay area counties. My doctor informs me that he's greatly concerned about the lack of medical care in Santa Cruz County due to the fact doctor's can't afford to live here because Medicare hasn't properly recognized this as "urban" County. My question is, when people start dying as a result of this inequity, how are you going to deal with that? Everyone knows that the cost of living has changed drastically in the last 10 years in Santa Cruz County. I couldn't afford to buy my own home at today's prices!!! Please do the right thing by finally acknowledging what the facts already speak for themselves, that Santa Cruz County should be defined as "urban" so we can feel less anxiety that our famalies can have access to quality healthcare.

Thank you.

Kim Begley-Brauer
(831) 345-7200

CMS-1429-P-3963

Submitter : **Ms. Aviva Pittle** **Date & Time:** **09/24/2004 06:09:10**

Organization : **Ms. Aviva Pittle**

Category : **Other Health Care Provider**

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-3964

Submitter : **Dr. Stacie Bertram** **Date & Time:** **09/24/2004 06:09:43**

Organization : **Bradley University**

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 24, 2004

To Whom It May Concern:

I am writing in support of the proposed personnel standards for physical therapy services that are provided 'incident to' physician services in the physician's office. It is my strong professional opinion 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 oppose the use of unqualified personnel to provide services described and billed as physical therapy services.

Just recently, a family member of mine received what they thought was physical therapy, delivered by personnel in a physician's office. They were never examined by a physical therapist, and their care was not directed by a physical therapist. They, and their insurance company however, were billed for physical therapy. My relative was very unsatisfied with their treatment and the results, and called me for my opinion of this particular PT, and whether this was standard care. It did not take me more than 2 minutes of conversation to determine that my relative did not, in fact, receive physical therapy from qualified personnel, and that their care was significantly substandard!

Physical therapists are highly educated individuals who are uniquely qualified to examine and treat disorders of the musculoskeletal and neurological systems. Most students who enter into the profession of physical therapy today will graduate with a clinical doctorate. The field of physical therapy has expanded substantially in the last 2 to 3 decades, and other medical personnel could not possibly stay abreast of the changes in my field, as well as keep up in their own!

Only individuals who graduate from an accredited program in physical therapy education should be delivering and billing for physical therapy. Physical therapist assistants (PTA) should only deliver care when operating under the supervision of a physical therapist. Any other scenario in my opinion, is at best misleading the patient, and at worst fraud.

Respectfully,

Stacie Bertram PT, PhD
Assistant Professor of Physical Therapy and Health Science
Bradley University
Peoria, IL

CMS-1429-P-3965

Submitter : **Date & Time:** **09/24/2004 06:09:47**

Organization :

Category : **Chiropractor**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

All qualified health care providers should be allowed to provide services to patients with a physician's prescription or under their supervision. Since chiropractors are primary care physicians, there should not be limits to prescribed services at chiropractic offices and/or under their supervision.

CMS-1429-P-3966

Submitter : **Mr. Joseph Bishop** **Date & Time:** **09/24/2004 06:09:16**

Organization : **Baptist Memorial Health Care Corporation**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am writing this comment to speak on the subject of "therapy - incident to. I am an athletic trainer/certified and licensed in the state of Mississippi to practice. I currently work for a hospital organization providing outreach sports medicine coverage and occupational health services. Limitation of the athletic training profession on the subject of "therapy - incident to" would be, I feel, very detrimental to the population served by our profession. The role of an athletic trainer is to provide preventive care as well rehabilitation services for any injured athlete. In the state of Mississippi, this typically occurs in lower income areas. Restriction of athletic trainers would be harmful due to the amount of coverage in these high need areas by qualified and competent health care professionals. Restriction of "therapy - incident to" to direct supervision by a physical therapist would severly hamstring the ability of the athletic trainer to continue to provide these high level services in todays health care market. Based on our state law alone, physical therapists would not be able to provide the services that athletic trainers are capable of offering and, coupled with this proposed restriction to reimbursement, would find themselves financially unable to provide these services. Limiting the reimbursement of the athletic trainer would not be a benefit for the patients we serve but would further limit their ability to access quality rehabilitative health care. I respectfully ask that CMS reconsider this provision to CMS-1429-P.

CMS-1429-P-3967

Submitter : **Mr. Soren Johansson** **Date & Time:** **09/24/2004 06:09:10**

Organization : **Elektra**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see our attached comments on behalf of Elekta.

The comments concern stereotactic radiosurgery.

CMS-1429-P-3967-Attach-1.doc

September 24, 2004

Via Electronic Submission

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Comments concerning Stereotactic Radiosurgery as presented in the CMS-1429-P (Proposed Rules)

Dear Administrator:

Thank you for the opportunity to comment on the CMS-1429-P proposed rules. On behalf of Elekta, Inc., we are submitting comments concerning the reduction of RVUs for stereotactic radiosurgery, which are proposed for the 2005 physician fee schedule. The changes that we refer to are posted in Addendum B – Relative Value Units and Related Information, in the August 5, 2004 Federal Register, page 47640. For reference, the CPT code for stereotactic radiosurgery is 61793.

CMS' Proposal:
CMS is proposing to reduce the facility practice expense RVUs and the mal-practice RVUs for stereotactic radiosurgery. The total facility RVUs are 31.60 for calendar year 2004. In calendar year 2005, CMS proposes 31.56 RVUs for radiosurgery, a decrease of 0.04 RVUs. The physician work component will not be affected. But, the facility practice and mal practice expenses will decrease by 0.03 and 0.01 RVUs, respectively.

Background:
It is helpful to understand the clinical history and coding of this procedure, in order to understand the potential causes of the reductions in RVUs. Cranial-based stereotactic radiosurgery, began in the 1960's in Stockholm, Sweden. In 1987, a neurosurgeon at the University of Pittsburgh Medical Center (UPMC) acquired the Gamma Knife, a multi-source cobalt^{60} based device, to perform cranial-based stereotactic radiosurgery. The stereotactic radiosurgery program at UPMC is a tremendous success. The neurosurgeons treat over 600 patients per year on two Gamma Knives. In the US, there are 85 operational Gamma Knives, many at other leading academic, neurosurgery centers. Cranial-based stereotactic radiosurgery is performed in both the hospital inpatient and outpatient settings.

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Cranial-based stereotactic radiosurgery has been clinically reviewed, since the late 1980's in the US, and the efficacy and cost resources of this procedure are well documented in American neurosurgical journals, including the *Journal of Neurosurgery*, *Neurosurgery*, and *Stereotactic and Functional Neurosurgery*. Due to the early successes of the Gamma Knife, other technologies have been developed, like linear accelerator (linac) based stereotactic radiosurgery. There are approximately 18,000 cranial-based stereotactic radiosurgery procedures performed by neurosurgeons per year in the US, and this number continues to increase. Medicare represents approximately 1/3 of these procedures, nationally.

Definition of Stereotactic Radiosurgery:
Stereotactic radiosurgery, as it was defined by its founding neurosurgeon, Professor Lars Leksell, is the "precise delivery of a single, high-dose of radiation to a discrete target in the brain." The doses delivered in cranial-based stereotactic radiosurgery are extremely high and can range from 20 to 90 Gy. The energy from these high doses could severely harm or kill the patient if not targeted accurately. Dr. Leksell developed this procedure as an alternative to craniotomy for those patients who could not undergo conventional surgery, or whose conditions were too risky due to the location of their disease. Clinical studies have shown that cranial based stereotactic radiosurgery, performed with a multi-source cobalt^{60} based device, offers the same, and often times better results than conventional surgery.

CPT Coding Changes:
Shortly after the University of Pittsburgh Medical Center acquired its Gamma Knife in 1987, CPT code 61793 was established by the American Medical Association in response to a request by neurosurgeons. The original CPT descriptor read, "stereotactic radiosurgery." In the late 1990's, two modifications were made to stereotactic radiosurgery's descriptor. First, the three technologies used to perform the procedure – multi-source cobalt^{60} based systems (Gamma Knife), linear accelerator and proton beam systems, were added to the descriptor. This addition occurred just after a similar change was made, by CMS' Coordination and Maintenance Committee, to the ICD-9 procedure code for stereotactic radiosurgery, 92.3. The code was divided into separate codes for each technology. Second, the phrase "one or more sessions" was incorporated into stereotactic radiosurgery's descriptor. This change directly conflicted with the "single-session" definition of the procedure. The current description of CPT 61793, as listed in the American Medical Association's 2004 Standard Edition, CPT handbook (copyright 2003) reads, "Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator), one or more sessions." There is also a statement about intensity modulated beam delivery planning and treatment (77301 and 77418), which has no relation to stereotactic radiosurgery.

CPT 61793 has evolved from a cranial-based surgical code to a 'catch all' for several types of procedures, some of which are completely unrelated. Elekta is aware and concerned that CPT 61793 is being used to represent other procedures, such as extracranial radiosurgery, for treatment of the spine, lung and pancreas, hypofractionated (few fractions) radiotherapy and stereotactic radiation therapy. Both extracranial radiosurgery and hypofractionated radiotherapy are relatively new and developing procedures (e.g. within the last 5 years, US). There is not much clinical evidence, in the form of published, clinical literature, regarding the efficacy of extracranial radiosurgery and hypofractionated radiotherapy.

From a clinical perspective, the doses delivered in extracranial radiosurgery and hypofractionated radiotherapy are much smaller (e.g. less than 10 Gy per fraction) than that delivered in cranial-based stereotactic radiosurgery (stated earlier). The doses delivered in stereotactic radiotherapy are less than 2 Gy per fraction. Also, extracranial radiosurgery, hypofractionated radiotherapy and stereotactic radiotherapy are almost exclusively performed in the outpatient setting. This also contrasts with the clinical characteristics of cranial-based radiosurgery.

The resources used and costs of extracranial radiosurgery, hypofractionated radiotherapy and stereotactic radiotherapy are significantly different from that of cranial-based stereotactic radiosurgery. For example, the equipment, treatment room, supply and staffing costs of hypofractionated radiotherapy are less than that required for cranial-based stereotactic radiosurgery. Moreover, extracranial, hypofractionated radiotherapy and stereotactic radiation therapy are not surgical procedures; therefore, they are less resource intensive than cranial-based stereotactic radiosurgery.

Extracranial radiosurgery, hypofractionated radiotherapy and stereotactic radiation therapy are usually performed by radiation oncologists with the assistance of radiation therapists. They do not typically involve neurosurgeons, except in some cases when the spine is involved. But even in these situations, a neurosurgeon's participation is rare after the first fractionated delivery of radiation. A few radiation oncologists have gone as far as trying to use CPT 61793 for professional billing of extracranial radiosurgery and hypofractionated radiotherapy. In some cases, they have been denied by insurers.

Problems:
The use of CPT 61793 for extracranial radiosurgery, hypofractionated radiotherapy and stereotactic radiation therapy is not consistent with the code's initial design and intended use - both from a clinical and cost perspective. The use of CPT 61793 for these procedures is causing the RVUs of the original procedure, cranial-based stereotactic radiosurgery, to decrease due to the differences in procedure resources. Therefore, the RVUs calculated by CMS and its consultants do not accurately represent the physician's work and the facility's practice expense for cranial-based stereotactic radiosurgery.

Extracranial Radiosurgery and Radiotherapy:
(Reference Table 3 – Proposed Practice Expense Supply Item Additions For 2004 (2005); **Marker, gold**, for radiosurgery-radiotherapy, pg 47499)

Elekta realizes there is significant research work being done in the areas of extracranial radiosurgery, extracranial, hypofractionated radiotherapy and image- guided radiotherapy with the use of different image-guidance technologies, like gold markers, for localization purposes. Therefore, image-guided codes are warranted for *extracranial* procedures involving the use of these additional resources. **However, the codes should not be associated with cranial-based stereotactic radiosurgery, since they are not applicable to this procedure.**

Recommendations:
Elekta recommends a meeting with CMS' staff to clarify the inconsistencies in the uses of CPT 61793 as outlined above. Elekta has ideas for correcting these problems and would like the opportunity to present them to CMS.

Elekta would like to emphasize that the issues presented in these comments are not new and have been addressed previously with CMS' staff in the Division of Outpatient Care, both through verbal and written communication. To clarify and correct CMS' coding policies concerning cranial-based stereotactic radiosurgery and other forms of radiosurgery, Elekta proposes a 'round table' discussion that would include experts in the radiosurgery and conformal radiation therapy fields, including neurosurgeons, radiation oncologists, medical physicists, and members of CMS' Physician Fee Schedule and Hospital Outpatient Care departments. This collaborative effort would help CMS sort through these recurring coding issues.

Thank you, again, for the opportunity to comment. Should you need to contact me, please feel free to call me at (800) 535 – 7355.

Sincerely,

Soren Johansson
Vice President
Elekta

Background of Elekta

Dr. Lars Leksell - the inventor of stereotactic radiosurgery, founded Elekta 25 years ago. Elekta is the only medical device company in the world, which supplies both linear accelerator and multi-source cobalt^{60} (Gamma Knife) technologies that are used for stereotactic radiosurgery treatment. Furthermore, the company holds the largest market share in this industry, and one of the largest market shares in the radiation therapy industry, with 1,400 installations in the world, and 430 installations in the US.

Elekta manufactures and sells stereotactic radiosurgery and conformal radiation therapy systems, in the US, under the following trademark names.

1. **Leksell Gamma Knife® (radiosurgery)** - a dedicated, neurosurgical tool, used for the treatment of intracranial, benign and malignant tumors, vascular malformations, and functional disorders. The Leksell Gamma Knife delivers a single, high dose of ionizing radiation to a discrete target in the brain. This surgical tool is used to ablate the lesion while minimizing the damage to the surrounding tissue and critical structures. The Gamma Knife is used at 85 acute care medical centers throughout the US, including many large academic centers like the Cleveland Clinic, Johns Hopkins University Hospital, the University of Maryland Medical Center, the Mayo Clinic, and the University of California at San Francisco (UCSF).

2. **Elekta (Philips) SRS 600® (stereotactic radiosurgery)** - a dedicated, 6 MV linear accelerator, which is used for the treatment of intracranial, benign and malignant tumors, vascular malformations, and extracranial malignant tumors. The linac produces high-energy, therapeutic X-rays and was designed for stereotactic radiosurgery – single session. However, the device can be used to deliver radiation over both single and multiple sessions (radiotherapy). The benefit of multiple session delivery, or hypofractionated radiotherapy, is the ability to treat larger tumors without destroying the surrounding healthy tissue. Like the Gamma Knife, the linac device is used by a neurosurgeon with the assistance of a radiation oncologist and a medical physicist for radiosurgery treatments. However, it is commonly used by a radiation oncologist for those extracranial indications that do not involve the spine and central nervous system. The procedures performed with the Elekta SRS 600 device are represented in Medicare's outpatient prospective payment system with HCPCS codes G0338, G0173, and G0251. The Elekta SRS 600 has been developed by and is being used by the leading linac-based radiosurgery center in the US, the University of Florida, Shands Hospital, among others.

3. **Elekta Synergy® (radiotherapy and hypofractionation)** - an image-guided robotic linear accelerator, recently FDA cleared. This linac device is the first system of its kind to provide 3D imaging of the target area during treatment delivery. Unlike the Gamma Knife system, which uses a minimally invasive frame to ensure accuracy, the Synergy system uses a 3D imaging system, which continually monitors the exact location of the treatment area while treatment X-rays are being delivered. Since this system is newly released to the market, Elekta anticipates that the Synergy radiotherapy system will be used by radiation oncologists for the treatment of extracranial tumors, which move during treatment, like those of the lung, prostate, and pancreas. The HCPCS codes, which might be used to represent outpatient procedures performed with this system, include G0338, G0339, and G0340. Several large academic centers, such as William Beaumont Hospital, Thomas Jefferson University Medical Center, and Temple University Health System, are expected to begin using this system in Calendar Year 2004.

