Submitter : Mr. Mitchell Callis **Date & Time:** 09/23/2004 05:09:30

Organization : Norfolk State University Sports Medicine

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached document.

CMS-1429-P-3300-Attach-1.doc

Mitchell S. Callis M.S., Ed., ATC
Norfolk State University
700 Park Avenue
Norfolk, VA 23504

September 22, 2004

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

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician 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,

Mitchell S. Callis M.S., Ed., ATC
Norfolk State University
700 Park Avenue
Norfolk, VA 23507

CMS-1429-P-3301

Submitter : Dr. Helen Straus **Date & Time:** 09/23/2004 05:09:21

Organization : Cook County Hospital (Stroger)

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment on file code CMS-1429-P. The smoothest and simplest way to ensure physician responsibility for billings made in a physician's name is to require that physician to maintain an adequate record of services provided and remittances. If an intermediary handles the billing, it should provide copies to the physician in a timely way as part of this process. If these records are not automatically provided to the physician, there exists the possibility that less physician oversight of the records will occur (and less direct physician responsibility for those records). Where an institution or other entity that has its own agenda and/or potential financial interests at stake is involved, there is additional opportunity for the goals of that institution to override the influence (and responsibility) of the physician. Thank you for your review of these comments.

Submitter : Ms. Fern Monaco **Date & Time:** 09/23/2004 05:09:29

Organization : Ms. Fern Monaco

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We implore 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 physician's prescription or under their supervision.

CMS-1429-P-3303

Submitter : Mrs. Judy Lenz, CMT **Date & Time:** 09/23/2004 05:09:31

Organization : ARE Health Services

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please support other health care providers besides Physical Therapists. Physical Therapists are good and I fully support their work but I have worked with clients that didn't get complete satisfaction or relief from their Physical Therapist who binifited from my Massage Therapy. Shouldn't I get paid also for my work? And not only Massage Therapists but a host of other therapists.

The Health care field is getting more and more specialized not less so. IE, my mom is a nurse and has worked in surgery, ICU, floor, administration, massage, hydrotherapy, all of which are now specialized fields. Shouldn't this also be reflected in the kinds of therapy available for Doctor's patients?

Please don't have so much prejudice as to believe that there is only one health care practitioner that can work with a Physician.

By limiting the kinds of therapy you pay for, you are limiting not only the people's free choice but the Doctor's also!

CMS-1429-P-3304

Submitter : **Date & Time:** 09/23/2004 05:09:17

Organization :

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I wish to comment on the August 5 proposed rule on "Revisions to payment policies under the physician fee schedule for calender year 2005". I support the CMS proposal in the rule that establishes standards for personnel providing physical therapy services in physician offices. Physical therapists are professsionally educated at the college or university level in programs accredited by the commission accreditation of physical therapy. Minimum educational requirement is post-baccaulaureate degree from an accredited program. A physical therapist must also be licensed in the states they practice in. I will have recieved three years worth of training by the completion of my program. In this training a huge emphasis is placed on anatomy and physiology, broad understanding of the body and its functions and comprehensive experience in patient care. All of this training increases the chances physical therapists will be able to obtain positive outcomes for individuals with disabilities and other conditions needing rehabilitation. Physical therapists are the only practitioners who have the education and training to furnish physcial therapy services, unqualified personal should not be providing these services. Delivery of so-called "Physical therapy services" by unqualified personnel is harmful to the patient and should not be allowed to be performed, especially to recieve reimbursment for these services. Section 1862(a)(20) of the social security act clearly requires that in order for a physcian 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 an accredited professional physical therapy education program. Thank you for your consideration of my comments.
Sincerely,
Kirsten Tullius Kuhnle, SPT

Submitter : Robyn Dobbins **Date & Time:** 09/23/2004 05:09:28

Organization : UMDNJ-SHRP

Category : Academic

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 23, 2004

To Whom It May Concern:

I would like to express my support on the CMS ?incident to? proposal. I strongly agree with the proposal that all physical therapy services ?incident to? physician services in a physicians office must be delivered by a physical therapist. Physical therapists are the ones who are trained in the specific area of exercise and rehab. I believe that it is in the best interest of the patients that the services be provided by a graduate of an accredited program where they were rigorously educated and trained in the specific area rather then someone who was trained in a physician?s office.

According to the New Jersey Physical Therapy Practice Act, a physical therapist is a person who is ?licensed to practice physical therapy? and no person is permitted to practice physical therapy without a license. The practice act also states that physical therapy is treatment administered by a licensed PT, PTA, M.D., D.O., or D.P.M.; if administered by anyone else it is not considered physical therapy. Therefore the physicians should not be able to bill for physical therapy if one of the aforementioned professionals did not administer the treatment.

In closing I believe it would be in the best interest of all those involved if the proposal was approved.

Sincerely,

Robyn Dobbins SPT

Submitter : Mr. Douglas Hilliard **Date & Time:** 09/23/2004 05:09:32

Organization : Therapeutic Muscle Specialists

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

Submitter : Ms. grace ladelfa **Date & Time:** 09/23/2004 05:09:28

Organization : massage therapy group

Category : Other Technician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Allowing a physician to only refer "incident to" services to physical therapists is grossly unfair to other qualified professional health care providers such as massage therapists, as well as to patients who can benefit greatly from their services. I have been able to relieve many patients from acute and chronic pain when they have not been able to find relief from physical therapy.

CMS-1429-P-3308

Submitter : **Date & Time:** 09/23/2004 05:09:58

Organization :

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

To whom it may concern, this letter is to inform you what An Athletic Trainer's scope of work involves: We manage and treat athletic injuries through a varitey of different ways. One of which is through Physical Rehabilitation. In our classes we as athletic training students sit right next to the physical therapists and recieve the same educational information/research. I actually think AT's are a bit more qualified to perform physical therapy for injured athletes becuase we first diagnose the injury and are able to understand the pathology of the injury and reahab, as not to aggervate the injury site even more. Now once the classes are over and we go onto our own clinics (PT and AT), I personally think that we (AT) have a more variety of injuries "avalible" to us, as to give us the experience and/or practice that we need to be experienced therapists.

Submitter : Dr. Rama Khalsa **Date & Time:** 09/23/2004 05:09:21

Organization : Safety Net Clinic Coalition of Santa Cruz County

Category : Rural Health Clinic

Issue Areas/Comments

Issues 1-9

GPCI

See attached document

CMS-1429-P-3309-Attach-1.doc

Attachment #3309

September 21, 2004

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

CMS Code 1429-P

The Safety Net Clinic Coalition of Santa Cruz County, a collaborative group of the safety net leaders in our County, has been advocating for change in our Locality 99 since our inception. We have identified the need to stabilize our physician manpower as a top priority. You can imagine our disappointment and frustration when we read the Proposed Rules governing the Physician Fee Schedule for Calendar year 2005 as printed in the Federal Register of August 5, 2004.

These new GPCIs exacerbate reimbursement deficiencies for the California counties of Santa Cruz, Sonoma, Monterey, San Diego, Sacramento, Santa Barbara and El Dorado. In particular, the county of Santa Cruz, when broken out from Locality 99, would otherwise reflect a 1.125 percent GAF - higher than the California Localities 17 (Ventura), 18 (Los Angeles) and 26 (Orange). The boundary payment difference between Santa Cruz County and its neighboring county of Santa Clara (Locality 9) is a whopping 25.1 percent. Such statistics demonstrate the fallacy of the GPCI formula and demand CMS develop either exceptions to the current rules that would correct for the Santa Cruz situation or refine the formula to more accurately reflect the true cost of medical practitioners. Not to do so perpetuates an inherently unfair and discriminatory formula.

In its August 5 notice, CMS states that on the issue of payment localities "[a]ny policy that we would propose would have to apply to all States and payment localities." Such an effort is commendable and bespeaks a desire to be fair to all physicians across the nation. However, the reality is that the governing statute does not prohibit individual State fixes or individual county or locality fixes. The CMS is not constrained by law from

developing a strategy - with or without the concurrence of the state medical association - to correct the discrepancies in the reimbursement levels to California counties and we request that it do so as part of this rulemaking process.

CMS cannot postpone a solution this year as it did last year. Failure to address the GPCI/locality issue in California only grows the problems and will make fixing it all the more difficult in the future. Further, it threatens to undermine medical care to Medicare beneficiaries. Evidence from the local medical society shows an increasing trend toward doctors refusing to accept new Medicare patients. Many doctors are simply leaving the county to practice elsewhere, depleting the county of its medical resources. To implement the August 5 proposed rules would be counterproductive to CMS' mission to make Medicare benefits affordable and accessible to America's seniors.

We object to the Proposed Geographic Practice Cost Indices for 2005 as printed in the Federal Register of August 5, 2004. We request that CMS define a method in which it can revise the GPCIs for those California counties - especially Santa Cruz - that exceed 5 percent of the national average and begin reimbursing doctors in those counties more appropriate to their true costs.

Sincerely,

Rama Khalsa, Ph.D.
Chair, Safety Net Clinic Coalition of Santa Cruz County

CMS-1429-P-3310

Submitter : Mr. Toby Stone **Date & Time:** 09/23/2004 05:09:37

Organization : Student -UMDNJ

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dear CMS,
I am writing in regard to the proposed 2005 Medicare physician fee schedule rule that requires that physical therapy services provided in a physician?s office incident to a physician?s professional services be provided by personnel who have met appropriate standards.
If treatment is provided in a physician?s office by unqualified personnel and subsequently billed as physical therapy services, this presents several risks to patients. Most importantly, when personnel who have not met a minimum standard of competency perform the supervision of physical therapy interventions, the patient?s safety becomes compromised.
Secondly, the efficiency of treatment can greatly suffer without the guided expertise of a licensed physical therapist or physical therapist assistant under the supervision of a physical therapist. While I have a great respect for the knowledge and skill of physicians, I believe that physical therapists are best suited to administer and tailor specialized treatment approaches to maximize patient goals in the most efficient manner.
I strongly feel that physical therapy is a highly specialized field that cannot be mastered by casual training. Students spend anywhere from 2 to 4 years in graduate educational programs at the masters or doctorate level and must then pass a rigorous board exam in order to demonstrate competency. If others are allowed to offer services that can be billed as physical therapy, the physical therapy profession takes a large step back and ultimately, the patients suffer.

Toby Stone
SPT

CMS-1429-P-3311

Submitter : **Date & Time:** 09/23/2004 05:09:32

Organization :

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I would like to voice my support for the proposed "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." It is imperative that physical therapists working in physician's offices be graduates of an accredited PT program, ensuring quality patient care, safety, and a professional standard. Unqualified personnel who are not graduates of an accredited PT program should NOT be allowed to practice our profession willy-nilly. Physicial therapists are professionally educated in full-time doctoral programs averaging 3 years in length, this in addition to having obtained their bachelor's degrees. Physicial therapists must take an exam in order to obtain their license after completing school, and are required to adhere to a professional code of conduct thereafter. Physicial therapists have extensive training in anatomy and physiology, as well as abnormal psychology, exercise physiology, and all aspects of quality and safe patient care. Thank you for considering my comments. Please consider supporting the proposed personnel standards for Medicare "Incident to" physical therapy services.

Submitter : Mrs. Janna Van Noy **Date & Time:** 09/23/2004 05:09:51

Organization : Mrs. Janna Van Noy

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am 51 years old and have lived with pain in my lower back and hip from an injury that I sustained when I was 17. I have lived with a pain in my upper back, lower neck for 11 years. It had created a hump on the base of my neck. Over the last 6 months I have began to have relief for the 1st time from this pain and the hump has dissapeared. I had tried physical Therapy in the past that my insurance paid for. It gave me very little relief from my neck and none on my lower back and hip. My relied I am experiencing now is all due to a great massage threripist who I pay out of my own pocket but it is made afforadable because of her affliation with differant insurance companies. Please consider this in your descion about making life harder for these dedicated and very concerned and talented MT's.

Submitter : Mr. Kevin Blosser **Date & Time:** 09/23/2004 05:09:17

Organization : Saginaw Valley State University

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See Attachment

CMS-1429-P-3313-Attach-1.doc

Kevin "Toby" Blosser, M.S. A.T.,C.
Head Athletic Trainer
Saginaw Valley State University
7400 Bay Road
University Center, MI 48710

September 23, 2004

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

Re: Therapy – Incident To

Dear Sir/Madam:

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

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

- "Incident to" has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY "incident to" service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. ***It is imperative that physicians continue to make decisions in the best interests of the patients.***
- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.
- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.
- Athletic trainers are highly educated. ALL certified or licensed athletic trainers ***must have a bachelor's or master's degree*** from an accredited college or university. Foundation courses include: human physiology, human anatomy, kinesiology/biomechanics, nutrition, acute care of injury and illness, statistics and research design, and exercise physiology. Seventy (70) percent of all athletic trainers have a master's degree or higher. This great majority of practitioners who hold advanced degrees is comparable to other health care professionals, including physical therapists, occupational therapists, registered nurses, speech therapists and many other mid-level health care practitioners. Academic programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) via the Joint Review Committee on educational programs in Athletic Training (JRC-AT).
- To allow *only* physical therapists, occupational therapists, and speech and language pathologists to provide "incident to" outpatient therapy services would improperly provide these groups exclusive rights to Medicare reimbursement. To mandate that only these practitioners may provide "incident to" outpatient therapy in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
- CMS, in proposing this change, offers no evidence that there is a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. ***In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of therapy services.***
- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to **prevent, assess, treat and rehabilitate** injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of walking in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.
- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

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

Sincerely,

Kevin "Toby Blosser, M.S. A.T.,C.