4. **Other products (radiation therapy)**
   Elekta also manufactures and distributes linear accelerators for conventional and conformal radiation therapy. In the area of conformal radiation therapy, Elekta is an important and significant supplier of intensity modulated radiation therapy (IMRT) equipment, such as the Precise® linear accelerator and mini multileaf collimator. Medicare has designated HCPCS codes 77301 and 77418 for those outpatient procedures in which these products are used.

CMS-1429-P-3968

Submitter : **Date & Time:** **09/24/2004 06:09:11**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

In response to the August 5 proposed rule on ?Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005?, I agree with the Centers for Medicare and Medicaid Services (CMS) proposal to require only physical therapist and/or physical therapist assistants under the supervision of the PT to provide physical therapy services to patients. As a student completing my final year of my clinical doctorate in physical therapy, I have first hand knowledge and experience of what is academically required and expected from those wanting to be a physical therapist. Like any other health care profession including (not an all inclusive list) medical doctor, physician assistant, nursing, optometry, dentistry, and dental assistant, physical therapy is a specialty. The common link between all health care providers is providing services to others in order to promote the well-being of the individual, but not all health care providers are experts or trained in every aspect of every health related field. As mentioned above, physical therapy is a specialty and requires unique skills and knowledge only acquired by going through an accredited physical therapy program.

Along with being a physical therapy student, I have also received physical therapy secondary to anterior cruciate ligament (ACL) surgery. After hurting my knee on the soccer field I went to my university?s student health service where a medical doctor diagnosed me with a pulled hamstring and told me I could play the following week. I did not feel it was a pulled hamstring and went to my primary care physician who diagnosed me with patellar femoral syndrome and told me I would be able to play soccer. The following week I played in the game, but my knee felt unsteady, but I thought it was weak due to the multiple ?problems? I had. During the game I went down again due to my knee giving out. I went to a third doctor who ordered an MRI, and it came back positive for an ACL tear. It took three doctors to diagnose me with an ACL rupture. None of them performed any special tests to rule in or rule out the possibility of one of the most common injuries in athletic females. As a future physical therapist, I already know how to diagnose an ACL tear as well as multiple other orthopedic impairments. If it took three doctors to get an appropriate diagnosis, how many problems would be misdiagnosed with other patients?

The reason for multiple disciplines in health care is to provide the best, effective, and most efficient treatment and care possible to those seeking help. Like any other specialty, physical therapy is a niche that only trained professionals can perform. If people are performing services without being properly educated, quality of care declines and increased costs are incurred. Physical therapy services should only be provided by those with a physical therapy and/or physical therapist assistant degree and license in order to avoid and prevent mistreatment of patients.

CMS-1429-P-3969

Submitter : **Ms. Wendy Buchanan** **Date & Time:** **09/24/2004 06:09:54**

Organization : **AMTA, NCBTMB**

Category : **Other Health Care Professional**

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-3970

Submitter : **Julie McKay** **Date & Time:** **09/24/2004 06:09:32**

Organization : **Julie McKay**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

Limiting services to PTs will limit the multitude of services that other highly qualified therapists make available to other clients. This will prevent optimal health care for individuals and be to the detriment of the individual seeking help.

CMS-1429-P-3971

Submitter : **Date & Time:** **09/24/2004 06:09:46**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am a Licensed Physical Therapist providing Physical Therapy in an outpatient orthopedic clinic in South Carolina. I have been in practice, in a variety of settings, for the past twelve years.

I am writing 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 individuals providing physical therapy services in a physician?s office be a licensed Physical Therapist (PT) or Physical Therapist Assistant (PTA) under the supervision of a licensed physical therapist. All licensed PT?s and PTA?s must be a graduate of an accredited professional Physical Therapy or Physical Therapist Assistant program. This is the only way to ensure that individuals providing these services have the knowledge and experience necessary to provide safe and effective interventions to patients. PT?s and PTA?s have an extensive background in the services being provided that are under consideration by CMS. Modalities, exercises or manual treatments being provided by individuals other than licensed PT?s or PTA?s puts the patient receiving these services at risk. There are many contraindications and precautions to performing most physical therapy procedures, i.e., ultrasound, electrical stimulation, exercises, joint mobilizations, and soft tissue massage. PT?s and PTA?s are knowledgeable about the parameters of each service and can justify why they are performing these procedures. Whereas, an unlicensed person would be performing these procedures simply because they were told to do so by the physician. I feel this puts the patient at a great risk. PT?s and PTA?s are also knowledgeable about how to change the parameters for each physical therapy procedure based on the patient?s response. I would question the ability of an unlicensed individual to do this.

I feel the safety and quality of care of all Medicare beneficiaries will be impacted in a positive way by implementing this proposed rule. I sincerely hope CMS takes action to ensure all its beneficiaries are being treated by a licensed physical therapist or physical therapist assistant in any setting where they are receiving physical therapy procedures.

Thank you for your time in considering my comments.

CMS-1429-P-3972

Submitter : Ms. Valerie Baldino, LMT, NCBTMB **Date & Time:** 09/24/2004 06:09:14

Organization : ABMP

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I encourage you NOT to pass this policy allowing only PTs to be referred from physicans for "incident to" services. Massage Therapists serve a vital role in the healing profession and should be allowed to provide services to medical and chiropractic patients. This profession has been around as long as the medical profession and it is time they were recognized for the vital role they play.

CMS-1429-P-3973

Submitter : **Miss. Gina Giovingo** **Date & Time:** **09/24/2004 06:09:27**

Organization : **American Physical Therapy Association**

Category : **Individual**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

CMS-1429-P-3973-Attach-1.doc

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

9/13/04

Dear Mr. McClellan,

I am writing in regards to the rule proposed by CMS that qualifications for individuals providing physical therapy services "incident to" a physician should meet personnel qualifications for physical therapy.

I write to you with strong support for CMS's proposed requirement that physical therapists working in a physicians office be graduates of an accredited professional physical therapy program. Currently, I am a physical therapy student at Marquette University in their Doctor of Physical Therapy program. My final year of schooling includes a semester of advanced coursework and a semester of clinical experience. Through my education I have had classes including extensive anatomy, physiology, neuroanatomy, neuro rehab, differential diagnosis, cardiopulmonary, evidence based decision making, kinesiology, pathophysiology, diagnostic imaging, tests and measures, wound management, and orthopedics. I have also had training in patient management, use of modalities, and have completed 2 clinical experiences: 4 weeks in a hospital setting, and 10 weeks in an outpatient clinic.

Marquette's program is accredited, which I found of high importance when looking for a school. Physical therapists coming from programs accredited by the Commission on Accreditation of Physical Therapy recognized by the U.S. Department of Education, will have common education and training necessary for the role of a physical therapist. All physical therapy programs must be accredited in order to gain licensure. The licensure exam for a physical therapist is a standard measure ensuring that those entering the physical therapy field are qualified to provide safe and effective treatment.

The only professionals with proper education and training to provide physical therapy services are physical therapists and physical therapist assistants under supervision of a physical therapist. Unskilled personnel fulfilling these services can potentially be harmful to the patient. The personnel will not understand the physiology of why a particular service is being performed, which makes them unable to effectively modify treatments based on the patients response. Physical therapists are educated on normal and abnormal responses of patients to treatments, and are able to make the necessary modifications and actions based on the patients responses. Physical therapists are also educated on the contraindications to certain types of therapy that an unskilled person would not be aware of and could potentially cause harm. Physical therapists also utilize

evidence based practice, which allows them to treat in ways that are proven effective and will maximize the benefit to the patient.

I want the important role of a physical therapist to remain of high importance within health care. The physical therapy services should only be performed by a licensed physical therapist or licensed physical therapist assistant with appropriate supervision of a physical therapist. I want patients trust in physical therapy services to remain strong and not to be questioned by inappropriate treatment from an unskilled person.

Thank you for your time and consideration of the above comments.

Sincerely,

Gina Giovingo, SPT.
Marquette University
Year-6 of the Doctor of Physical Therapy Program
750 N. Eighth Street #408
Milwaukee, WI 53233
414-303-1448
gina.giovingo@mu.edu

CMS-1429-P-3974

Submitter : **Mr. Carlos Ortiz** **Date & Time:** **09/24/2004 06:09:49**

Organization : **CVS pharmacy**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please accept comments on behalf of CVS regarding file CMS-1429-P.

CMS-1429-P-3974-Attach-1.doc

September 24, 2004

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

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

To Whom It May Concern:

CVS Pharmacy is providing comments with regard to the proposed rule published August 5, 2004. This proposed rule would make changes to the payment methodology for drugs and DME covered under the Medicare Part B program. Additionally, it would also change some of the requirements regarding the processing of drugs and DME under this program.

CVS operates approximately 5,400 pharmacies in 36 states and the District of Columbia. Substantially all of these pharmacies are enrolled as providers in the Medicare Part B program.

Section 302 - Clinical Conditions for Coverage of DME

This section would create new standards for the coverage of DMEPOS, including drugs and supplies. CVS would like to address the following issues:

- As stated above CVS operates pharmacies in 36 states and DC. Thus we are especially concerned about any variability between the 4 DMERCS. We would request that the conditions for clinical coverage for DMEPOS be handled/addressed at a national level thus eliminating any DMERC variability.
- CVS also believe that the requirement for any insulin dependency code for diabetic supplies is unnecessary. No other third party payer requires this code and obtaining the code is often difficult and time consuming.

Section 303 – Payment for Covered Outpatient Drugs and Biological

CVS is extremely concerned about several aspects of this section. Specifically we are concerned about the utilization and calculation of Average Sales Price, the adequacy of the supply fee, and issues related to billing requirements.

Average Sales Price (ASP)

The proposed rule defines ASP as a manufacturer's total sales less any sales exempted from the ASP divided by the total number of units of such drug sold by the manufacturer in the quarter, less any units from sales exempted from the ASP calculation. The manufacturer is required to deduct the following: volume discounts, prompt pay discounts, cash discounts, free goods, charge backs and rebates.

Retail pharmacy is not the beneficiary of most of the specified discounts made available by drug manufacturers on their products. Basing a provider's reimbursement on an acquisition cost that is not achievable is not appropriate and would result in a system that is not viable.

CVS believes that ASP, as proposed, is an inappropriate methodology for reimbursement for the following reasons:

- **ASP reduces pharmacy reimbursements based on rebate payments from manufacturers that pharmacies do not receive:** Branded pharmaceutical manufacturers do pay significant rebates, particularly on single-source branded medications. However, these rebates are generally paid to fiscal intermediaries who do not pass any part of them onto retail pharmacies. Including such rebates in an ASP calculation would reduce reimbursement to retail pharmacies where there is no commensurate reduction in purchase price to the pharmacy.
- **ASP ignores class of trade realities:** As a class of trade, community pharmacy pays significantly higher prices for brand name drugs as compared to all other classes of trade. In contrast, hospitals and clinics are able to buy branded drugs at a significant discount to retailers due to their class of trade distinction. Thus, this ASP definition will create a reimbursement rate that will both disadvantage community pharmacy and at the same time provide an excessive reimbursement to other classes of trade. Unless CMS proposes eliminating the class of trade system entirely, community pharmacy would likely be faced with selling Part B products below acquisition cost.
- **ASP will not be determined "real time" and this stale data will impact reimbursements**: The proposed rule requires manufacturers to submit average sales price within 30 calendar days of the quarter's close. This will likely result in a derived ASP that is 2-6 months out of date. Given the typical price increases on brand name pharmaceuticals of 5-7% annually, retailers would systematically be penalized since reimbursements will be based on much lower prices that no longer exist. It is critically important to understand that these increases are unilateral changes by manufacturers that providers cannot control. Retailers are typically notified of a price increase only after the manufacturer has put the price

increase into effect. It would be unprofitable for a retailer to participate in a system that established reimbursement in this manner.

- **Current pricing methodology would preclude retailers from earning a return on its investment to realize cash discounts/prompt pay discounts:** Earning such a discount is predicated upon a purchaser's desire to pay the invoice within the allotted time period. Therefore, cash discounts/prompt pay discounts are available primarily to those purchasers that are willing to invest in and maintain an infrastructure to support warehousing, distribution, and billions of dollars in inventory, in order to adequately service our customers and earn a discount for doing so. If these discounts are included in the calculation of ASP, it would make little or no sense to support a warehousing and distribution infrastructure, or even pay invoices early, to qualify for the incentive since the lower level of reimbursement would eradicate the incentive.
- **ASP is not transparent nor readily available:** Unlike other commonly used metrics (i.e. AWP and WAC), ASP will not be a publicly available and auditable figure. Thus pharmacies will not be able to quantify the profitability of this book of business until after the fact.
- **New pricing methodology would eliminate the incentive for community pharmacy to drive generic utilization for Part B product:** The average brand reimbursement is approximately $103.48 versus the average generic of $18.47; this is the greatest savings opportunity for Medicare. Community pharmacy has been a great force in promoting the use of generic drugs in the marketplace. Applying ASP plus 6% to generics would not generate enough revenue to cover community pharmacy's cost to dispense a prescription. If the ASP of this item is $10 then reimbursement would become $10.60. Every pharmacy would lose money dispensing these medications since the average cost to fill a prescription is approximately $7.50.

Supplying Fee

While we are pleased that CMS intends to establish a Supplying Fee, CMS needs to publish the exact fee in the final rule since it was not included in the proposed rule. Additionally, we are concerned that the proposed $10 fee may be inadequate for the following reasons:

- Given that the average cost to dispense a non-Medicare prescription ranges from $7.50-$8.00, and that there is a considerable amount of additional work in filling and billing Medicare Part B prescriptions, $10.00 is an inadequate amount.
- For immunosuppressive drugs, especially the initial prescription, pharmacies must obtain significant additional information prior to submitting a claim, thus further increase the cost to the pharmacy.

Issues Relating to Billing Requirements

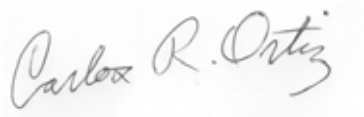
Because of the additional burden to fill and process Medicare Part B prescriptions, CVS supports all attempts by CMS to simplify the process. We would encourage CMS to incorporate the following in the final rule:

- CMS should require all 4 DMERCs to implement any changes incorporated in the final rule.
- Medicare is the only significant payer that still requires “batch billing” of claims instead of an online real-time adjudication. This lack of an online system results in a significant increase in initially rejected claims that require reprocessing. An online real-time system would also facilitate other functions such as real-time eligibility verification of both the recipient and drug, a more complete patient history if the recipient is using multiple pharmacies, and the elimination of time constraints to process paper or batch claims.

CVS supports many of the changes that CMS either has already implemented or is proposing as part of the proposed rule. These include clarification that pharmacies do not need to obtain an actual written prescription prior to filling a prescription, that on cross over claims CMS will indicate on the remittance advice whether the claim was paid by Medicare or rejected and crossed over to another payer. We also appreciate consideration by CMS to adopt usage of the DEA number rather than the UPIN number. Most other payers utilize the DEA number and it is readily available on most prescriptions.

In conclusion, we appreciate the opportunity to comment on this proposed rule. We would urge CMS to utilize its regulatory discretion, as well as the discretion granted under the Medicare Modernization Act, to establish an appropriate reimbursement formula for Medicare Part B drugs that allows community pharmacies to adequately cover their costs and earn an appropriate return on investment while continuing to provide this essential service.

Sincerely,



Carlos R. Ortiz, R.Ph.
Vice President of Government Affairs

/rjs

CMS-1429-P-3975

Submitter : test **Date & Time:** 09/24/2004 06:09:54

Organization : test

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

This is a test.

CMS-1429-P-3975-Attach-1.doc

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-3976

Submitter : **Merlen Borgialli** **Date & Time:** **09/24/2004 06:09:06**

Organization : **NATA**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 20-29

THERAPY STANDARDS AND REQUIREMENTS

To whom it may concern:I've been an Athletic Trainer for 17 years and I'm very concerned with the lastest proposal in Medicare revisions.I've been in a clinical setting for over 16 years and your revision proposal would prevent me from providing care to those that I've cared for in the past and in the future. Not only would it jeopardize my position but rather thousands of positions in our profession nation wide. Please reconsider this proposal and the future treatment that you will be denying to medicare patients.

Sincerely, Merlen Borgialli ATC

CMS-1429-P-3977

Submitter : **Mr. Michael Claytor** **Date & Time:** **09/24/2004 06:09:48**

Organization : **International Massage Association**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

With all due respect to physical therapists I must protest the stated intention to LIMIT professional health care of this nature to physical therapists. I have been a massage therapist for 11 years and have been told of the frustration of clients after having received treatment for an unresolved ailment/injury from a PT who acted in a limited manner. ALL of these clients felt that I as a massage therapist treated their problem in a more expansive and thorough approach. They told me that my work was not limited to a specific, immediate and proximal area but was broader and geared to adjacent areas, contributing factors and areas of the body.
The exclusive approach is limiting and depriving to patients. Just as more people are utilizing "alternative therapies" the opportunities for good treatment are being limited for specious reasons.

CMS-1429-P-3978

Submitter : Ms. Lisa Schwarz **Date & Time:** 09/24/2004 06:09:11

Organization : Midwestern University

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

As a physical therapist and an athletic trainer, I strongly support the proposed personnel standards for PT services that are provided incident to physician services in the phsyicain's office. I have over 15 years of experience as a PT. Clinically, most of my practice has been in out patient practice. For the last 6 years I have taught physical therapy. I am also an athletic trainer. I feel that this background gives me perspective on this issue.

Physical therapists (and PT students under supervision) and PTAs (under supervision of a PT) are the only individuals who have the training to deliver physical therapy services. Delivery of PT services by unqualified personnel can have a negative impact of patient outcomes and potentially put the patient at risk. My concern is that individuals such as athletic trainers do not have adequate training and background on medically complex patients and do not have adequate training on aging and how the effects of aging impact the clinician's cliical decision-making. This is of great concern. Not having adequate background education on aging (specifically the latter part of the spectrum) could lead to less effective and potentially harmful treatment decisions. Examples include progressing exercises too quickly, leading to muscle and joint pain/injury.

The issue of adequate background and training with medically more complex paitients is of particular concern with older patients. As patients age, it is increasingly more likely that they will have significant medical histories that need to be taken into consideration. Examples of these conditions include caridac conditions and diabetes that present very differntly later in life than they do earlier in life for fit healthy individuals that athletic trainers are qualified to treat. Not taking these factors into consideration can lead to potential for serious harm to the patient.

I see this first-hand when students who are trained as ATCs return to school to become PTs. They realize that these areas are areas they were not previously trained in as athletic trainers.

In conclusion, while athletic trainers have adequate training to work with young healthy populations, they are not adequately trained to work with older, potentially less healthy individuals.

Thank you for your consideration.

CMS-1429-P-3979

Submitter : Mr. Michael Weinper, MPH, PT **Date & Time:** 09/24/2004 07:09:15

Organization : Physical Therapy Provider Network (PTPN)

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dear Dr. Mclellan:

I'm writing you on behalf of over 1000 independent physical therapy practices in 23 states consisting of over 4000 physical therapists in independent practice. Please accept this as our comments on the August 5, 2004 proposed rule on revisions to the physician fee schedule for the upcoming year.

PTPN and it's members strongly support the CMS proposal that qualifications of individuals providing physical and occupational therapy services 'incident to' a physician's service should meet the existing qualifications and training standards for those professions. In other words, incident to services billed as physical or occupational therapy should be held to the same standard as physical and occupational Therapy in the private practice setting.

We applaud CMS's proposed change that will level the playing field thereby providing Medicare recipients with the same standard of care that is delivered in the independent therapist's office. Under the current regulations, such services in physician offices are often performed by staff who are not properly trained to render those services. Not only is the quality of care typically compromised, the Medicare recipient, and the Medicare program are not getting what they are entitled to for the fees paid for those services.

Since the enactment of the Stark II regulations, we have noticed many physicians initiating such services in their offices often providing those services through inadequate personnel. 'Physical Therapy' and 'Occupational Therapy' are not generic terms. Such professional services should only be rendered by people qualified to perform those services through the proper training and typically licensure. Existing law allows physicians to provide these services often times through unlicensed persons who do not have the skills and ability to assess problems, treat conditions and properly progress and educate the patient as is done by professional therapists.

In my travels and discussions with therapists around the country I have heard hundreds of anecdotes whereby patients have been mistreated in physician's offices only to later be referred to a physical therapist or occupational therapist. They often comment 'this is a lot more than I ever received at my doctor's office' and, usually these patients respond in short order to rehabilitation services delivered by the professionals in these disciplines. Another change that has been proposed by your agency is that services performed by Physical Therapy Assistants (PTAs) and Certified Occupational Therapy Assistants (COTAs) 'require only direct supervision for Medicare coverage'. We support the adoption of this change as well as 'direct supervision' should suffice when Medicare patients are seen by these qualified supportive personnel. In discussions with my colleagues in physical and occupational therapy who are members of our Network, and in accordance with our supervision requirements, direct supervision should adequately insure that Medicare patients receive proper care when such services are delegated to the supportive personnel. That is not to say that such treatment and such services provided by supportive personnel should not be closely monitored. We require that the professional supervising the PTA or the COTA see the patient at least each week and progress treatment and make changes in treatment programs as appropriate.

Should you be in need of any additional supportive information or wish further comments from me or our organization, please do not hesitate to contact me. Thank you once again for allowing us the opportunity to support this change in the incident to aspect of Medicare regulations.

Michael Weinper, M.P.H., P.T.
President, CEO

CMS-1429-P-3979-Attach-1.doc

CMS-1429-P-3980

Submitter : Ms. Dolly Lefever **Date & Time:** 09/24/2004 06:09:15

Organization : Birthsong/New Conceptions

Category : Nurse Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

This is from the perspective of personal experience and also results seen in my clientele. Physiotherapy, the recognised treatment for 'all' physical rehabilitation/ correction is very limited when it comes to chronic illness and pain. I personally have gained relief from pain, increased flexibility and off drugs after I started regular massage and rolfing therapy. I have been able to decrease usage of these sessions after initial intense (weekly) treatments. I have had significant medical cost problems ie- glucose intolerance and now the potential for Diabetes from the drug -Methotrexate. That cost to Medicare is going to be significant!! Massage and Rolfing have decrease costs to Medicare by getting me off expensive drugs and there is NO side effects like Diabetes. Please do not illiminate choice. If you look at statistics, you will find that Medication prescribed and taken correctly causes huge expenditures and potential debilitating chronic disease (or death- of course that means Medicare saves on the dead person!) The cost of Massage and Rolfing with its excellent results is minimal compared to the cost of medications and their side-effects. Legislators need to open their eyes insead of bowing to powerful drug company and the AMA.
Dolly Lefever ANP,CNM,FNP.

CMS-1429-P-3981

Submitter : **Dr. Jeffrey Sands** **Date & Time:** **09/24/2004 07:09:51**

Organization : **Fresenius Medical Care NA**

Category : **Physician**

Issue Areas/Comments

Issues 20-29

IMPACT

We congratulate CMS on its intention to provide reimbursement for preoperative vessel mapping for creation of hemodialysis vascular access (AV fistula, AV graft) for patients requiring future or ongoing hemodialysis. Performance and coverage for preoperative imaging both by Doppler ultrasound angiography is the standard of care for all vascular surgery including carotid endarterectomies, peripheral vascular bypass and aortic surgery. Arterial and venous mapping in preparation for dialysis access creation has been shown to significantly improve the outcomes of access surgery by identifying suitable vessels (arteries and veins) for use in AV fistula creation. Published studies have shown that approximately 50% of usable vessels cannot be identified by physical exam alone. Marked increases in successful AV fistula creation and reduction in early fistula failure have been demonstrated and documented in numerous publications.1-8 This improvement in outcome has significant implications for Medicare beneficiaries. Patients with AV fistula have significantly fewer complications and improved survival when compared to similar patients with AV grafts or central venous catheters.9--11 Extending coverage for arterial and venous mapping is therefore consistent with best practice, other Medicare coverage decisions, CMS initiatives such as ?Fistula First? and in the interest of improving patient outcomes.12

The proposed regulation as written however will not achieve these intended goals.13 Currently most vascular imaging is performed by vascular laboratories in hospitals, freestanding independent diagnostic testing facilities (IDTF) and physician offices under the supervision of radiologists, vascular surgeons or other appropriately trained physicians. These laboratories have well-established standards and requirements for imaging quality, documentation and regulatory review. Limiting reimbursement to studies performed only by the operating surgeon would prevent preoperative mapping from being
performed in most of the best vascular labs and become a further barrier to its use to increase AV fistula prevalence. Limiting coverage to only venous mapping is also problematic. Adequate arterial inflow is a key component of obtaining a functioning arterio-venous fistula. Proper preoperative evaluation includes performance of arterial Doppler ultrasound (CPT 93930, 93931) to ensure appropriate inflow. This is especially true in the ESRD population of elderly and diabetic patients who frequently have extensive peripheral vascular disease and arterial calcification. Tying coverage specifically to subsequent surgery is also problematic. Not all imaged patients will be candidates for AV fistula or AV graft creation. Previous studies have shown that upon imaging only approximately 80% of incident patients approximately two thirds of the Catheter patients and approximately three quarters of AV graft patients have suitable sites for AV fistula creation.14, 15 Therefore would be expected that approximately 20- 40% of preoperative studies would not lead to subsequent AV fistula creation. Lack of reimbursement for these studies would create a financial burden on vascular labs and present a significant barrier to preoperative imaging in AV fistula creation. Lastly, it is frequently necessary to perform formal angiography and/or venography in addition to Doppler ultrasound. Huber et al. reported that contrast imaging at the time of surgery resulted in alteration of the operative plan in 19% of patients.6 It is inappropriate to unduly limit these studies.

CMS-1429-P-3981-Attach-1.pdf

Fresenius Medical Care

September 14, 2004

Dear Sirs:

We would like to take this opportunity to comment upon the proposed rules for venous mapping (CMS -- 1429 -- P) published on July 27, 2004. This letter represents the views of Fresenius Medical Care NA and the individual physician signatories.

First, we congratulate CMS on its intention to provide reimbursement for preoperative vessel mapping for creation of hemodialysis vascular access (AV fistula, AV graft) for patients requiring future or ongoing hemodialysis. Performance and coverage for preoperative imaging both by Doppler ultrasound angiography is the standard of care for all vascular surgery including carotid endarterectomies, peripheral vascular bypass and aortic surgery. Arterial and venous mapping in preparation for dialysis access creation has been shown to significantly improve the outcomes of access surgery by identifying suitable vessels (arteries and veins) for use in AV fistula creation. Published studies have shown that approximately 50% of usable vessels cannot be identified by physical exam alone. Marked increases in successful AV fistula creation and reduction in early fistula failure have been demonstrated and documented in numerous publications.[1-8] This improvement in outcome has significant implications for Medicare beneficiaries. Patients with AV fistula have significantly fewer complications and improved survival when compared to similar patients with AV grafts or central venous catheters.[9--11] Extending coverage for arterial and venous mapping is therefore consistent with best practice, other Medicare coverage decisions, CMS initiatives such as "Fistula First" and in the interest of improving patient outcomes.[12]

The proposed regulation as written however will not achieve these intended goals.[13] Currently most vascular imaging is performed by vascular laboratories in hospitals, freestanding independent diagnostic testing facilities (IDTF) and physician offices under the supervision of radiologists, vascular surgeons or other appropriately trained physicians. These laboratories have well-established standards and requirements for imaging quality, documentation and regulatory review. Limiting reimbursement to studies performed only by the operating surgeon would prevent preoperative mapping from being performed in most of the best vascular labs and become a further barrier to its use to increase AV fistula prevalence. Limiting coverage to only venous mapping is also problematic. Adequate arterial inflow is a key component of obtaining a functioning arterio-venous fistula. Proper preoperative evaluation includes performance of arterial Doppler ultrasound (CPT 93930, 93931) to ensure appropriate inflow. This is especially true in the ESRD population of elderly and diabetic patients who frequently have extensive peripheral vascular disease and arterial calcification. Tying coverage specifically to subsequent surgery is also problematic. Not all imaged patients will be candidates for AV fistula or AV graft creation. Previous studies have shown that upon imaging only approximately 80% of incident patients approximately two thirds of the Catheter patients and approximately three quarters of AV graft patients have suitable sites for AV fistula creation.[14, 15] Therefore would be expected that approximately 20- 40% of preoperative studies would not lead to subsequent AV fistula creation. Lack of reimbursement for these studies would create a financial burden on vascular labs and present a significant barrier to preoperative imaging in AV fistula creation. Lastly, it is frequently

Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000

necessary to perform formal angiography and/or venography in addition to Doppler ultrasound. Huber et al. reported that contrast imaging at the time of surgery resulted in alteration of the operative plan in 19% of patients.[6] It is inappropriate to unduly limit these studies.

An alternative approach to provide coverage for preoperative imaging would be to extend coverage for arterial (CPT 93930, 93931) and venous (93970, 93971) mapping by making "evaluation for AV fistula or AV graft creation" an indication and medical justification for performance of Doppler ultrasound of the upper extremity arteries and/or veins utilizing the existing codes for upper extremity imaging (arterial--CPT 93930, 93931 and venous—CPT 93970, 93971). This would allow studies to be performed in existing accredited vascular laboratories and ensure conformance to appropriate reporting and regulatory requirements. Studies performed by physicians as part of their physical exam that do not meet record reporting and regulatory requirements could be billed as part of a top-level or enhanced evaluation and management (E and M) code. This approach would provide a standard mechanism for enhanced reimbursement for physical examinations that include the use of small portable Doppler equipment. Currently only small numbers of physicians use Doppler Ultrasound as part of their routine physical examinations. This is expected to increase rapidly with the availability of relatively inexpensive handheld and mobile Doppler ultrasound equipment.

Thank you for the opportunity to comment upon the proposed rules for venous mapping (CMS -- 1429 -- P). We look forward to the improvement in patient outcomes that will result from providing coverage for arterial and venous mapping as a standard component of evaluation for dialysis access placement.

Sincerely:

Jeffrey J. Sands MD MMM
Vice President and Medical Director:
Disease Management/Demonstration Project
Fresenius Medical Care NA
Office: 407-566-0683
Email: jeffrey.sands@fmc-na.com

J. Michael Lazarus MD
Chief Medical Officer and Senior Vice
President of Clinical Quality
Fresenius Medical Care NA

Eduardo Lacson, Jr., MD, M.P.H.
Director, Clinical Research & Technology Assessment
Fresenius Medical Care NA

Nathan Levin, MD
Medical & Research Director
Renal Research Institute

References:

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10. Dhingra RK, Young EW, Hulbert-Shearon TE, Leavey S, Port FK: Type of vascular access and mortality in US hemodialysis patients. Kidney International V60 (2001) 1443-1451.
11. Pastan S, Soucie JM, McClellan WM; Vascular Access and Increasing Risk of Death Among Vascular access Patients. Kidney International 62 (2002) 620-626.
12. K/DOQI Clinical Practice Guidelines for Vascular Access 2000; National Kidney Foundation. Am J Kidney Dis 37: S137-S181, 2001 (suppl 1).
13. Sands JJ, Ferrell LM, Perry MA; Systemic Barriers to Improving Vascular Access Outcomes. Advances in Renal Replacement Therapy V9, No2 April 2002 109-115
14. Sands J, Espada C, Ferrell L, and Lazarus J: 73% of patients with prosthetic bridge grafts have suitable sites for secondary arterio-venous fistula creation. *NKF* spring clinical meeting abstract: April 2001.
15. Sands J, Espada C, Ferrell L, and Lazarus J: 65% of patients with cuffed catheters have adequate vasculature for arterio-venous fistula creation. *NKF* spring clinical meeting abstract: April 2000.