Submitter : Mr. Joel Menges **Date & Time:** 09/23/2004 05:09:02

Organization : Lancaster School of Massage

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do NOT pass this policy limiting "incident to" referals from physicians to physical therapists only. There are many effective complentary and alternative approaches that are qualified for physician referals.

Thank you

Submitter : Mr. Maris Prieditis **Date & Time:** 09/23/2004 05:09:07

Organization : Performance Physical Therapy Services

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

CMS-1429-P-3315-Attach-1.doc

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,

Maris Prieditis
2802 11th Street
Winthrop Harbor, IL 60096

CMS-1429-P-3316

Submitter : Mrs. Shannon Courtney **Date & Time:** 09/23/2004 05:09:14

Organization : University of Northern Colorado

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I would like to respond to the 'incident to therapy services' from physicians offices. First of all to dictate who a physician can refer a patient to is limiting the physician rights and the patients rights to service. I have been responsible for educating student athletic trainers in the collegiate setting for close to 20 years now and to think that the students that I have helped educate will be limited in job employment due to the perception that these are just students out there working on injured individuals providing rehabilitative services without any formal education is an insult. Pehaps the those professionals behind this change in service and reimbursement have found that certified athletic trainers do actually provide a better more funtional service than they do because they only learn in a clinical setting. Why would these other therapists want to become certified as athletic trainers if they feel that our qualification are substandard. It is concerning to me that CMS is asking for these changes when having a variety of professionals that patients and physicians can utilize would be a benefit. As I stated previously, I have been in the business of educating athletic trainers for many years, many of these athletic trainers have gone on into the physical therapy field. With out their background in athletic training they would not be the quality physical therapists that they are today. What background do physical therapists have in the sports area? How many hours are they contributing to a practical rotation in this area. How many hours do they volunteer to help out a high school or tournament to provide injury care to participants. If the physical therapists truly think they can provide the best care then they should be there at the time of injury. Out patient services is the exact area that athletic trainers specialize in. The APTA is incorrect in their statments that unqulified and uneducated students are working on patients. That is an insult to the physician and their ability to refer their patients to quality care. I would encourage CMS to research the job qualification and educational background concerning athletic trainers and their ability to provide out patients services. In this day and age of ever rising health care costs to limit services to one entity will only encourage and support the monopoly and continued rise in health care services.

Submitter : Mrs. Susan Brookes **Date & Time:** 09/23/2004 05:09:24

Organization : Brookes Muscle Therapy

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

How could it possibly be in anyone's best interest to limit the Physician referral of 'incident to' services to only Physical Therapists? Please do NOT pass this policy. Are Physicians not in the best position to determine what care/services would best fit the needs of each individual patient? Working under the supervision of, or with a written prescription from a Physician, all qualified health care providers should be permitted to provide services to patients.

May we all continue to work together for the best medical care possible for our communities.

Sincerely,
Susan Brookes, NCTMB, AMTA

CMS-1429-P-3318

Submitter : Dr. Nancy Walker **Date & Time:** 09/23/2004 05:09:21

Organization : bryn Mawr Medical Specialists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am writing with concern regarding the reimbursement for Infliximab, an intravenous medication used to treat rheumatic conditions. Currently, the fee schedule for this infusion is the
published average selling price (ASP) plus 6%.

I support the transition from a drug acquisition based system to that of a practice expense based scenario. There are significant challenges in acquiring and providing pharmaceutical
products to Medicare Beneficiaries under the new ASP methodology. The ASP + 6% that I use in rheumatology is not reflective of the price by which many physicians acquire the product. Under the current definition discounts provided by manufacturers to wholesalers, Pharmaceutical Benefits Managers and hospital systems are not passed on to the providers, and as a result the
ASP is far below the actual acquisition price by which a physician can purchase.

I support the concept of a patient management code to capture costs incurred in managing a difficult and chronic condition such as rheumatoid arthritis. Each infusion of infliximab poses a
small but signifiant risk to patients. All infusions in my practice are given under physician supervision. Adverse reactons such as fevers, nausea, shortness of breath and hypotension
are managed on site. I support the addition of a new code to capture the unique challenges facing providers who treat patients with biologic treatments.

If reimbursement levels reach a point where an individual practice cannot maintain the infusion service now provided a patient shift to the hospital would occur and cause a dramatic cost impact
to Medicare. In addition, infusions easily and conveinently scheduled for patients would no longer
be available.

Please recognize the importance of maintaining a level of reimbursement that preserves the physician office as a viable site of care for the appropriate patients who need injected or
infused therapies.

Sincerely,

Nancy Walker MD,MPH

CMS-1429-P-3319

Submitter : Ms. Cyndi Kettmann **Date & Time:** 09/23/2004 06:09:16

Organization : Sutter Health

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Sutter Health Comments Attached as Word Document
File Code CMS-1429-P,Re:GPCI

CMS-1429-P-3319-Attach-1.doc

September 22, 2004

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

File Code CMS-1429-P, Re: GPCI

To Whom It May Concern:

We appreciate the opportunity to comment on the referenced proposed rule dealing with physician payment localities. Because Sutter Health serves more than twenty Northern California counties and has care centers in more than 100 communities, we feel we are in a unique situation to provide insights into the practical impact of the Medicare Physician Fee Schedule.

Sutter Health has long advocated for fair and adequate reimbursement for physicians and has been particularly troubled by a flaw in the physician fee schedule that unfairly impacts physicians practicing in certain areas. The problem stems from the methodology used in 1997 to create new payment "localities." Under the physician fee schedule each locality has a unique geographic adjustment factor that reflects the relative resource costs difference among all localities. This factor is applied to the base rate to determine the adjusted rate to be paid to physicians in the respective locality.

The 1997 methodology established unique localities with costs that were at least 5 percent higher than the combined average cots of all lower-cost localities in the state. The rest of the localities, i.e. those with cost equal to or less than the 5 percent threshold, within the state were combined into a single "rest-of-state" locality because, it was assumed, their costs were relatively homogenous. These rest-of-state localities are called "Locality 99."

We believe the major flaw in this methodology is that Medicare did not start in 1997 by looking at the relative costs difference of each county, instead it used the localities established in 1967 for Medicare's reasonable charge based physician payment system. The current localities in all states were established under the 5 percent threshold noted above by comparing the then existing locality costs—not by comparing individual county costs. The result is, at least in California, that the state's Locality 99 includes at least ten counties with cost differences exceeding 5 percent.