CMS-1429-P-3982

Submitter : **Mr. Mark Calandro** **Date & Time:** **09/24/2004 06:09:24**

Organization : **M.A.C. Therapies, Inc.**

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 THERAPIST. ALL QUALIFIED HEALTH CARE PROVIDERS SHOULD BE ALLOWED TO PROVIDE SERVICES TO PATIENTS WITH A PHYSICIANS PRESCRIPTION OR UNDER THEIR SUPERVISION!!!!

CMS-1429-P-3983

Submitter : **Ms. Monica OLeary** **Date & Time:** **09/24/2004 06:09:44**

Organization : **AMTA**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Passing this policy is not in the best interests of Medicare patients. Patients should be able to visit all qualified health care providers including Massage Therapists. Patients with a physician's prescription or under a physician's supervision need to be able to receive massage therapy under Medicare. It's possible by lowering patients' stress levels, we can lessen costs from additional health care.

Thank you,
Monica OLeary

CMS-1429-P-3984

Submitter : **Ms. Barbara Chang** **Date & Time:** **09/24/2004 06:09:39**

Organization : **Hemophilia Federation of America**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

The Hemophilia Federation of America appreciates the opportunity to comment on this proposed rule.

CMS-1429-P-3984-Attach-1.doc

September 24, 2004

Delivered Via Electronic Mail

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

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

Dear Dr. McClellan:

The Hemophilia Federation of America (HFA) appreciates this opportunity to add our comments to those submitted to the Centers for Medicare and Medicaid Services (CMS) by the hemophilia community regarding the proposed rule which was published in the Federal Register on Thursday, August 5th, 2004 (69 Federal Register 74884).

The Hemophilia Federation of America is a national nonprofit organization that assists and advocates for the blood clotting disorders community such as those with hemophilia and von Willebrand's Disease. HFA serves as a consumer advocate for safer blood products, affordable and obtainable health insurance coverage, and a better quality of life for all persons with bleeding disorders. HFA officers and staff are actively involved with the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and Congress to promote blood safety and availability and to address reimbursement methodologies, lifetime insurance cap reform and other important community issues. The vision of HFA is that the blood clotting disorders community has removed all barriers to both choice of treatment and quality of life.

The Hemophilia Federation of America has invoked that vision when developing these comments for the Centers for Medicare and Medicaid Services (CMS). For the reasons described below, we believe that the change from the Average Wholesale Price (AWP) system to the Average Sale Price (ASP) system carries the terrible potential to severely undermine access to hemophilia patient care and, thereby, set back the many gains in health and medical efficiency the Hemophilia Community and its allies, among which we count CMS, have attained over the last 30 years. To this effect, HFA has sent several scheduling requests to your office requesting an appointment to discuss these important matters in person. Inexplicably, to date we have not received a response. We again respectfully ask for time to discuss this very significant issue face-to-face.

As you know, hemophilia is a hereditary blood clotting disorder that results in excessive bleeding which occurs spontaneously and/or after injury. Hemophilia is treated with factor replacement therapies. Clotting factor concentrates are available in plasma-based form and a synthetic or recombinant analogue.

Administration of this vital therapy requires the intravenous infusion of blood clotting products to replace the missing or deficient proteins needed for the blood clot. Infusions must be given as soon as possible after the start of a bleeding episode. Alternately, due to their very frequent bleeding, some patients are prescribed doses of factor at regular intervals as preventative prophylaxis treatment. In addition, many patients develop antibodies or inhibitors to the very factor therapies that prevent or stop their bleeding episodes. These "inhibitor" patients must have access to different factors than those patients with the same type of hemophilia who have not developed inhibitors.

It is perfectly understandable, therefore, that our community -- The Hemophilia Community – is vitally concerned with the availability, cost, and purity of replacement factor products. Factor replacement therapies, critical to the health and, often, the lives of persons with bleeding disorders, are very expensive in some instances exceeding one million dollars in a given year. Surely CMS likewise understands that the hemophilia community depends upon these products to live productive, normal lives. Accordingly, we are confident that CMS would not adopt a rule, such as the one proposed, that threatens to erect a barrier between our community and access to treatment.

HFA is working to ensure that the hemophilia patient community has the choice of product, choice of treatment regimen, and choice of provider to ensure safety and supply. It has been brought to our attention that the 2005 payment rates for most Medicare Part B drugs, including anti-hemophilia factor concentrate therapies, will be based on Average Sale Price (ASP). This new system likely will drastically reduce payment rates to the point that patient access to these life-changing therapies will be compromised. According to this proposed rule, the ASP rate for Factor VIII recombinant would be $.92 per unit which represents a 29% decrease from the current rate of reimbursement. While we do not presume to tell CMS what exact methodology to reimburse anti-hemophilia factor concentrates, we need to call to CMS' attention that the proposed level is so unacceptable for the factor industry and could have serious consequences for our community's access to these therapies.

Indeed, if the Medicare reimbursement is cut as proposed, providers might decide no longer to treat Medicare patients with hemophilia. Inciting hemophilia home care providers to exit the market, thus negatively impacting hemophilia patient care, cannot make sense medically or economically. Unable to find coverage, these patients would go to the emergency room for treatment. Our organization has collected anecdotal but consistent and reliable evidence that too often emergency room settings provide poor hemophilia treatment. The standard of care as a response to trauma is to infuse with factor as soon as possible. Our organization has evidence to say that does not happen, and patients' health and lives are placed at risk. Moreover, even if properly done, ER care is much more expensive and slower than home infusion of clotting factor. There is no economy or medical sense in pushing hemophilia patients into ERs.

The Medicare statute requires that CMS provide for a separate add-on payment to the entity that furnishes hemophilia clotting factor on January 1, 2005 to compensate for items and services related to the furnishing of the anti-hemophilia concentrates. CMS has proposed an add on of $.05 per unit of factor. HFA is concerned that the proposed amount is not sufficient to accomplish this goal. Our organization understands that the hemophilia home care providers are recommending an add-on fee of $.20. While we will not presume to say that the providers' recommendation is right, we do say that the proposed rule if enacted will negatively impact our community, something CMS, we are sure, does not want. In sum, if the final rule is implemented with the $.05 add-on fee, hemophilia home care providers will exit the market and patients will have to turn to the emergency room where our community has valid concerns over the level and cost of care.

HFA appreciates the opportunity to provide comments on these important issues with the proposed rule and we hope CMS will give careful consideration to our concerns and take the necessary steps to correct them. If you have any questions please feel free to contact us directly at the Hemophilia Federation of America's national office at (332) 261-9789. Thank you for your assistance in this important matter to the hemophilia community.

Sincerely,

Barbara Chang
President

Carl Weixler
First Vice President

CMS-1429-P-3985

Submitter : **Mr. Robert Casmus** **Date & Time:** **09/24/2004 06:09:15**

Organization : **Catawba College - Athletic Training**

Category : **Other Health Care Professional**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Robert Casmus, M.S., ATC-L
Catawba College
Salisbury, NC 28144

9/24/04

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATT: CMS-1429-P
PO 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. This reduces the quality of health care for Medicare patients and ultimately increases costs associated with this service and place undue burdens on the healthcare system.

"Incident to" has, since the inception of the Medicare program has been utilized by physicians to allow others, under the physician's direct supervision, 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 administered.

Athletic trainers are highly educated. All Certified or licensed athletic trainers MUST HAVE A BACHELOR'S or MASTER'S DEGREE from an accredited university. Foundation courses include: human anatomy and human physiology, kinesiology/biomechanics, nutrition, acute care of injury and illness, statistics, research and design, therapeutic modalities and rehabilitation, and exercise physiology. Seventy percent (70%) 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 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 therapist, occupational therapists, and speecha and language pathologist 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 physician's 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 appearences, 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 statuatory 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.

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

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

Sincerely,

Robert J. Casmus, M.S., ATC-L
Head Athletic Trainer
Catawba College
Salisbury, NC 28144

CMS-1429-P-3986

Submitter : **Mr. Scott Shields** **Date & Time:** **09/24/2004 06:09:25**

Organization : **Aventor**

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

On behalf of Dey, L.P., I am pleased to present the following comments regarding Section 305--Payment for Inhalation Drugs. Attached are the full comments and an executive summary of the comments.

CMS-1429-P-3986-Attach-1.doc

CMS-1429-P-3986-Attach-2.doc

DATE: September 24, 2004

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attention CMS-1429-P

P.O. Box 8012

Baltimore, Maryland 21244-8012

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

Dear Sir or Madam:

Dey, L.P. is pleased to submit the following comments regarding the above-referenced proposed rule (Proposed Rule).[1] Dey, L.P. welcomes the opportunity to work with the Centers for Medicare and Medicaid Services (CMS) in refining reimbursement policies for Part B drugs in 2005 and subsequent years.

Dey, L.P. develops, manufactures, and markets prescription pharmaceuticals for the treatment of respiratory illnesses, including chronic obstructive pulmonary disease (COPD), a condition that represents a significant financial burden for the Medicare program and a serious threat to patient longevity and quality of life.

We are providing comments on issues associated with the Proposed Rule that pertain to Section 305 – Payment for Inhalation Drugs in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

Section 305 – Payment for Inhalation Drugs

Nebulizers versus MDIs

We feel compelled to correct the record regarding the stance CMS has taken regarding the relative and comparative value of nebulizers versus MDIs. In the portion of the Proposed Rule preamble pertaining to MMA Section 305, CMS states that Medicare beneficiaries have a "strong" financial incentive to use nebulizers since the alternative inhalation drug delivery mechanism, metered dose inhalers (MDIs), currently are not covered under Part B, and beneficiaries will have to wait until January 2006 to be covered under the new Part D drug benefit. CMS also states that, based on a literature review, nebulizers are no more effective than MDIs in delivering bronchodilators, and CMS predicts a substantial shift from nebulizers to MDIs once the latter become covered under Part D beginning in 2006.[2] We fear CMS is underestimating the patient preference for nebulized respiratory medication which is based on improved quality of life, not financial incentives.

While it is true that some studies have shown that nebulizers and inhalers are equally effective, the performance of inhalers was augmented by spacers.[3,4,5] Spacers are

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[1] 69 Fed Reg 47488 (Aug. 5, 2004).
[2] 69 Fed Reg at 47546, 47548.
[3] Turner MO, Patel A, Ginsburg S, Fitzgerald JM. Bronchodilator delivery in acute airflow obstruction. A meta-analysis. *Arch Intern Med*. 1997 Aug 11-25;157(15):1736-44.

designed to deliver MDI-delivered medication more effectively. In common practice, studies have shown that patients use spacers with inhalers approximately 50 percent of the time; without accessories such as spacers, much of the medication may be left in the mouth and throat, thus reducing absorption and efficacy.[6, 7,8]

In addition, the literature is replete with studies showing that many patients, up to 89%, do not employ proper inhaler technique.[9,10,11] Therapeutic benefit depends on sufficient deposition of drugs in the medium and small airways; this is largely determined by a competent inhaler technique.[12,13] The most recent report of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) states that "COPD patients may have more

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[4] Duarte AG, Momii K, Bidani A. Bronchodilator therapy with metered-dose inhaler and spacer versus nebulizer in mechanically ventilated patients: comparison of magnitude and duration of response. *Respir Care*. 2000 Jul;45(7):817-23. (Comment: attach references as an appendix at the end)

[5] Schuh S, Johnson DW, Stephens D, Callahan S, Winders P, Canny GJ. Comparison of albuterol delivered by a metered dose inhaler with spacer versus a nebulizer in children with mild acute asthma. *J Pediatr*. 1999 Jul;135(1):22-7.

[6] Selroos O, Halme M. Effect of a volumatic spacer and mouth rinsing on systemic absorption of inhaled corticosteroids from a metered dose inhaler and dry powder inhaler. *Thorax*. 1991 Dec;46(12):891-4.

[7] Dow L, Phelps L, Fowler L, Waters K, Coggon D, Holgate ST. Respiratory symptoms in older people and use of domestic gas appliances. *Thorax* 1999; 54: 1104-1106. Fifty-four percent of the study population using MDIs used spacers; 45 percent of the study population using MDIs did not us a spacer.

[8] Bynum A, Hopkins D, Thomas A, Irwin C, Copeland N. The Effect of Telepharmacy Counseling on Metered-Dose Inhaler Technique Among Adolescents with Asthma in Rural Arkansas. Presentation. The University of Arkansas for Medical Sciences. 2000 American Telemedicine Association Annual Meeting. Accessed September 15, 2004 at http://www.atmeda.org/news/2000_presentations/Rural/Bynum.pps. Fifty-one percent of the study population did not use spacers with MDIs.

[9] Erickson SR, Horton A, Kirking DM. Assessing metered-dose inhaler technique: comparison of observation vs. patient self-report. *J Asthma.* 1998;35(7):575-83.

[10] ICSI Health Care Guidelines: Chronic Obstructive Pulmonary Disease, Third Edition/Dec 2003. Accessed September 2, 2004 at http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=157.

[11] Johnson DH, Robart P. Inhaler technique of outpatients in the home. *Respir Care*. 2000 Oct;45(10):1182-7.

[12] Newman SP, Pavia D, Clarke SW. How should a pressurized beta-adrenergic bronchodilator be inhaled? *Eur J Respir Dis* 1981;62:3–20.

[13] Newman SP, Moren F, Pavia D, et al. Deposition of pressurized aerosols in the human respiratory tract. *Thorax* 1981;36:52–5.

problems in effective coordination and find it harder to use a simple Metered Dose Inhaler (MDI) than do healthy volunteers or younger asthmatics."[14]

Market research has confirmed the practical superiority of nebulizers to MDIs, as judged from the patients' perspective. One study compared the value of nebulizer systems with MDIs from the patient's perspective, based on an analysis of 1,369 questionnaires.[15] According to the study, nebulizer systems were preferred and considered by patients to be more effective at symptom control than MDIs. Key findings were as follows:

- Fifty-seven percent (57%) of patients surveyed said their symptoms were better controlled with a nebulizer system than with an MDI.
- Eighty-two percent (82%) said the nebulizer system controlled their symptoms for a longer period of time than the MDI.
- Over 80% of patients said the nebulizer system had given them a better quality of life than an MDI alone. Nearly 70% of patients surveyed said the nebulizer system had helped them avoid a trip to the emergency room.
- Fifty-six percent (56%) of these patients said use of a nebulizer system helped to avoid hospitalization.
- Fifty-eight percent (58%) of these patients had avoided unscheduled office visits by using their nebulizer systems.

[14] Global Initiative for Chronic Obstructive Lung Disease, Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2004 Update), at 68, available at http://www.goldcopd.com.

In short, nebulizers are the preferred method of delivery of bronchodilators for a large proportion of COPD patients, including Medicare beneficiaries. In the preamble, CMS expresses concern that the access of beneficiaries to nebulized bronchodilators in 2005 might be restricted, due to the reduction in Part B payment rates for frequently used bronchodilators.[16] We agree this is a serious concern, but we submit that it is not a short-term problem that will disappear in 2006. Beneficiaries' continued need for nebulized bronchodilators, even after MDIs become covered under Part D, will make it all the more essential that CMS adequately reimburse providers for these drugs under Part B on an ongoing basis.

Service Fee

CMS is proposing to establish a separate dispensing fee for inhalation drugs, presumably greater than the current five dollar monthly fee that is unique to this group of drugs.[17] As noted in the preamble, inhalation drugs require additional pharmacy support activities to preserve their safety and efficacy and ensure their proper use. Dey, L.P. supports the proposal to pay for the costs associated with additional pharmacy services, since these services are critical to ensure continued beneficiary access to inhalation drugs.

Dey, L.P. believes a "service fee", in addition to the dispensing fee, is required to cover the operating and patient-support expenses performed by pharmacies. Such expenses include, but are not limited to, the following:

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[15] Safian Communications, Inc. Patient Assessment of Efficacy of Nebulizer Systems on Their Respiratory Health. April 1995 (report available on request).
[16] 69 Fed. Reg. at 47549.
[17] Proposed Rule, 69 Fed Reg 47549.

- Patient support costs
    - monitoring/oversight of home-care patient by licensed respiratory therapists and equipment technicians
    - customer service (24-hour on-call support)
- Pharmacy operating costs
    - pharmacy personnel (pharmacists, technicians, warehouse, shipping, management, administrative)
    - facility costs (rent, furniture and fixtures, utilities)
    - freight costs (overnight delivery)
    - information systems
- Administrative functions
    - claims processing
    - quality improvement programs
    - regulatory compliance
    - professional liability insurance

Dispensing Fee

We support CMS' current policy of providing one dispensing fee if two or more drugs are combined in single unit-dose vials, as the pharmacy activities needed to ensure safety and efficacy remain the same in scope.

In addition, Dey believes the need for and the amount of the dispensing/service fee should be addressed within the context of understanding the purpose of the fee, as it

currently exists, and any additional or transitional fee that might be developed for the future. Inhalation drugs are the only Part B medical products with a dispensing fee. The fee was developed to cover the additional costs of handling and dispensing prescriptions delivered through a nebulizer, which is covered as durable medical equipment (DME).

If CMS does not provide a dispensing/service fee that adequately covers pharmacy costs for carrying and dispensing bronchodilators and providing necessary patient back-up, there are indications that the access of Medicare beneficiaries to these drugs may be severely jeopardized. For example, one major chain of home health suppliers recently reported that, "in the absence of a reasonable dispensing fee to cover the necessary costs incurred in providing these nebulizer medications in the home setting to COPD patients . . ., Lincare plans to cease providing respiratory therapy drugs . . . ."[18] Similarly, in a survey recently conducted for the American Association for Homecare by Muse & Associates, 89 percent of the suppliers responding to the survey said that they would discontinue providing inhalation drugs to Medicare beneficiaries if no payment was available to offset the additional costs (beyond the acquisition cost of the drugs) of providing such drugs.[19]

We urge CMS to conduct a study of the appropriate pharmacy activities and their costs to arrive at a dispensing/service fee that is sufficient to cover the expenses identified above. Although we commend CMS for seeking data on an appropriate amount for a dispensing

[18] Inside CMS, Aug. 12, 2004, at 12.
[19] Medical News Today, Aug. 27, 2004, available at http://www.medicalnewstoday.com/medicalnews.php?newsid=12583.

fee, we believe that a study conducted by CMS itself is preferable in order to ensure reliability of data and an accurate fee amount.

We support the notion of a variable or need based, incremental dispensing/service fee for inhalation drugs. This would be similar to CMS's dispensing fee proposal for transplant drugs, which would provide a designated fee for the first 30 days post-transplant that accommodates the unique needs of this patient group.[20] In a comparable fashion, COPD patients' needs for additional services are often strongly correlated with exacerbations, of which many COPD patients are likely to have two to four annually.[21] At the time of these intermittent disease flare-ups, their treatment regimens generally change significantly. We suggest that CMS consider the need for a variable or "need-based" dispensing fee as part of the Chronic Care Improvement Program Demonstration.

Pharmacy Compounding

CMS asks for comments on the appropriate dispensing fee to "cover the shipping, handling, **compounding**, and other pharmacy activities…"[22] Dey, L.P. favors the need for appropriate payment for dispensing costs. However, we are concerned about the safety issues of including pharmacy compounding in the list of activities that a dispensing fee is intended to cover. We believe CMS should ensure that compounding is done on a patient-name prescription basis, and that pharmacies use all compounding and admixing

[20] Proposed Rule, at 47523.
[21] Garcia J, Jenkinson S. Practical Pearls from the GOLD Guidelines on COPD. Accessed August 11, 2004 at http://www.chestnet.org/education/online/pccu/vol17/lessons3_4/lesson04/print.php. The most common causes of an exacerbation are pulmonary infections and air pollution; other conditions producing the symptoms of an acute exacerbation of COPD include pneumonia, myocardial ischemia, congestive heart failure, pneumothorax, pleural effusion, pulmonary embolism, cardiac arrhythmia, esophageal reflux, and noncompliance with medications.

precautions to ensure product sterility and freedom from microbe ingress contamination. Patient safety is crucial, and the quality of the compounded product should be comparable to a commercial drug product.

Another area of concern regarding compounding is that the FDA prohibits pharmacy compounding of two or more separate FDA-approved products when a combination product approved by the FDA is commercially available.[23]

Specifically, in the past six months alone, several pharmacies have received warning letters from the FDA for, among other things, (1) preparing drug products that are commercially available, and (2) compounding drugs "without the necessary controls to ensure drug product sterility and potency."[24,25]

Violations of the FDA policy against compounding commercially-available drugs affect DuoNeb® (ipratropium bromide and albuterol sulfate) Inhalation Solution, since it is a currently marketed, sterile, non-allergenic, premixed combination drug; these manufacturing processes are designed to lower the risk of drug cross-contamination and to minimize waste. The premixed, unit-dose combination of the two agents within DuoNeb® Inhalation Solution enhances patient safety by minimizing the chance for

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[22] *Id.*, at 47549 (emphasis supplied).
[23] Food and Drug Administration. Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.
[24] FDA warning letter to Axium Healthcare Pharmacy, June 7, 2004, at http://www.fda.gov/cder/warn/2004/AXIUM%20%20wl.pdf.
[25] FDA warning letter to Gentere, Inc., July 13, 2004, at http://www.fda.gov/foi/warning_letters/g4863d.htm.

medication errors, and it eliminates the need for the Medicare patient to nebulize two different solutions, resulting in faster treatment times and improved compliance.

As for the second category of violation – compounding drugs "without the necessary controls to ensure drug product sterility and potency" – quite obviously patient safety is at risk, and a threat to public health is created. We also note that, in 2002, the FDA sampled 29 drugs from compounding pharmacies and found that 10 were subpotent.[26] In all, the compounded drugs sampled by the FDA registered a 34 percent failure rate – far in excess of the comparable two percent rate for commercially-available drugs.[27]

We recognize that compounded products can be covered under certain circumstances, and that the costs of such products might be included appropriately in a dispensing fee. However, we are concerned that the Durable Medical Equipment Regional Carriers (DMERCs) will interpret CMS's preamble statement concerning dispensing fees for compounded products to support reimbursing compounded albuterol and ipratropium when the resulting compound is essentially a copy of DuoNeb.[28] This may be in violation of section 50.4.7 of the Medicare Benefit Policy Manual ("Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act").[29] Exhibit A, attached, contains additional detail about when pharmacy-compounded drug products should not be covered by Medicare. As explained in Exhibit

[26] Report: Limited FDA Survey of Compounded Drug Products. Food and Drug Administration. Accessed August 24, 2004 at http://www.fda.gov/cder/pharmcomp/survey.htm.
[27] *Id.*
[28] See, e.g., CIGNA Healthcare Medicare Administration. Albuterol and Ipratropium – Revised Coding Guidelines. Region D DMERC Dialogue. Spring 2004: 12. Accessed August 31, 2004 at http://www.cignamedicare.com/dmerc/dlog/dlog2004/spring_2004/040212a.html.

A, the preparation of compounds that are essentially copies of commercially available products is contrary to FDA policy on the legitimate bounds of pharmacy compounding, and may constitute the marketing of a new drug without premarket approval.[30] As a result, the policy of reimbursing compounded albuterol and ipratropium combinations that are copies of DuoNeb® Inhalation Solution is inconsistent with Medicare policy and regulations that prohibit reimbursement for drugs that require FDA approval but do not have such approval. Nevertheless, all four DMERCs cover albuterol and ipratropium combinations when they are compounded by a pharmacist for use in a nebulizer.

We believe that any CMS policy (or associated language) that directly addresses compounding should specifically state when compounding is appropriate and when it is not. CMS policy should be consistent with FDA policy 1) prohibiting pharmacy compounding when a commercial product is available, and 2) the need to have adequate environment and controls to ensure sterility and quality. CMS should avoid any indirect or implicit approval of pharmacy compounding that is clearly inappropriate. When it comes to pharmacy compounding, patient safety can be at risk, and we strongly encourage CMS to ensure that Medicare policy protects beneficiaries in a manner that is consistent with the protections offered to all consumers by the FDA.

Dey, L.P. supports an appropriate dispensing fee for pharmacies, so that they can supply inhalation drugs to beneficiaries. However, Dey, L.P. suggests that CMS amend the

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[29] Centers for Medicare and Medicaid Services. Carriers Manual, Part 3, Chapter II, §2049.4(C)(6). Accessed August 31, 2004 at http://www.cms.hhs.gov/manuals/14_car/3b2049.asp?.

preamble language addressing dispensing fees for pharmacy activities related to furnishing beneficiaries with inhalation drugs by inserting the phrase "in a manner consistent with FDA requirements" following the word “compounding”. This would eliminate any possibility of CMS being viewed as supporting acts that are inconsistent with FDA’s Compliance Policy Guide, section 460.200 (Pharmacy Compounding).[31]

Dispensing Fee for Duets

Dey understands that when some pharmacists are presented with a prescription for compounding two or more drugs they will dispense the drugs separately and instruct the patient to compound the drugs themselves. As a result, the pharmacist collects multiple dispensing fees, instead of the single dispensing fee for providing multiple drugs in a single unit-dose vial. Having elderly patients compound drugs under nonsterile, unsafe conditions introduces serious public health issues, such as contamination with mold or bacteria, and inconsistent dosing (which may lead to subpotent or superpotent drug combinations).

Leaving the responsibility of compounding to patients effectively rewards the pharmacist (by providing multiple dispensing fees) for inappropriately transferring the responsibility for patient safety to the patient.

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[30] Food and Drug Administration. Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.

[31] Food and Drug Administration. Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). Accessed May 3, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/default.htm.

We suggest that CMS institute an exception to the rule under which it now invariably pays pharmacists a dispensing fee for each drug dispensed. This exception would apply to drugs for which the physician wrote a prescription directing the constituent drugs to be compounded. In the case of any such prescription, the pharmacist would be required to append a modifier to the HCPCS code for each drug intended to be compounded, but which is dispensed separately.[32] Drugs that have the "compounding" modifier, and appear on the same claim, would signal the carriers to provide one dispensing fee for those drugs identified by the modifier. By eliminating the financial incentive to shift the responsibility of compounding to patients, CMS will help preserve patient safety and reduce reimbursement costs.

90-Day Prescriptions

CMS has asked for comments about its proposal to allow beneficiaries to have a prescription for a 90-day supply of inhalation drugs filled and supplied; current guidelines provide that beneficiaries generally cannot obtain more than a month's supply of inhalation drugs.[33]

Dey, L.P. supports this important change in Medicare policy for those drugs or compounds that have FDA approval, and data showing that the product can maintain the

[32] There is precedent for adding modifiers to drugs that are compounded; the modifiers –KQ and –KP are added to HCPCS codes for drugs that are compounded, and signal carriers to adjust payment levels accordingly.
[33] 69 Fed. Reg. at 47549.

necessary stability level during a 90-day time period.[34] Dey, L.P. believes this proposal would have the following benefits for beneficiaries:

- **More convenient for beneficiaries,** since COPD is a chronic condition and, for some patients, a 90-day supply would be more accommodating to the elderly population.
- **Lower costs to dispensing pharmacies**, due in large part to costs of processing one rather than three transactions.

Conclusion

Dey appreciates the opportunity to comment on these important CMS proposals that will affect Medicare beneficiaries' access to life-saving and quality-of-life enhancing medications. However, we believe that the proposed changes affecting inhalation drug therapy may not reflect a cohesive strategy, because they appear based on an incorrect assumption that nebulizer-based therapy is not a medical necessity for some patients. In addition, including pharmacy compounding as an activity whose costs may be included in the dispensing fee is troublesome, given that on certain occasions pharmacy compounding is not appropriate but is nonetheless reimbursed under current DMERC policy.

We urge CMS to revisit the proposed changes regarding a revised (or incremental) dispensing fee by conducting a study of the appropriate activities and their costs, and by

[34] Please note that in many instances, pharmacy-compounded solutions for nebulization inhalation therapy may not meet this criterion for stability over a full 90 days.

considering the considerable operating and patient-support expenses borne by pharmacies. The concept of a "service fee" may be a more appropriate description of the various pharmacy activities and expenses.

We suggest that CMS institute an exception to the rule under which it now invariably pays pharmacists a dispensing fee for each drug dispensed. This exception would apply to drugs for which the physician wrote a prescription directing the constituent drugs to be compounded. In the case of any such prescription, the pharmacist would be required to append a modifier to the HCPCS code for each drug intended to be compounded, but which is dispensed separately. Drugs that have the "compounding" modifier, and appear on the same claim, would signal the carriers to provide one dispensing fee for those drugs identified by the modifier.

With regard to the 90-day prescription, we would urge CMS to ensure that the policy is defined to indicate that only drugs that are proven to be physically, chemically and microbiologically stable for at least 90 days following dispensing would be covered.

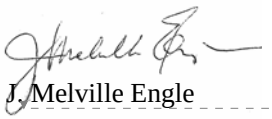
Dey believes that CMS needs to make policy for inhalation products in the overall context of respiratory disease costs to the Medicare program. It is important to get the right prescriptions to patients using the most appropriate delivery mechanism, be it nebulizers, MDIs, or dry powder inhalers (DPIs), all of which are found in clinical practice guidelines and will be included in Medicare's benefits as of 2006. CMS and its contractors need to strive for consistency with FDA polices, ensuring that payment policy

changes do not create incentives for activities that are not consistent with the assurances provided to the public by the FDA.

Building on our letter to then-CMS Administrator Thomas Scully regarding Medicare payment reform for Part B drugs (42 C.F.R. Part 405 (CMS-1229-P)) on October 13, 2003, we would like to reiterate our observation that the costs and value that are added to a drug product as it moves along the healthcare delivery chain, from manufacturer to dispenser, is the appropriate way to analyze and calibrate payment issues, including the need for and the amount of any dispensing fees.

Thank you for the opportunity to present our views with respect to these proposed revisions to CMS policy.

Sincerely,



J. Melville Engle

President and CEO

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EXHIBIT A

Circumstances Where Compounded Combination Albuterol and Ipratropium Should Not Be Covered Under Medicare

Coding for DuoNeb® Inhalation Solution, Albuterol, and Ipratropium

In the spring of 2004, the DMERCs issued revised coding guidelines for HCPCS J7621,[35] which were effective as of January 1, 2004.[36] The revised guidelines indicate that HCPCS J7621 "may only be used when [albuterol and ipratropium] are provided in combination by a manufacturer or repackager in a vial with a single National Drug Code (NDC) number," and that "despite the narrative description of the code, J7621 must not be used for compounded inhalation solutions of [albuterol and ipratropium]."[37] Currently, DuoNeb® Inhalation Solution is the only manufactured, FDA-approved combination of albuterol and ipratropium.