We appreciate that CMS requested public comment in August 2003 on the status of physician payment localities. Furthermore, we appreciate that CMS recognizes our ongoing concerns in California that the existing physician payment localities in our state fail to adequately adjust for the considerable variations in practices expenses in this state. However, we are concerned that CMS has yet been able to find an adequate solution as it indicated in November of 2003, when CMS responded that the physician payment localities would "necessitate further review and study." A solution was again delayed most recently in August of 2004, as CMS stated in a proposed rule: "we have not yet been able to come up with a policy and criteria that would satisfactorily apply to all situations."

While we certainly appreciate that it will be difficult to provide a solution that will be satisfactory for all situations, this flaw in the methodology will only exacerbate an already dire situation. We wish to call to your attention that the problem, while severe in 2004, will become desperate in 2005 and 2006 under your proposed rule.

First and foremost, the economic trends in California contrast significantly to what has occurred in other smaller, more homogeneous states. California's 58 counties have demonstrated, since 1999, considerable polarization of geographic adjustment factors (GAFs) that is unique nationally. These unique trends call for an immediate remedy distinctly tailored to the problem in this state.

In addition, the proposed published GAFs for 2005 for California's current localities show two important trends: a rapid relative inflation of GAF values for many Bay Area counties, and a comparable increase in costs in two Bay Area counties currently assigned to California Locality 99, Santa Cruz and Sonoma counties. The central valley of California is seeing similar trends. Payment boundaries across county lines are important factors to be considered as new payment rules are proposed. We are concerned that two of our communities will experience the greatest payment boundaries in the nation: Sonoma County (payment boundary of 14%) and Santa Cruz County (payment boundary of 25.1%).

Clearly, without some immediate action, the payment disparities amongst California physicians will continue to escalate. We strongly urge that CMS act now to establish new payment localities within California where payment mismatches and boundary payment discrepancies demand such corrective action. **CMS should act now to establish new payment localities for any county within Locality 99 whose individual county GAF is greater than the proposed GAF for Locality 99. This would re-designate ten California counties into their own payment localities: Santa Cruz, Sonoma, Monterey, San Diego, Santa Barbara, Sacramento, El Dorado, Placer, San Luis Obispo, and San Joaquin.** A national policy may follow from this locality revision.

We understand the difficulties involved with the constraints of budget neutrality if CMS were to designate these ten counties into their own payment localities. However, we believe the impact

on the remaining Locality 99 counties could be distributed in such a way so as to preserve budget neutrality for California and ensure that the proposed (rural) Locality 99 counties would be held harmless (held at their 2004 payment values).

In addition we recognize and support the unique role that state medical societies play in crafting a reasonable and equitable solution to the physician payment schedule, particularly as it impacts multi-locality states. We have worked closely with our colleagues at the California Medical Association on this effort and understand that the state medical society continues to be committed to working with CMS to establish a long-range policy acceptable to California's physicians. While we support overall policy reform, we hope that an equitable interim solution could be developed prior to January 1, 2005. Consequently, we strongly urge corrective action and a revision of your proposed rule at this time that could address those physicians' needs, and Medicare beneficiaries access, in the referenced counties most dramatically impacted.

Thank you for providing us the opportunity to comment on this important issue.

Sincerely,

Cyndi Kettmann
Senior Vice President, Public Affairs
Sutter Health
2200 River Plaza Drive
Sacramento, CA 95833
916-286-6706 – office
916-286-8107 – fax
kettmaca@sutterhealth.org

CMS-1429-P-3320

Submitter : Dr. Ralph Robert Franks **Date & Time:** 09/23/2004 05:09:54

Organization : Cooper University Hospital

Category : Physician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

CMS-1429-P-3320-Attach-1.txt

Attachment #3320

"http://www.cms.hhs.gov/regulations/ecomments"

Ralph R. Franks, Jr., D.O.
Cooper University Hospital
Bone and Joint Institute
6117 Centennial Boulevard
Voorhees, NJ 08043

September 1, 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, as primary care, sports and occupational medicine physician, to express my concern over the recent proposal that would limit providers of "incident to" services in my office and clinics. If adopted, this would eliminate the ability of qualified health care professionals who provide these vital services (with much success) in the past. 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.

Furthermore, I strongly urge you to consider the following points as you proceed in the decision-making process:

"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. I have the right to delegate the care of my patients to trained individuals (including certified athletic trainers) whom I deem knowledgeable and trained in the protocols to be administered. My 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 me in terms of who I can utilize to provide ANY "incident to" service. Because I accept legal responsibility for the individual under my 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 I and all other 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 and insurer.

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.

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

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

CMS, in proposing this change, offers no evidence that there is a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single

professional group who would seek to establish themselves as the sole provider of therapy services.

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

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

Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program, every professional sports team in America and many corporations, including mine, to work with athletes and physically active people to prevent, assess, treat and rehabilitate injuries sustained during athletic competition and the physical activity of daily life. In addition, dozens of athletic trainers have accompanied the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of walking in a local 5K race or injured on the job 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.

It has been my pleasure to work with Certified Athletic Trainers during many aspects of my career. As a new physician, I have been able to observe them in a variety of settings from the training room to the operating room to the examination room. I can confirm that they are invaluable as members of the healthcare team for patients.

They have a broad knowledge base that allows them to quickly and accurately DIAGNOSE and TREAT not only musculoskeletal conditions but also basic medical conditions. This necessity to do this quickly and accurately has allowed them to be successful in a variety of areas within medicine. They have become an invaluable healthcare resource for our high school and collegiate athletes. They have demonstrated their importance in rehabilitation both in academic settings and in physical therapy clinic hours. They are invaluable as providers of physical therapy modalities in many office settings. They have PUBLISHED extensive data both on diagnosis and treatment of athletic and musculoskeletal injuries and the treatment of said injuries in many accepted medical journals. This fact alone is reason to reconsider this decision.

In my practice area, certified athletic trainers are crucial to many practices. They often are the link between the physician and patient through their education, diagnositic skills and rehabilitative expertise. They have the education and skill to diagnose and treat under standing orders on our athletic fields when physicians cannot be present. They also have the expertise to work in the clinic on patients who need physical modalities and

therapy. In seeing the injury occur and being the qualified first responder, they have an insight into orthopedic and sports medicine injury that physical therapists, although another important healthcare provider, do not possess. The ATC has the ability to diagnose and treat where the physical therapist is responsible for treatment only.

I urge you to reconsider this current proposal. Limiting "therapy-incident to" charges to physical and occupational therapists will not only not be in the best interest of patients but will also eliminate the use of a valuable allied healthcare professional to the physician. To say that a certified athletic trainer does not have the ability to give the same treatment to an injured college athlete during one part of the day not have the ability to give treatment for the same condition to the patient in the private clinic is ludicrous. It demonstrates lack of foresight and familiarity with the value that the certified athletic trainer brings to the healthcare arena.