For pharmacy-compounded combination preparations of albuterol and ipratropium, the revised coding guidelines state that suppliers should bill Medicare using HCPCS codes J7619 for albuterol and J7644 for ipratropium, and to use the appropriate modifier:

KP – First drug of a multiple drug unit-dose formulation

[35] HCPCS J7621 – Albuterol, all formulations, including separated isomers, up to 5 mg (albuterol) or 2.5 mg levalbuterol), and ipratropium, up to 1 mg, compounded inhalation solution, administered through DME).
[36] CIGNA Healthcare Medicare Administration. Albuterol and Ipratropium – Revised Coding Guidelines. Region D DMERC Dialogue. Spring 2004: 12. Accessed August 10, 2004 at http://www.cignamedicare.com/dmerc/dlog/dlog2004/spring_2004/040212a.html.
[37] *Id.*

KQ – Second or subsequent drug of a multiple drug unit-dose formulation[38]

FDA Prohibition of Certain Types of Pharmacy Compounding

Although the DME coding guidelines mention "compounded combination preparations of albuterol and ipratropium," the FDA policy discourages certain types of pharmacy compounding. This policy is articulated in Compliance Policy Guide (CPG), Section 460.200, issued on June 7, 2002.[39] The CPG contains factors that the agency considers in deciding whether to exercise its enforcement discretion. One factor is whether a firm **compounds drug products that are commercially available, or which are essentially copies of commercially available FDA-approved products**.[40]

If one or more of the factors identified in CPG section 460.200 are present, such compounding pharmacies may be manufacturing drugs which are subject to the new drug application (NDA) requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA), but for which the FDA has not approved an NDA, or which are misbranded or adulterated. If the FDA has not approved the manufacturing and processing procedures used by these facilities, the FDA has no assurance that the drugs produced are safe and efficacious. Safety and efficacy issues pertain to such factors as chemical stability, purity, strength, bioequivalency, and bioavailability. Dey, L.P. is concerned that patients may be receiving unsafe, unsterile drugs of unknown potency and composition, a needless risk

[38] Ibid.
[39] Compliance Policy Guidance for FDA Staff and Industry. Sec. 460.200 (Pharmacy Compounding). Food and Drug Administration. June 7, 2002. Accessed August 10, 2004 at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html.
[40] Emphasis supplied. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially

when, in the case of pharmacy-compounded albuterol and ipratropium, an FDA-approved inhalation solution is available in DuoNeb® Inhalation Solution.

Based on 1) the NDA requirements of the FFDCA, and 2) CPG §460.200, pharmacy-compounded combinations of albuterol and ipratropium that contain equivalent amounts of the active ingredients in DuoNeb® Inhalation Solution are prohibited by the FDA.

Medicare Denial of Payment for Certain Types of Pharmacy Compounding

If pharmacy-compounded combinations of albuterol and ipratropium are prohibited by the FDA, then chapter 15, section 50.4.7 of the Medicare Benefit Policy Manual, entitled "Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act," should apply. The applicable portion of §50.4.7 reads as follows:

> Section 1862(a)(1)(A) of the Act requires that drugs must be reasonable and necessary in order to be covered under Medicare. This means, in the case of drugs, the FDA must approve them for marketing. Section 50.4.1 instructs carriers and intermediaries to deny coverage for drugs that have not received final marketing approval by the FDA, unless instructed otherwise by CMS. The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §180, instructs carriers to deny coverage of services related to the use of noncovered drugs as well. Hence, if DME or a prosthetic device is used to administer a noncovered drug, coverage is denied for both the nonapproved drug and the DME or prosthetic device.[41]

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available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.

[41] Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual. Chapter 15 (Covered Medical and Other Health Services); §50.4.7 (Denial of Medicare Payment for Compounded Drugs

Based on the Medicare Benefit Policy Manual, the DMERCs may be approving claims for drugs that require FDA approval but are not FDA-approved. Therefore, payment for combination products containing albuterol and ipratropium, and the nebulizers used to administer the drugs, should be limited to FDA-approved formulations that can be classified using the Spring 2004 DME revised coding guidelines for HCPCS J7621.

Suggested Solution to Protect Against Incorrect Payment of Prohibited Albuterol and Ipratropium Pharmacy Compounding

Dey, L.P. requests that CMS develop a Correct Coding Initiative (CCI) edit that would identify claims with albuterol and ipratropium using the KP and KQ modifiers. The CCI edit would instruct the DMERC to deny payment for such claims.

Produced in Violation of Federal Food, Drug, and Cosmetic Act). Rev. 13. May 28, 2004. Accessed August 11, 2004 at http://www.cms.hhs.gov/manuals/102_policy/bp102c15.pdf.

Executive Summary
Comments to "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule"

Dey, L.P. is providing comments on the following issues discussed in the above-referenced proposed rule (Proposed Rule) and its preamble:[1]

- Section 305 – Payment for Inhalation Drugs
  - Nebulizers versus Metered Dose Inhalers
  - Dispensing Fee
  - Dispensing Fee for Duets
  - Compounding
  - 90-Day Prescriptions

Dey appreciates the opportunity to comment on these important CMS proposals that will affect Medicare beneficiaries' access to life-saving and quality-of-life-enhancing medications. However, we believe that the proposed changes affecting inhalation drug therapy may not reflect a cohesive strategy, because they appear to us to be based on an incorrect assumption as to the medical necessity of nebulizer-based therapy by some patients. In addition, including pharmacy compounding as an activity whose costs may be included in the dispensing fee is troublesome, given that on certain occasions pharmacy compounding is not appropriate but is nonetheless condoned by current DMERC policy.

Regarding an "appropriate" dispensing fee, we would urge CMS to conduct a study of the appropriate pharmacy activities and their costs. We believe this approach would yield a more accurate fee amount than from requesting such data and information via comments to proposed rules. In addition, the concept of a "service fee" may be a more appropriate description of the various pharmacy activities and expenses, including pharmacy operating costs, patient-support costs, and administrative functions.

We suggest CMS consider creating a HCPCS modifier for drugs that the prescribing physician intended to be compounded, but which the pharmacist dispensed separately in non-compounded formulations. We believe this would help discourage pharmacists from leaving the responsibility of compounding to the patients, who will be combining the drugs in non-sterile, uncontrolled conditions.

With regard to the 90-day prescription, we would urge CMS to ensure that the policy is defined to indicate that only drugs that are proven to be physically, chemically and microbiologically stable for at least 90 days following dispensing would be covered.

Dey believes that CMS needs to make policy for inhalation products in the overall context of respiratory disease costs to the Medicare program. It is important to get the right prescriptions to

[1] 69 Fed Reg 47488 (Aug. 5, 2004).

patients using the most appropriate delivery mechanism, be it nebulizers, MDIs, or DPIs – all of which are found in clinical practice guidelines and will be included in Medicare's benefits as of 2006. CMS and its contractors need to strive for consistency with FDA polices, ensuring that payment policy changes do not create incentives for activities that are not consistent with FDA's policies on pharmacy compounding.

Building on our comments from last year,[2] we would like to reiterate our observation that the costs and value that are added to a drug product at it moves along the healthcare delivery chain, from manufacturer to dispenser, is the appropriate way to analyze and calibrate payment issues, including the need for and the amount of any dispensing fees.

Thank you for the opportunity to present our views with respect to these proposed revisions to CMS policy.

[2] Letter to then-CMS Administrator Thomas Scully regarding Medicare payment reform for Part B drugs (42 C.F.R. Part 405 (CMS-1229-P)) on October 13, 2003.

CMS-1429-P-3987

Submitter : **Mr. Jeffrey Blanchard** **Date & Time:** **09/24/2004 06:09:30**

Organization : **Therapeutic Associates**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a licensed physical therapist in Salem, Oregon and am the director of TAI Valley South Physical Therapy. I received my Masters Degree from Duke University in 1998 and sat for the Boards Exam in July of the same year. I have seen physical therapy help hundreds of people in the last 6 years. I have also seen injury due to people being "treated" by people who do not have a good understanding of biomechanics and pathology.

I strongly support CMS's proposed requirements that if physicians are going to advertise and offer physical rehabilitation to patients, that this is done by a licensed physical therapist, or a licensed physical therapy assistant under the supervision of a physical therapist. In order to practice physical therapy, I had to complete 7 years of schooling (4 years undergrad and 3 years graduate). We were schooled in many different areas in order to make us specialists in rehabilitation. These areas include, but are not limited to: pathology, anatomy, neuroanatomy, kinesiology, and orthopedic issues, to just name a few. We train on site with patients in a number of areas including hospitals, clinics, and schools. We are very qualified for what we do when we obtain our license.

The delivery of "physical therapy services" by an unqualified person would be less productive as well as potentially harmful. I have seen patients harmed by receiving exercise from unqualified individuals as well as patients harmed by hands on treatment given by others without adequate knowledge of the condition. This resulted in further injury which took longer to heal and was a greater cost to the insurance company as a result. I would not choose to see a personal trainer if I had dislocated my shoulder.

Thank you for your consideration of my comments. I hope that my profession, as well as our patients, will be protected by responsible legislation.

Jeffrey Blanchard, MS, PT
Director of Physical Therapy
TAI Valley Physical Therapy South
503-585-4824

CMS-1429-P-3988

Submitter : Ms. Jennifer Lesko **Date & Time:** 09/24/2004 06:09:45

Organization : Ms. Jennifer Lesko

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

Dear Administrator McClellan,

I am a physical therapist in the state of Washington. I have practiced physical therapy in an out-patient orthopedic and skilled nursing facility setting for the last 4 years. 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 the CMS?s proposed requirement that physical therapists working in physician?s offices be graduates of accredited professional physical therapist programs. Just as other licensed health care providers, physical therapists must be licensed in their practicing state and are held accountable for their professional actions. Currently, 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. To ensure patient safety and appropriate care, unqualified personnel should not be providing physical therapy services.
Physical therapists are professionally educated at the college or university level in programs accredited by the Commission on Accreditation of Physical Therapy, an independent agency recognized by the U.S. Department of Education. 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 functional outcomes for individuals with disabilities and other conditions needing rehabilitation. This education and training in progressing patients toward functional independence is particularly important when treating Medicare beneficiaries.
The delivery of so-called ?physical therapy services? by unqualified and untrained personnel is harmful to the patient as well as a financial burden to the system. The therapy cap, a financial limitation on the provision of therapy services is scheduled to become effective January 1, 2006. If a patient with a rotator cuff strain or partial tear receives improper treatment, that injury may progress into a full tear requiring surgery and prolonged rehab. This patient would also most likely exceed his/her cap on therapy before receiving proper care from a physical therapist. All of these factors would lead to a decrease in functional independence and negative outcomes for this patient.
Thank you for you consideration of these comment.
Sincerely,
Jennifer A. Lesko MS,PT
Director
Therapeutic Associates, Inc. Queen Anne Physical Therapy
(206)352-0105 fax (206)352-0106
jlesko@taiweb.com

CMS-1429-P-3989

Submitter : **Ms. Helen Reese** **Date & Time:** **09/24/2004 06:09:40**

Organization : **Prosthetic Laboratories/Silhouette Shoppe**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Do not want this to go into effect

CMS-1429-P-3990

Submitter : **Mr. Rich Lumazza** **Date & Time:** **09/24/2004 06:09:58**

Organization : **Rich Lumazza Therapy**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

PLEASE DO NOT PASS THIS POLICY WHEREBY A PHYSICIAN CAN ONLY REFER "INCIDENT TO" SERVICES TO PHYSICAL THERAPIST. ALL QUALIFIED HEALTH CARE PROVIDERS SHOULD BE ALLOWED TO PROVIDE SERVICES TO PATIENTS WITH A PHYSICIANS PRESCRIPTION OR UNDER THEIR SUPERVISION!!!!

CMS-1429-P-3991

Submitter : **Michelle Rice** **Date & Time:** **09/24/2004 07:09:12**

Organization : **Hemophilia of Indiana**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

September 24, 2004

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule. File Code CMS-1429-P (69 Fed. Reg. 47488, August 5, 2004)

Dear Mr. McClellan,

I am writing to you on behalf of the bleeding disorder community in the state of Indiana to urge you to reconsider the NPRM proposed recommendation for a separate add-on payment of $0.05 per unit for items and services related to the supply of blood-clotting factor.

As a mother of two sons with hemophilia, I can attest to the impact home-infusion has on the quality of life for those affected with hemophilia. Trips to the emergency room, which used to be a routine occurrence prior to home-infusion, now happen infrequently. Joint damage due to untimely treatment of bleeding episodes and subsequent hospitalization has also been minimized.

Failure to adequately reimburse those who provide full-service hemophilia care will have a negative impact on Medicare beneficiaries. If Medicare beneficiaries do not have access to home therapy, any savings to the Medicare program will be short term. While it is understandable in times of budget crisis to look for cost savings measures, it is important that Medicare not lose sight of the individual. Home therapy has allowed hemophilia to evolve into a manageable chronic condition rather than a crippling, life threatening disease.

Once again, I am urging you to reconsider the NPRM?s current proposal and to reevaluate the value and importance of the high quality and clinically appropriate services provided by full-service hemophilia homecare providers to Medicare beneficiaries.

Sincerely,

Michelle Rice

CMS-1429-P-3992

Submitter : **Mr. William Hoffman III** **Date & Time:** **09/24/2004 07:09:27**

Organization : **Novartis Nutrition Corporation**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

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.

CMS-1429-P-3993

Submitter : Ms. April Simcak, CMA **Date & Time:** 09/24/2004 07:09:17

Organization : Elegant Essentials

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

As a Medical Assistant (CMA) and an office manager for a mastectomy boutique, I am quite shocked to find that CMS is comtemplating a provision of the Medicare Modernization Act that would greatly affect ladies who are post-mastectomy (removal of on or more breasts due to breast cancer). At current, part of the service we provide them is the attaining of the prescription from their physician. This may be considered a convenience, but for some ladies this is a step that saves them time, embarrassment, and even inconvenience, especially if they themselves are not mobile. We supply post-mastectomy supplies to many ladies in nursing facilities, ladies who are invalids or shut-ins. These ladies have a hard enough time getting in to see a physician. let alone obtaining a prescription from their MD and then coming to us. We offer home visits to our ladies as well, especially the ones in the aforementioned situations.We here at Elegant Essentials also service ladies who have moved out of state or are visiting their families in our area. It would be quite rude and not to mention an inconvenience for these ladies to be expected to obtain a Rx and then use it within 30 days. Breast cancer is not prejudiced. It targets ladies of all ages, colors, and stature. Some of our ladies work full time, not allowing them the freedom to visit us whenever they choose. Offering mail order, as well as the convenience of obtaining a Rx for them, allows them to continue to work and pay taxes and into Medicare. Some women do not understand what to ask their physician for. Many of our ladies can not even pronounce prosthesis, let alone know how to ask their physician for a prescription giving them PERMISSION to replace a breast with a false one. Also, many ladies end up needing a new post-mastectomy item after a physician appointment, or months before. Most physicians require an appointment to write a prescription. This in turn generates additional claims to and payments from CMS. Please reconsider exclding post-mastectomy items from this provision. The effects from a mastectomy are permanent. One does not need a physician to tell them that their breast is still absent. Current Medicare parameters are very adequate. Face to face prescription requests would be impeding to all involved: Medicare beneficiaries, physicians, suppliers, as well as Medicare.
Thank you for your consideration of this appeal.

CMS-1429-P-3994

Submitter : **Date & Time:** **09/24/2004 07:09:27**

Organization :

Category : **Individual**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I disagree that only physical therapists are the only qualified health care practitioners that physicians can a should refer patients. The current wording is too limited and should be expanded to include certified massage therapists, chiropractors and other certified bodywork professionals. As a certified massage therapist with over 600 hours of coursework and clinic time, my experience and skill should also qualify for referral.

CMS-1429-P-3995

Submitter : **Date & Time:** **09/24/2004 07:09:07**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist assistant student. 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 am against this regulation for the following reasons. Physical therapists and physical therapist assistants are required to be under the supervision of physical therapists. They are the only practitioners who have the education and training to perform physical therapy services. Unqualified personnel don?t have the ability to perform quality services. PT's and PTA'S are educated professionals have a broad understanding of the body and its functions, and have a widespread patient care experience. This background and preparation permit physical therapists to obtain constructive results for individuals with disabilities and other conditions needing rehabilitation. PT?s and PTA?s expertise are particularly helpful to Medicare beneficiaries. The delivery of physical therapy services by the incompetent consists of unsubstantiated care in which all disadvantages should be strictly reviewed.
Thank you for your consideration.

CMS-1429-P-3996

Submitter : **Mr. Terry Lamb** **Date & Time:** **09/24/2004 07:09:05**

Organization : **Hemophilia Community**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I am of the hemophilia community I have hemophilia I am factor 8 severe the worst type that you can have.So that means that too have a good quality of life that so so many of you take for granted for us it means the vary best health care that we can possibly get.
So please before you make any cuts or changes in any plans please consider our well being and how it would be if you or one of your love ones were too have hemophilia I know you would be writing letters and making pleas too everyone for the best health care and plans possible.
Thanks Terry Lamb.

CMS-1429-P-3997

Submitter : **Dr. Richard Gans** **Date & Time:** **09/24/2004 07:09:03**

Organization : **American Academy of Audiology**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for comments on: Practice Expense, Section 611 Therapy-Incident To, and Coding-Telehealth

CMS-1429-P-3997-Attach-1.doc

AMERICAN ACADEMY OF AUDIOLOGY

11730 Plaza America Drive, Suite 300, Reston, VA 20190-4798 • 1-800-AAA-2336

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: **File Code CMS-1429-P; Comments on Practice Expense, Section 611, Therapy-Incident to, and Coding-Telehealth**

The American Academy of Audiology appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' proposed rule updating and amending the Medicare Physician Fee Schedule for calendar year (CY) 2005. 69 Fed. Reg. 47488 (Aug. 5, 2004).

PRACTICE EXPENSE

The Academy is very concerned about the drastic reduction in Practice Expense Relative Value Units (RVUs) assigned to CPT code 92547 (Supplemental electrical test). Even factoring in the anticipated two percent increase in the conversion factor in 2005, reimbursement for CPT 92547 would plummet from $43.68 to $3.03, a decrease of 93 percent.

CPT code 92547 is an add-on procedure that is billed when vertical electrodes are used during balance assessment procedures. Vertical channel electrodes are used in conjunction with other procedures in the ENG battery[1] (*i.e.*, CPT codes 92541 through 92545) or with vertical axis rotational tests (CPT code 92546). Placement of electrodes around the eyes allows measurement of eye movements in the horizontal plane. When CPT 92547 is performed, an additional pair of electrodes in the vertical axis allows measurement of eye movements in the vertical plane. Typically, the examiner uses a two-channel recording instrument to analyze eye movements in the horizontal and vertical axes. Vertical axis recordings are diagnostic. The examiner uses the vertical channel to distinguish eye blinks from true nystagmus, to detect upbeating or downbeating nystagmus, and to detect and analyze oblique or torsional eye movements.

[1] The electronystagmography (ENG) test battery typically consists of saccade tests, gaze tests, tracking or smooth pursuit tests, optokinetic tests, positional tests (typically a minimum of four positions), positioning tests (*e.g.*, Dix-Hallpike procedure), and caloric stimulation (typically warm and cool water or air stimuli in both ears). These tests assess the integrity and function of the oculomotor systems, cellebellar-brainstem systems, and vestibular (inner ear) systems. The vertical electrode is also used diagnostically in vertical axis rotational tests (commonly called rotary chair). In combination with other audiometric, otolaryngologic, and neurologic tests, balance assessment tests are useful in determining the cause of vertigo, dizziness, or unsteadiness.

As an add-on code, CPT 92547 is typically billed eight times – once for each of the four base codes (CPT codes 92541, 92542, 92544, and 92545) and once for each caloric vestibular test (typically four) making up the ENG battery. In those instances where caloric vestibular tests yield a hypo-reactive labyrinth, ice water caloric tests (typically one for each ear) may be administered. Under American Medical Association (AMA) guidelines, add-on codes should be reimbursed at a rate lower than the reimbursement rates for base codes. However, CPT 92547 was assigned RVUs such that it was reimbursed more than the ENG base codes. Because of this high reimbursement rate, the AMA issued interim guidance stating that CPT 92547 should be billed only once per ENG battery, as if it were a separate procedure, pending revaluation by the AMA's Practice Expense Advisory Committee (PEAC).

This year, the PEAC proposed revising the value of CPT 92547 downward, and CMS proposes to accept the PEAC recommendation. While the Academy accepts that a reduction in the Practice Expense RVUs assigned to CPT 92547 is in order, we believe that if CPT 92547 is to be re-valued as an add-on code, then it should be billable as an add-on code, as currently stated in the CPT Manual. The Academy urges CMS to clarify that CPT 92547 may be billed multiple times in the same testing battery (*i.e.*, once for each of the base codes that make up the ENG battery).

The impact of the proposed reduction will be dramatic. Even if audiologists are able to bill for CPT 92547 eight times for an ENG battery, Medicare reimbursement still will only be $24.24, 45 percent less than Medicare reimbursement for CPT 92547 billed once in 2004.

SECTION 611

As required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), CMS is proposing to add a new Medicare benefit – an initial preventive physical examination – for new beneficiaries whose first Part B coverage period begins on or after January 1, 2005. We commend CMS for recognizing that hearing and balance are important aspects of a patient's health status and level of safety and for including screening tests for hearing impairment and falls risk as part of the initial exam.[2]

It is essential that Medicare beneficiaries who fail the hearing and/or balance screening test be referred to an audiologist for a full hearing and/or balance assessment. Where the screening tests reveal that a beneficiary has a hearing or balance impairment, CMS should direct physicians and other qualified providers to refer the beneficiary to an audiologist for complete diagnostic testing. Medicare beneficiaries and many primary care physicians may not be aware that audiologic (or vestibular) testing by a qualified audiologist is necessary to determine the nature, cause, and degree of a hearing (or balance) impairment. They also may not realize that a hearing or balance problem may be a symptom of a medically treatable condition. Therefore, it is important that CMS direct physicians to refer beneficiaries who fail the hearing or balance

[2] Falls are a particularly important cause of morbidity among the elderly. Each year, roughly 20 to 30 percent of persons older than 65 sustain a serious fall, and approximately 9,500 elderly die as a result of complications associated with a fall. The estimated cost of caring for elderly persons who fall is about $12.4 billion a year. Colon-Emeric, C, and Liang, B. Falls in older adults: assessment and intervention in primary care. *Hospital Physician*, April 2002, 55-66.

screening tests to the health care professional most qualified to perform and interpret further diagnostic tests.

The Academy also believes that CMS should provide additional guidance regarding appropriate hearing and balance screening instruments. While the Academy generally agrees that CMS should not prescribe the particular screening tests used in the examination, we are concerned that, without guidance from CMS, some physicians and other providers may use discredited screening tests and fail to detect many patients with impaired hearing or balance. For example, it is well known that the forced whispered test is still used by many physicians to screen for hearing loss, even though most audiologists consider it to be of little value.[3]

The Academy does not advocate the use of whispered voice, tuning fork, or finger-rub tests as screening instruments for hearing impairment. Typically, the whispered voice test is administered by whispering several test words at some distance from the patient ear out of field of vision and asking the patient to repeat the words. While both U.S. and Canadian Preventive Task Forces cited literature on the efficacy of whispered voice tests compared to pure-tone screening, in typical practice settings whispered voice tests are inherently inaccurate, inconsistent, subjective, and insensitive, particularly for high-frequency hearing losses.[4,5] Such tests tend to miss milder and high-frequency hearing losses that nevertheless warrant the attention of the physician. The tuning fork test is performed by holding a vibrating fork one inch from the patient's ear and withdrawing it. The test is only capable of detecting hearing loss at a single low frequency and therefore is not suitable for screening older people who characteristically lose hearing in higher frequencies. The finger-rub test is carried out by rubbing thumb and forefinger together and slowly withdrawing the hand until the patient no longer hears it. Like the whispered voice test, the finger-rub test is inherently inconsistent because of inter-observer variability. Pure-tone screening has become the standard method for measuring hearing ability.

The Academy would be glad to work with CMS to develop guidelines regarding appropriate screening instruments for hearing and balance impairment. While CMS may wish to issue national coverage determinations (NCDs) in the future, we hope CMS will set some parameters for acceptable screening tests in the preamble to the final rule itself.

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[3] The Departments of Defense and Veterans Affairs no longer consider the forced whisper test an acceptable screening tool. For a more detailed discussion of the limitations of the forced whisper test, *see* Newby, *Audiology* (1972); Davis and Silverman, *Hearing and Deafness* (1970); and Rintelmann, *Hearing Assessment* (1979). See also Federal Highway Administration, Role of Driver Hearing in Commercial Motor Vehicle Operation: An Evaluation of the FHWA Hearing Requirement ("…. the forced-whisper test is not as reliable or valid as a hearing test based on pure-tone audiometry").

[4] King, P. (1953). Some Imperfections of the Free-Field Voice Tests. Journal of Laryngology and Otology, 67, 358-364.

[5] Wilbur, L.A. (1991). Pure Tone Audiometry: Air and Bone Conduction. In Rintelman, W.F. (ed), Hearing Assessment (2nd Edition), Austin: Pro-Ed.

For hearing impairment, the Academy recommends that an appropriate screening test should consist of a case history (which would likely be part of the initial preventive physical in any event), an otoscopic examination of the ear, and a pure tone screening test. The pure tone audiometric screening test uses pure tones at three frequencies (*i.e.*, 1000 Hz, 2000 Hz, and 4000 Hz) at 25 dB HL; a patient that is unable to hear the tone at one or more frequencies fails the test. While the pure tone test is the gold standard, family practice physicians that do not have audiometers in their offices should be allowed to use a questionnaire or "paper screen" such as the Hearing Handicap Inventory for the Elderly – Screening Version (HHIE-S) or the National Institute for Deafness and Communication Disorders (NIDCD) screening test. (Copies of both the HHIE-S and NIDCD screening tests are attached.)

For falls risk, the Academy recommends that an appropriate screening test would consist of two or more of the following tests:

- One-leg balance test - In this test, the patient is asked to balance on one leg for 5 seconds. This test assesses balance, but not gait.

- Functional reach test - The patient stands upright and bends forward with the shoulder flexed 90 degrees to determine the maximal forward reach beyond arm's length. This test assesses only forward balance.

- Berg balance scale - This is a 14-item test that uses a five-point scale to measure balance, but it does not assess gait.

- Tinetti gait and balance test - This test assesses both balance and gait through performance of daily activities.

All of these tests are simple, easy to administer, and brief.[6] Use of any single test alone has relatively low sensitivity and is likely to miss many individuals at risk of falling. Research indicates that a combination of at least two of these tests will have a far higher sensitivity than a single test.[7]

As stated above, beneficiaries that fail the hearing screening and/or the balance screening should be referred to an audiologist for a complete diagnostic audiological assessment.

THERAPY – INCIDENT TO

The proposed rule would establish minimum qualifications for individuals furnishing outpatient rehabilitative therapy services to Medicare beneficiaries. This change is being proposed in response to evidence that some physicians were permitting unqualified individuals to perform therapy services, which the physicians billed to Medicare as "incident to" services.

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[6] Colon-Emeric, C, & Liang, B. Falls in older adults: assessment and intervention in primary care. *Hospital Physician*, April 2002, 55-66. A more detailed description of these tests can be found here.

[7] *Id.*

As the Academy has stated in the past, CMS also should set minimum standards for individuals furnishing covered audiology services to Medicare beneficiaries. There is a growing problem of unqualified individuals furnishing audiology services to Medicare beneficiaries. The Academy recently sent a letter to the Office of Inspector General and CMS discussing this problem. A copy of this letter is attached. The Academy has been advised by CMS that physicians may bill Medicare for audiology tests performed by their office staff as "physician services." When audiology tests are billed as physician services, CMS does not know who performed the tests and therefore cannot determine whether the tests were performed by qualified personnel. Medicare beneficiaries generally also have no way of knowing whether they are receiving services from qualified individuals.

We again urge CMS to set minimum qualifications for individuals furnishing covered audiology services to Medicare beneficiaries. The administration and interpretation of hearing and vestibular diagnostic tests require years of specialized training, including a masters or doctoral degree in audiology, and are far too complex to be performed by technicians, nursing staff, and other untrained personnel. The Academy believes that hearing and balance tests should be covered by Medicare only when personally performed by a physician or a "qualified audiologist" as defined in 42 U.S.C. § 1395x(ll)(3)(B).

CODING – TELEHEALTH

In the preamble to the proposed rule, CMS notes that the statute does not authorize Medicare coverage of telehealth services furnished by audiologists. However, CMS states that it is "exploring this issue as part of a report to Congress…. on additional sites and settings, geographic areas, and practitioners that may be reimbursed for the provision of telehealth services."[8]

The Academy believes that most audiology services can be performed remotely as telehealth services and meet the CMS criteria for Medicare coverage. This includes diagnostic services covered by Medicare, such as auditory brainstem response testing and mapping and reprogramming of cochlear implants. Remote control software applications make it possible for audiologists to control computers and computer peripherals (*e.g.*, audiometers, auditory brainstem response systems, and otoacoustic emissions systems) at remote locations. In many cases, a facilitator at the remote site may be needed to perform limited services such as headphone placement and otoscopic examination of the ear. There is no reason why Medicare should cover such telehealth services when furnished by a physician but not when furnished by a qualified audiologist.

We encourage CMS to recommend Medicare coverage of telehealth services by audiologists in its report to Congress. This can be accomplished by amending the statute to add audiologists to the list of practitioners that may provide telehealth services in the Medicare program. We would be glad to provide CMS with any information it needs to address this issue in its report.

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[8] 69 Fed. Reg. at 47512.

SUSTAINABLE GROWTH RATE

The proposed rule confirms that a payment cut of 3.7 percent would have occurred under the Sustainable Growth Rate (SGR) formula in CY 2005 if there had not been Congressional action. The SGR formula clearly is not producing reasonable payment rates. The steady reductions in Medicare reimbursement it has produced in recent years are not sustainable. Flaws in this formula led to a 5.4% payment cut in 2002, and additional cuts in 2003 through 2005 were averted only after Congress intervened. The Medicare Trustees have projected that the situation will again be in crisis with rate cuts of 5 percent a year in 2006 through 2012.

The Administration has the authority to take additional action in the 2005 fee schedule rule to help ease the problems created by the Medicare payment formula. For example, drug products are not a physician, or other health professional, service and should not be included in the SGR pool. Drugs have consumed an ever-increasing share of SGR dollars. The Academy recommends that CMS announce its intention to use its administrative authority to remove drugs from the SGR pool. We hope that CMS will exercise its authority and not rely exclusively on Congress to remedy this problem.

* * * * *

The American Academy of Audiology is grateful for the opportunity to share its views with CMS.

Respectfully submitted,

Richard Gans, Ph.D.
President

Attachments

Hearing Handicap Inventory for the Elderly (HHIE-S)

The Hearing Handicap Inventory for the Elderly - Screening (HHIE-S) can be used to screen elderly patients for problems associated with hearing impairment. The instrument can be used together with hand-held audioscopes in primary care settings lacking audiometric facilities.