I implore you to not allow patients to suffer by passing this proposal. Once passed, a valuable allied healthcare resource would be lost and those who will miss it the most are the physicians who have come to trust and value the outstanding work done by our certified athletic trainers.

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,

Ralph R. Franks, Jr., D.O.

Submitter : Mr. Art Kent **Date & Time:** 09/23/2004 05:09:41

Organization : Sastun Center of Intregreative Health Care

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I ask you not pass this policy where a physician can only refer "incident to" services to physical therapists. This is a time when medical doctors continue to explore and integrate trained practitioners in a variety of fields to assist in the health and wellbeing of patients. We choose a doctor we trust and we trust they would not align themselves with practitioners who are not of the highest caliber for fear loosing that trust. This policy does nothing to serve the public. It continues to further in tying the doctors hands in their choice of restoring health for their patients.

Submitter : Julia Hanline **Date & Time:** 09/23/2004 05:09:23

Organization : Balancing Point Therapeutic Massage

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We ask 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-3323

Submitter : Mrs. Daria Sonnenfeld **Date & Time:** 09/23/2004 05:09:12

Organization : Mile Bluff Medical Center

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

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.
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.
Please do not make the proposed changes.
Sincerely,
Daria L. Sonnenfeld
Certified/Licensed Athletic Trainer

Submitter : Mr. Zachary Sowa **Date & Time:** 09/23/2004 05:09:03

Organization : Decatur Memorial Hospital

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 23, 2004

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

Dear Sir/Madam:

I have over ten years experience working in various healthcare settings. I currently work with an orthopaedic physician as a physician extender providing excellent care under his supervision. I am very insulted by the suggestion that ?Therapy-incident to? services should only be provided by a physical therapist, PT assistant, occupational therapist, OT assistant, or speech therapist. I do not have a problem with placing restrictions on what profession has direct access to patients. This ensures that the provider has been well trained and is qualified to perform those services. I have a problem with the fact that Certified Athletic Trainers are not included in the list of healthcare professionals qualified to perform these services. Please reconsider this proposal. It would be a detrimental to the quality of care provided to thousands of people.

Sincerely,
Zac Sowa, MS, ATC/L

CMS-1429-P-3325

Submitter : Mr. Peter Hoekstra **Date & Time:** 09/23/2004 05:09:22

Organization : U.S. House of Representatives

Category : Congressional

Issue Areas/Comments

Issues 1-9

SECTION 303

September 23, 2004

The Honorable Tommy G. Thompson
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Mr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Thompson and Administrator McClellan;

I am writing to comment on the Proposed Rule CMS-1429-P, Section 303, which was printed in the Federal Register on August 5, 2004.

The West Michigan Regional Cancer and Blood Center in Free Soil, Michigan serves hundreds of cancer patients each year. This cancer clinic is located in a rural community in my Congressional District, and plays an important role in providing access to high-quality cancer treatments for many of my constituents.

Oncology providers across the nation have expressed their widespread concern that the Average Sale Price (ASP) reforms in Section 303(a) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) will result in Medicare reimbursement levels below the true costs of providing care. They have also expressed concern about the lag in time between the purchasing of pharmaceuticals and the ASP reimbursements from Medicare.

Under the old Average Wholesale Price (AWP) methodology, Medicare outpatient drugs and biologics were often reimbursed at artificial levels. Restructuring efforts in the MMA recognized that the AWP system did not take into account the costs associated with administering drugs to patients, but overcompensated for the actual costs of these pharmaceuticals. I am pleased that the MMA instituted reforms to make the reimbursement system fairer for seniors and providers with an ASP methodology that recognizes the costs associated with administering outpatient drugs and biologics to patients. However, I am also concerned that these important ASP reforms could have the unintended consequence of inhibiting patient access in small, rural facilities that lack the purchasing power of drug purchasing intermediaries or large urban cancer treatment centers.

As you work to finalize the ASP prospective payment policies for Section 303 of the MMA, I implore you to consider the unique challenges of small rural cancer treatment facilities and work to reimburse them in a manner that adequately reflects both the cost of administering drugs and the true pharmaceutical costs. The MMA brought about unprecedented relief for Medicare rural health care providers, and it is my hope that ASP reform efforts will not create new inequities between rural and urban providers.

I look forward to working with you to maintain access to high-quality cancer treatments for seniors living in rural communities.

Sincerely,

Peter Hoekstra
Member of Congress
Michigan's Second District

Submitter : Mr. Brian Neilson **Date & Time:** 09/23/2004 05:09:52

Organization : Bonita Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

Issues 10-19

DEFINING THERAPY SERVICES

Only licensed physical therapists should be able to provide physical therapy services. Physician incident to laws will open the door to possible fraudulent use of non-licensed employees and bill with PT codes. The quality of such care is very questionable. Physical Therapists are held to a high standard of licensure. Incident to issues could allow monopolies to form and may be a breeding ground for fraudulent practice. I believe that Physical Therapists should be protected by the professional laws of the state of California and that Physical Therapy services should only be allowed to be performed by Licensed PTs.

Submitter : Mr. Dustin Ebesu **Date & Time:** 09/23/2004 05:09:23

Organization : Massage Therapists Association of Hawaii

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

Submitter : Mr. **Date & Time:** 09/23/2004 05:09:16

Organization : Mr.

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

The purpose of this letter is to inform everyone that the possibility of Medicare regulations no longer allowing physicians to be reimbursed for therapy services administered by a certified athletic trainer in a physicians office is a bad idea. This could snowball and cause other insurance companies to follow Medicare regulations causing all services by athletic trainers the inability of reimbursement in any clinical setting.

This is a bad idea in that this could put the patients care at a low priority. This could cause other health care professions to become upset and not do as thorough a job for the patient. So, the way the patient is suppose to get treated is not being done to the full extent. I know it is unethical but it could happen. Also, athletic trainers are very qualified to work with any type of patient in need of rehabillitation. Compared to the PT's, OT's, PTA's, and OTA's, the athletic trainer is just as qualiied, if not more qualified. In most cases of training, according to the federal government, the preparation of an athletic trainer is equivalent to PT's and more significant than an OT, OTA, or a PTA. It wouldn't make sense to allow some one less qualified to work with a patient in need of assistance. Athletic trainers also, through education, have a lot of the same classes as a PT would have. Athletic trainers don't just take the classes in their curriculum, graduate, then get a job, they have to graduate and then take the certification exam of everything they could have possibly learned. This makes sure the AT is qualified. A Certified athletic trainer knows how to prevent, assess, and treat/rehab various kinds of injuries. They know information about all systems of the body just like a physical therapist would. Athletic trainers already provide assistance under supervision in athletic training rooms, sports medicine clinics, and hospital settings. So, why should they not be able to give patients quality care? It is really the patients who are losing out.