Question	No	Sometimes	Yes
Does a hearing problem cause you to feel embarassed when you meet new people?	0	2	4
Does a hearing problem cause you to feel frustrated when talking to a member of your family?	0	2	4
Do you have difficulty hearing when someone speaks in a whisper?	0	2	4
Do you feel handicapped by a hearing problem?	0	2	4
Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbors?	0	2	4
Does a hearing problem cause you to attend religious services less often than you would like?	0	2	4
Does a hearing problem cause you to have arguments with family members?	0	2	4
Does a hearing problem cause you difficulty when listening to television or radio?	0	2	4
Do you feel that any difficulty with your hearing limits hampers your personal or social life?	0	2	4
Does a hearing problem cause you difficulty when in a restaurant with relatives or friends?	0	2	4

Interpretation
- minimum score 0
- maximum score 40

HHIE-S score in study population	pretest probability of hearing impairment	likelihood ratio (95% confidence interval)	post-test probability of hearing impairment
0-8	30%	0.36 (0.19 - 0.68)	13%
10-24	30%	2.30 (1.22 - 4.32)	50%
25-40	30%	12.00 (2.62 - 55.00)	84%

HHIE-S score	sensitivity	specificity	positive predictive value	negative predictive value	test accuracy
> 8	72%	77%	58%	86%	74%
> 24	41%	92%	67%	78%	76%

References:

Lichtenstein MJ, Bess FH, Logan SA. Validation of screening tools for identifying hearing-impaired elderly in primary care. JAMA. 1988; 259: 2875-2878.

NIDCD National Institute on Deafness and Other Communication Disorders
Improving the lives of people who have communication disorders
ONE OF THE NATIONAL INSTITUTES OF HEALTH

Ten Ways To Recognize Hearing Loss

The following questions will help you determine if you need to have your hearing evaluated by a medical professional:

Do you have a problem hearing over the telephone?

Yes ☐ No ☐

Do you have trouble following the conversation when two or more people are talking at the same time?

Yes ☐ No ☐

Do people complain that you turn the TV volume up too high?

Yes ☐ No ☐

Do you have to strain to understand conversation?

Yes ☐ No ☐

Do you have trouble hearing in a noisy background?

Yes ☐ No ☐

Do you find yourself asking people to repeat themselves?

Yes ☐ No ☐

Do many people you talk to seem to mumble (or not speak clearly)?

Yes ☐ No ☐

Do you misunderstand what others are saying and respond inappropriately?

Yes ☐ No ☐

Do you have trouble understanding the speech of women and children?

Yes ☐ No ☐

Do people get annoyed because you misunderstand what they say?

Yes ☐ No ☐

If you answered "yes" to three or more of these questions, you may want to see an otolaryngologist (an ear, nose, and throat specialist) or an audiologist for a hearing evaluation.

The material on this page is for general information only and is not intended for diagnostic or treatment purposes. A doctor or other health care professional must be consulted for diagnostic information and advice regarding treatment.

Excerpt from NIH Publication No. 01-4913

For more information, contact the NIDCD Information Clearinghouse.

http://www.nidcd.nih.gov/tools/printer.asp?ref=http://www.nidcd.nih.gov/health/hearing/10ways.asp

AMERICAN ACADEMY OF AUDIOLOGY

11730 Plaza America Drive, Suite 300, Reston, VA 20190-4798 • 1-800-AAA-2336

August 13, 2004

Dara Corrigan
Acting Principal Deputy Inspector General
Office of the Inspector General
Department of Health and Human Services
5250 Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms. Corrigan,

The American Academy of Audiology would like to bring to your attention a problem that is causing a great deal of concern to our profession. The Academy is receiving an increasing number of reports from around the country that unqualified individuals are furnishing audiology services to Medicare beneficiaries and other patients. We strongly believe this is a growing problem that poses a risk to patient care as well as a risk of over-utilization of Medicare and other federally reimbursable services.

The Academy is the largest professional audiology organization in the country, representing more than 9,000 audiologists nationwide. Audiologists, as defined in both the Medicare and Medicaid statutes, are health care professionals who have received master's or doctoral degrees from accredited university graduate programs to diagnose, treat, and manage individuals with hearing loss and balance disorders.

Description of the problem

The Academy has long been concerned that some physicians have their office staff (*e.g.*, nurses, receptionists) perform hearing and vestibular diagnostic tests on patients with minimal or no physician supervision. Recently, this practice appears to have become more widespread. In some instances, use of untrained personnel is an organized effort being done on a large scale. It has even received the blessing of the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS), the professional association of otolaryngologists. AAO-HNS offers a certificate program that purports to train office personnel to administer audiologic diagnostic tests; the centerpiece of this program is a two-day training workshop. (A description of the program from the AAO-HNS website is attached to this letter.)

The Academy is also hearing more reports of audiologic testing being done by machines called "otograms." When these otograms are used, it is not clear that any health care professional is involved in selecting, administering, or interpreting the tests. We have been

informed that otograms are being marketed aggressively to primary care physicians so that they can perform hearing tests in their own offices.

The Academy has received a number of reports from audiologists who see this problem in their own practices and communities. One audiologist, who requested anonymity because of fear he would lose his job, reported that his company was hiring and training audiology "technicians" with only a high school education and no previous training or experience in audiology to perform hearing tests. Another audiologist employed by a large multi-physician practice reported that her practice had purchased an otogram manufactured by a company called Tympany. Office staff who are neither physicians nor qualified audiologists use this machine to perform audiology diagnostic tests and bill them to Medicare and other payors. On its website (http://www.tympany.net), the manufacturer Tympany claims that tests performed using the otogram are diagnostic tests covered by Medicare, not screening tests. Medicare carriers that receive bills for these tests from a physician practice will have no way of knowing that the tests were performed by a machine operated by untrained staff.

Why allowing unqualified individuals to furnish hearing and vestibular diagnostic tests compromises patient care

A number of audiology procedures require expertise that a "technician" lacks. If a technician or other unqualified individual performs these tests, serious conditions may be missed and the patient's health may be put at risk. It takes years of education and training to be able to select the appropriate battery of tests, perform and interpret such tests, and recognize medically treatable conditions. Needless to say, if a technician cannot reliably furnish these tests, a machine like the otogram cannot do so either.

The increasingly common practice of excluding audiologists from the hearing health care team has serious consequences, even where a physician is supervising the testing. Although Medicare covers hearing and vestibular tests performed by physicians, physicians actually are not trained to administer audiologic tests, nor are they trained to assess the validity of audiologic tests performed by others. As a result, a physician may not spot inconsistencies in test results. Physicians, like audiologists, are trained in the interpretation of valid audiologic tests. Without a qualified audiologist in the loop, hearing and vestibular problems may be misdiagnosed, as can be seen from the following discussion of particular test procedures:

- Pure tone audiometry threshold, air only (CPT code 92552) and air and bone (CPT code 92553)

  The Hughson-Westlake procedure is employed to establish hearing thresholds, the actual and specific amount of hearing loss in decibels (level of volume) at a specific frequency (pitch). When performing this procedure, masking is used to prevent the non-test ear from participating in the test. This is done to determine the type of hearing loss (e.g., conductive versus sensorineural) and to determine whether a unilateral hearing loss exists. Masking levels are different for air conducted and bone conducted signals. Using inappropriate masking levels or no masking will result in a misdiagnosis. A misdiagnosis may cause a physician to recommend surgery that is

inappropriate and/or unnecessary. Using inappropriate masking levels or no masking may also fail to diagnose an asymmetrical hearing loss or a unilateral hearing loss caused by an undetected acoustic neuroma and/or brainstem lesion. The indications of these conditions are often subtle, and only a qualified audiologist has the training to recognize these indicators and create an appropriate test battery. An untrained person will not know when it is necessary to use masking or how to use masking effectively.

- Comprehensive audiometry threshold evaluation (CPT code 92557)

  This code is actually a bundling of the CPT codes 92553 (pure tone audiometry threshold air and bone), 92555 (speech audiometry threshold), and 92556 (speech audiometry threshold with speech recognition). CPT code 92555 is a series of two-part words or spondees that are given to the patient, gradually reducing the volume in order to find the level at which the patient is able to repeat 50% of the words, in order to determine the patient's threshold of hearing speech. It is imperative to understand the relationship between this speech threshold and the pure tone audiogram in order to establish the validity and reliability of the testing as well as to ascertain the appropriate presentation levels for CPT 92556, speech audiometry. Establishing the maximum score for speech understanding depends upon finding the correct intensity level to present the information and knowing the factors that will influence the level chosen. In many cases the only abnormal finding on an audiogram is a poor speech discrimination score in one ear that may not be attributed or expected given the configuration of the hearing loss. In addition, presentation at several levels of intensity may be necessary to see if rollover is present. Rollover, which refers to a decrease of 20% or more in speech recognition scores with increases in volume, may be a sign of acoustic neuroma. A non-audiologist would not know when this testing is appropriate. The appropriate battery of tests cannot be predetermined, but rather must be determined as the testing proceeds and test results become available. A non-audiologist simply does not have the training to select the appropriate battery of tests, interpret the test results, or produce a definitive diagnosis that can be used to prescribe an efficacious treatment plan.

- Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive (CPT code 92585), comprehensive or diagnostic evaluation (comparison of transient and/or distortion product otoacoustic emissions at multiple levels and frequencies (CPT code 92588), acoustic reflex testing (CPT code 92568) and acoustic reflex decay (CPT code 92569)

  These codes are other examples of complex procedures that an audiologist may need to perform to further delineate a site of lesion. For example, CPT 92585 is performed when an asymmetric hearing loss presents, as in the case of an acoustic neuroma. Other applications may include confirming a suspected demyelization disorder, assessing cochlear implant candidacy or confirming a non-organic hearing loss. These highly technical and knowledge-based tests should only be done by those trained to perform these tests and interpret the findings: a qualified audiologist.

Only screening procedures such as CPT code 92551 (pure tone screening test) or CPT code 92587 (otoacoustic emissions screening) might be competently performed by non-audiologists. These tests are most often performed using automated instrumentation with built-in protocols and parameters that provide only a pass or fail result.[1]

For all of the other procedures discussed above, it is unfathomable to consider untrained personnel performing these tests when the possible outcomes include undiagnosed or misdiagnosed hearing loss, as well as failure to diagnose such potentially life-threatening conditions as acoustic neuromas or brain stem lesions.

How this problem results in over-utilization of Medicare services

When unqualified individuals or machines furnish Medicare-covered services, this also creates a danger of over-utilization of Medicare services. Since any physician can hire a "technician" or purchase an "otogram" machine, any physician, regardless of specialty or training, can offer audiology services and bill them to Medicare. The barriers to entry are minimal.

Legal issues involved

Originally, we believe that physicians billed for audiology services performed by their office staff as "services incident to a physician's professional service." 42 U.S.C. § 1385x(s)(2)(A). However, in 2000, the Centers for Medicare & Medicaid Services (CMS) issued regulations establishing criteria for such "incident to" services, which provided that services having their own separate benefit category in the statute must be billed under that benefit category and may not be billed as "incident to" services. 42 C.F.R. § 410.26. Since diagnostic tests have a separate benefit category (*see* 42 U.S.C. § 1395x(s)(3)), they may not be billed as "incident to" services.

Recently, CMS has advised us that physicians may bill Medicare for audiology services performed by their non-physician staff as "physician services."[2] According to CMS, "physicians may bill for diagnostic audiology services, or any other services within their scope of practice under state law, when the service is performed by their staff, in their offices, under their direction, and when those services are not billed as incident to the physician's service." The requirement that the tests be performed under the physician's direction provides little protection, since the level of supervision required for hearing tests (when not performed by a qualified audiologist) is "general supervision" (*i.e.*, the tests must be under a physician's overall direction, but the physician need not be present during the testing). 42 C.F.R. § 410.32(b)(3)(i).

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[1] Under state law, audiology aides or assistants are limited to performing these screening tests, where they are permitted to do any testing at all. If an audiology aide working under the supervision of a qualified audiologist is not allowed to administer diagnostic tests, it makes no sense that a person with no audiology training or a machine should be allowed to perform such tests.

[2] Letter from Dorothy Shannon, CMS, to Robert Hahn, counsel to the American Academy of Audiology, dated October 16, 2003 (copy attached).

Thus, under CMS' interpretation of the law, physicians legally may have unqualified staff furnish hearing and balance tests to Medicare beneficiaries without the physician being present for the tests, and then bill Medicare for those services.[3] Moreover, when a Medicare carrier receives the bill for those services from the physician, the carrier has no way of knowing who actually performed the services. The Medicare beneficiary, likewise, has no way of knowing whether he or she has received accurate hearing and/or vestibular testing services.

Suggested measures to address the problem

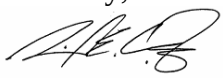
The Academy urges the Office of Inspector General (OIG) and CMS to investigate the problem of unqualified individuals performing hearing and vestibular tests. We believe there are several steps that CMS and OIG can take to address this problem. These include the following:

- OIG can conduct a study of this problem, for example, surveying physicians who bill Medicare for audiology services in a particular area to determine who is actually performing the tests. This would reveal the extent to which untrained personnel are performing these services. It was an OIG study (OEI-02-09-00590) that caused CMS to propose adopting qualification and training standards for therapists furnishing outpatient therapy services as "incident to" services. 69 Fed. Reg. 47488, 47550 (Aug. 5, 2004); *see also* 68 Fed. Reg. 49030, 49059 (Aug. 15, 2003).

- CMS can raise the level of physician supervision required for audiology diagnostic tests when not performed by a "qualified audiologist" from general supervision to personal supervision.

We appreciate your time and consideration of this vital issue. The American Academy of Audiology would like to meet with you at your convenience to discuss this matter further. We look forward to hearing from you. Please contact Robert Hahn, Counsel to the Academy, at 202-789-1212 should you have any questions.

Sincerely,



Richard Gans, Ph.D.
President

CC: Mark McClellan, M.D., Administrator, Centers for Medicare & Medicaid Services
Herb Kuhn, Director, Center for Medicare Management
Sean Tunis, M.D., Director, Office of Clinical Standards and Quality

Attachments

[3] In many states, this is a violation of state licensure and scope of practice laws. However, most states rarely enforce these laws.

CMS-1429-P-3998

Submitter : **Miss. Kathryn Hoffmann** **Date & Time:** **09/24/2004 07:09:18**

Organization : **Miss. Kathryn Hoffmann**

Category : **Individual**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

Dear Mr. McClellen,

I write to voice my opinion that qualifications of individuals providing physical therapy services ?incident to? a physician should meet personnel qualifications for physical therapy in 42 CFR ?484.4.
I am a student currently enrolled in the Physical Therapy Assistant program at Northern Virginia Community College where I am pursuing an Applied Associates of Sciences. I hope to sit for the Virginia licensing boards in the fall of 2006. Years ago, I sustained a severe injury to my knee. I underwent several surgeries and was instructed at strengthening exercises by the staff of the surgeon?this is what I was told was ?physical therapy?. Although I was a model patient, my recuperation was long, painful and incomplete. Only after two more surgeries over the next two years?with the same results-- was I referred outside the surgeon?s practice for physical therapy. I have now regained 95% function and am now pain free 99.9% of the time. I became interested in pursuing a PTA license, and credit my ability to do so, because of having received the benefits of quality physical therapy from a licensed physical therapy professional.
I strongly support CMS?s proposed requirement that physical therapists working in physician?s offices be graduates of accredited professional physical therapist programs. Physical therapists and Physical Therapy Assistants receive extensive education in anatomy and physiology, the treatments and modalities of physical therapy, and in patient care skills, to include decision making as to the most appropriate intervention for a patient during the course of treatment. PTs and PTAs are thoroughly tested not only in the educational environment, but also by the state issuing their license. This background and training enables physical therapists to obtain positive outcomes for individuals with disabilities and other conditions needing rehabilitation.
The value of licensure as a standard is obvious- Licensure assures quality patient care! Licensed practitioners are fully accountable for their professional actions. 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.
Thank you for your consideration of my comments. Sincerely, Kathryn A. Hoffmann

CMS-1429-P-3999

Submitter : **Ms. Ellen Schuster** **Date & Time:** **09/24/2004 07:09:42**

Organization : **Trinity Medical Center**

Category : **Critical Access Hospital**

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do not pass this proposal
Program will not accept letter explaining further reasons for urging non-passage of this proposal