CMS-1429-P-3329

Submitter : **Date & Time:** 09/23/2004 05:09:19

Organization :

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dear Sir or Madam:

I am writing this letter to oppose physical therapy services being provided by non-licensed physical therapist or physical therapy assistants. Educated physical therapists and physical therapy assistants should be the only professionals who perform physical therapy interventions. I feel that patients would feel much better knowing that physical therapy services are being rendered by educated and licensed individuals in that field, and not someone who has been trained.

Submitter : James J. Savidge **Date & Time:** 09/23/2004 05:09:46

Organization : International Massage Therapy Association

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

It is not in anyones interest to limit "incident to" services only to physical therapists. Other modalities may be more appropriate in individual cases and more effective in restoring health to patients. This will save time and money for the program and ensure the medicare program can meet its goals.

Submitter : Mr. Jeff Aussprung **Date & Time:** 09/23/2004 05:09:14

Organization : Watertown Memorial Hospital

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file.

CMS-1429-P-3331-Attach-1.doc

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

Jeff Aussprung
125 Hospital Drive
Watertown, WI 53098

September 23, 2004

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

Re: Therapy – Incident To

Dear Sir/Madam:

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

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

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

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

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

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

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

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

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

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

only these practitioners may provide “incident to” outpatient therapy in physicians’ offices would improperly remove the states’ right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

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

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

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

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

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

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

Sincerely,

Jeff Aussprung

CMS-1429-P-3332

Submitter : Mrs. MaryAnn Hoffman **Date & Time:** 09/23/2004 05:09:39

Organization : American Physical Therapy Association

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

The sister of my employee went to her physician who told a medical assistant to apply a hot pack to the patient's shoulder. There was no covering on the hot pack which was strapped to the shoulder and a third degree burn was sustained. There was no supervision of this personnel by the physician. Incident to services by the physician is a joke. Ultrasound machines are hanging on the wall with instructions next to them. The medical assistant has no idea that bone and nerve damage can be done by improperly performed ultrasound. I've treated the physician's office mistakes.

THERAPY STANDARDS AND REQUIREMENTS

The education and training of both the physical therapist and physical therapist assistant is far superior to that of anyone employed by a physician, including the physician, when it comes to application of modalities. Physicians order modalities inappropriately when referring to the physical therapist and the PT educates the physician constantly. None of us can know everything and the collaborative effort on behalf of the patient is the key. Sales people are in the business of collecting commissions on the basis of helping the physician increase their revenue centers by the use of modalities. Instruction of non-qualified personnel is totally inadequate. The public is at risk.

THERAPY TECHNICAL REVISIONS

I am in favor of this change and feel that the public is protected by the change. The physicians really stand to lose very little since there is no reimbursement for application of heat or cold and only $11.95 for ultrasound on the Medicare fee schedule.

Submitter : Mr. Jose Rommel Bajar **Date & Time:** 09/23/2004 05:09:54

Organization : Dubuis Hospital

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 23, 2004

To whom it may concern.

Greetings! My name is Jose Rommel R. Bajar, I am a physical therapist license in the state of Texas. I am writing this letter to make a comment on the August 5 proposed rule on ?Revisions to payment Policies Under the Physician Fee Schedule for Calendar Year 2005?.

I would like to support the idea that only a licensed physical therapist and/or physical therapist assistant should be the one to provide physical therapy services and have the right to bill such services. Unqualified professionals even working in a physicians office does not make it right to provide physical therapy services and billed such services under physical therapy.

We are trained professionals to evaluate and assess specific musculoskeletal conditions and provide specific interventions for treatment. I was so appalled to personally witness a Chiropractic clinic, with 12 unlicensed personnel that provide physical therapy services for 80 patients that goes to their clinic everyday. I don?t think this practice is just for these patients, they received hot packs TENS and Ultra sound. The exercises are not geared toward specific group of muscles that needs attention. And then, they will be billed for PT services and no PT has ever seen them. The worse thing is , they will reach their cap without even seeing a physical therapist. When time comes that they would like to see a licensed PT, they will not be granted to have one since they used their cap already.

I firmly believed that if CMS would help to regulate this situation, abuses like this be put into halt. Additionally, the outcomes of patient receiving physical therapy will be better. They will not only receive hot packs, TENS and Ultrasound ---they will get what they deserve --- an individualized treatment program based on a physical therapist assessment.

I hope that this ?proposed rule to require that physical therapy services provided in a physician?s office incident to a physician?s professional services must be furnished by personnel who meet certain standards? be implemented.

Thank you!!!

Sincerely,
Jose Rommel R. Bajar,PT
License #1103638 ?Texas
Dubuis Hospital
Phone #409-924-3910

Submitter : Ms. Lisa Arrington **Date & Time:** 09/23/2004 05:09:02

Organization : Muscular Therapy

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We ask that you DO NOT approve this policy where a physician can only refer "Incident to" services to physical therapists. All Licensed health care professionals should be allowed to provide services to patients with a physicians prescription and/or under their supervision. Other therapies have proven to be less costly, and very
effective.

Thank You

Submitter : Mrs. Ronni Socha **Date & Time:** 09/23/2004 06:09:36

Organization : National Athletic Trainers Assocation

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

To Whom It May Concern:

I am writing in reference to Medicare's proposed changes to the 'Therapy-Incident To' services.
I am a certified athletic trainer that has been employed in both the Division I University and private clinic setting. Certified Athletic Trainers are educated and trained in the treatment and rehabilitation of a wide variety of injuries and medical conditions. We have well-developed relationships with physicians that enable us to provide the best possible medical care to athletes and the general population. I believe that the physician is best-equipped to make decisions regarding the health care of a patient when they are provided with a variety of qualifed allied health professionals to refer patients to, including certified athletic trainers. Restricting the physicians right of referral to all qualified allied health professionals is poorly conceived and could have a detrimental effect on the welfare of Medicare patients. I believe any attempt by government entities or other organizations to change this heretofore established right and purview of the physician is clearly not in the best interest of the patient.
I unequivocally request that no changes be made to Medicare or other provisions affecting 'Therapy-Incident To' services reimbursement from CMS.
Sincerely,
Ronni K. Socha, M.Ed., ATC

Submitter : Mrs. Dee Aussprung **Date & Time:** 09/23/2004 05:09:26

Organization : Watertown Memorial Hospital

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file.

CMS-1429-P-3336-Attach-1.doc

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

Dee Aussprung
125 Hospital Drive
Watertown, WI 53098

September 23, 2004

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

Re: Therapy – Incident To

Dear Sir/Madam:

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

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

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

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

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

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

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

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

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

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

only these practitioners may provide “incident to” outpatient therapy in physicians’ offices would improperly remove the states’ right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

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

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

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

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

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

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

Sincerely,

Dee Aussprung

Submitter : Mrs. Marquita Madruga **Date & Time:** 09/23/2004 05:09:50

Organization : Mrs. Marquita Madruga

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

My name is Marci Catallo-Madruga and I am a current member of the Student Assembly Nominating Committee, a component of the APTA. I am currently a third year student in the Doctoral of Physical Therapy program at Regis University in Denver, CO. I wish to comment on the ?Therapy-Incident To? proposed rule on ?revision to payment policies under the physician fee schedule for calendar year 2005.?

As a student looking to be employed in May of 2005, I would like to offer my comments in support of the rule requiring that physical therapists working in physicians offices be graduates of an accredited professional physical therapy program. I further suggest that the rule include licensure for the physical therapists, because it is their right to practice that would be under scrutiny if there were a complaint or legal action filed. Licensure is the highest standard to which a therapist can be held professionally and it is imperative for the future of the profession to have a set of standards by which they hold all with the title of physical therapist.

In 1992 the American Medical Association and American Physical Therapy Association determined that patients seen in physician owned clinics had less hands on care, 43% more visits than patients in non-physician owned clinics, and cost 31% more per year. The increase in number of visits can be attributed to lack of appropriate care provided by unqualified personnel. Unqualified personnel include anyone who has not graduated from an accredited physical therapy program who is billing for physical therapy services.

The level of education physical therapists and physical therapists assistants receive is higher in musculoskeletal dysfunction and management of common musculoskeletal disorders. The extensive training in anatomy, physiology and motor behavior allows physical therapists to work with patients to obtain the greatest possible outcomes. There are no instances where it is appropriate for unqualified persons to provide physical therapy services to patients treated in a physician owned clinic. There are some instances where patients have been seen by unqualified personnel and billed for physical therapy services. This is a violation of the patients bill of rights to be informed of and receive services from qualified personnel and be billed accordingly. In cases that deal with Medicare, beginning January 1, 2006 patients may exceed the $1590 cap with out ever being seen by a physical therapist. This can negatively impact patient care by decreasing the potential for recovery, satisfaction from services, and increase the likely hood that the patient will seek more expensive surgical procedures in the future as opposed to physical therapy services.

I would Like to bring to light a more personal case. Last winter my grandfather recieved care in a physician office for a back injury through medicare and was billed for Physical Therapy Services. The person giving his treatment was not a Physical Therapist. His care consisted of hot pack treatments, gentle stretches, and a set of pictures for therapeutic exercise. He still ahs his back pain without resolution of any symptoms, but is now seeing a physical therapist. If the Medicare Cap were in place he would be unable to get proper care at all.
Thank you for your time.
MCM

Submitter : Ms. Linda Lemire **Date & Time:** 09/23/2004 05:09:16

Organization : AMTA, NCTMB

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you NOT to pass this policy where 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. Physical Therapists do physical therapy. There is much more available out there by competent therapists who can increase the quality of life and health of your patients. Thank you.

CMS-1429-P-3339

Submitter : Mrs. Mary Beth Nawrocki **Date & Time:** 09/23/2004 05:09:56

Organization : Watertown Memorial Hospital

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file.

CMS-1429-P-3339-Attach-1.doc

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

Mary Beth Nawrocki
125 Hospital Drive
Watertown, WI 53098

September 23, 2004

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

Re: Therapy – Incident To

Dear Sir/Madam:

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

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

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

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

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

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

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

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

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

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

only these practitioners may provide “incident to” outpatient therapy in physicians’ offices would improperly remove the states’ right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

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

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

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

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

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

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

Sincerely,

Mary Beth Nawrocki

Submitter : Lauretta Crites **Date & Time:** 09/23/2004 05:09:09

Organization : Lauretta Crites

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do NOT create policy where 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-3341

Submitter : Mrs. Karen Iehl-Morse **Date & Time:** 09/23/2004 05:09:10

Organization : University of Illinois-Champaign

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Writing in opposition of porposal CMA-1429-P. This proposal would limit patient access to qualified health care providers of "incident" to services, such as certified athletic trainers in physician offices and clinics. This would reduce the quality of health care for physically active patients. Limiting access to qualified health care providers will cause delays in the delivery of health care, which will in turn increase health care costs and tax an already heavily burdened health care system. Athletic trainers are multi-skilled health care professionals who can make significant contributions to health care. Athletic trainers are highly educated as evident by their recognition by the American Medical Association as an allied health care profession. If this proposal would pass, it would threaten the employment of athletic trainers who are employed as physician extenders in clinics and physician offices. I believe this proposal should be rejected in order to protect the rights of our patients and my right as a health care practitioner.

CMS-1429-P-3341-Attach-1.doc

September 23, 2004

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

Re: Therapy – Incident To

Dear Sir/Madam:

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,

Karen A. Iehl-Morse, M.S., ATC/L
Assoc. Athletic Trainer

Submitter : Mrs. Dawn Alzuraqi **Date & Time:** 09/23/2004 05:09:01

Organization : Mrs. Dawn Alzuraqi

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Not allowing medicare reimbursement/payment for massage therapy would be a deteriment to senior patients well being. Though massage therapy can be a part of a physical therapy treatment plan, many physical treatments are anything but physical/personal. Our seniors need to have the option of more than being placed on a machine to stimulate muscle massage, only treating a specific area. Personalized treatment plans should be that, personal, and many of our seniors having a personal contact/relationship assists in a more dynamic healing assisting in other areas of their health. If massage therapists have a proven record of care with success, their services are just as important if not more important than many other health care providers, providing treatment for the entire person.

CMS-1429-P-3343

Submitter : Ms. Barbara Marone **Date & Time:** 09/23/2004 06:09:34

Organization : ACEP

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached Word file:

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

The attachment to this document is not provided because:

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

Submitter : Wendy Isom, LMBT **Date & Time:** 09/23/2004 05:09:42

Organization : American Massage Therapy Association

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

CMS-1429-P-3345

Submitter : **Date & Time:** 09/23/2004 06:09:39

Organization :

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

CMS-1429-P-3345-Attach-1.doc

Erika Anattol
6040 S Fife St
Tacoma, WA 98409

September 22, 2004

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

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my alarm 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, including Certified Athletic Trainers (ATC's), 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. This proposed CMS action is clearly driven by the financial interest of other groups and by all appearances 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.

Certified Athletic Trainers are multi-skilled professionals that are clinically educated and practically skilled to care for physical injuries, illnesses, and related conditions. In order for an athletic trainer to become credentialed one must:

1) Attend an accredited 4 year college or university and complete an athletic training curriculum based educational program. Please note that 70% of credentialed athletic trainers have earned a master's degree or higher.
2) Successfully complete an athletic training program.
3) Pass the BOC national certification examination

The title of ATC means certain standards of education have been met and the individual is practically skilled and qualified to provide medical services as an athletic trainer. It is ludicrous to suggest ATC's are academically and practically unqualified.

Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers accompanied the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States.

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. 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.

CMS has no standing or 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.

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,

Erika Anattol MS, ATC

Submitter : Miss. Stephanie Holkins **Date & Time:** 09/23/2004 06:09:53

Organization : Miss. Stephanie Holkins

Category : Nursing Aide

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Massage Therapists should be allowed to provide medically related care to physicians' patients.

Submitter : Mr. Harrison Pearce **Date & Time:** 09/23/2004 06:09:52

Organization : National Athletic Trainers Association

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Harrison Pearce
38 Fisk Street
Manasquan,NJ,08736
September 23,2004

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

Dear Sirs/Madam

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

I have had the pleasure of working with both an athletic trainer and physical therapist in the clinical setting. The care and treatment for my injury by the athletic trainer was equal to if not better than that of the physical therapist. I received more personal attention from the athletic trainer than I did from the very busy physical therapist. I preferred working with the athletic trainer because I felt as if I had their full attention and was not rushed through my session. Not to say that the physical therapist was lacking in skill or professionalism but they seem to have such a heavy workload and so many patients it was hard for them to give me the individualized attention I required. The physical therapists should be happy to have another qualified health care professional to assist them with their busy workload as opposed to being threatened by their expertise.

I strongly believe it would be a crime for the government to take away avaliable options for the physician and Medicare/Medicaid patients. It should be left up to the treating physician ultimately who treats their patient. As long as the person is a fully trained professional there should be no limits placed upon them as long as they are following the direction of the treating physician. Living in the United States gives you the freedom of choice and if this proposal is adapted you have eliminated the freedom of choice and created a dictatorship. You are in essense telling Medicare/Medicaid patients that the only people they are allowed to go to for rehabilitation is a physical therapist. You are monopolizing the health care system and limiting the peoples options. If you allow this to occur you are ultimately hurting all health care providers by taking away choices.

It is imperative that physicians continue to make decisions in the best interest of the patients. If it is not broken why fix it I must ask; or maybe this could be construed as an unprecedented attempt by CMS, at the request of a specific type of health professional, to seek exclusivity as a provider of therapy services. You members voting on this issue must take a stand and not give in to one specific group and to allow all professionals the same opportunities in the health care system. Certified Athletic Trainers are very qualified individuals and should not be excluded from the Health
Care System.

Please consider not changing the system just to accommodate one specific group, because as I have said before you are taking away my choices and my doctors choices when it comes to my ultimate care. I have worked to hard for my medicare benefits and would hate to have my choices limited because one group is threatened by another.

Sincerely,
Harrison Pearce
Medicare patient

Submitter : Dr. Lonnie Paulos **Date & Time:** 09/23/2004 06:09:56

Organization : Advanced Orthopedics and Sports Medicine

Category : Physician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please view attached document. Thank you for your time in this matter.

Sincerely,

Lonnie E. Paulos, MD

CMS-1429-P-3348-Attach-1.doc

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

Lonnie E. Paulos, MD
Advanced Orthopedics and Sports Medicine
5250 S. Commerce Dr.
Murray, UT 84107

September 22, 2004

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

Dear Sir/Madam:

I am a physician writing to express my concern over the recent proposal that would limit providers of "Therapy-incident to" services in physician offices and clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. 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, 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 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 patients with comprehensive health

care. The patient would be forced to see the physician and separately seek therapy, causing significant inconvenience and additional expense.

- 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 care, greater cost and a lack of local, 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 also cost time and travel expense. Delays would hinder the patient’s recovery and/or increase recovery time, which 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 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.
- CMS 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. This action could be construed as an unprecedented attempt by CMS 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.
- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

It is not necessary or advantageous for CMS to institute the changes proposed, and I request that the change not be implemented. This CMS recommendation is a health care access deterrent.

Sincerely,

Lonnie E. Paulos MD

CMS-1429-P-3349

Submitter : Ms. Elizabeth Broadhead **Date & Time:** 09/23/2004 06:09:25

Organization : The Healing Spirit

Category : Nurse

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 and/or under their supervision. Not all Physical Therapists are qualified to provide a broad range of services to individuals. I have seen people injured because the Physical Therapist lacks the education and knowledge to provide incident to services. For example, I have seen and experienced caring for patients in which they have been injured by the PT, i.e. The therapist fractured the patient's leg. PT's are not educated in massage or other therapies which have been proven to be of benefit through extensive medical studies. Please do not pass this as it will hurt people in the long run. This would be a very shortsighted decision. Medical care is already severely curtailed by managed care and people are not getting the care they deserve and need. It is no wonder that nurses like myself are leaving the field because of decisions such as this proposed bill.

Thanks for your help!

Submitter : Mr. Paul St. John **Date & Time:** 09/23/2004 06:09:36

Organization : St. John-Clark Pain Treatment Center

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you not to 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. Physical therapy is one of the greatest forms of preventive healthcare available and should be looked at before medicinal treatments are administered.

CMS-1429-P-3351

Submitter : Lisa Gutierrez **Date & Time:** 09/23/2004 06:09:51

Organization : Lisa Gutierrez

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Six months ago, I was in a head on collision on the interstate. I suffered soft tissue and muscle damage. Thankfully, my chiropractor sent me to a massage therapist. I don't know how I would have made it through the pain and healing process without massage therapy. It would be a terrible mistake to pass this policy. A physician should be able to decide the method of treatment for each individual patient based on the patient's injuries.

Submitter : Dr. John Dsurney **Date & Time:** 09/23/2004 06:09:16

Organization : Dr. John Dsurney

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

DIAGNOSTIC PSYCHOLOGICAL TESTS

I am in favor of the change to permit psychologist to supervise technicians performing psychological test. For one, psychologist are better qualified to use these test and many physicians may have had no training at all in the use of these test. Hence, it only makes sense to have those most qualified to use the tests provide supervision of those administering them.

CMS-1429-P-3353

Submitter : Hallie Sawyers **Date & Time:** 09/23/2004 06:09:22

Organization : Soul Song

Category : Health Care Professional or 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-3354

Submitter : Ms. Emily Skarzenski **Date & Time:** 09/23/2004 06:09:07

Organization : Ms. Emily Skarzenski

Category : Other Health Care Provider

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

Submitter : Mrs. Catherine Omstead **Date & Time:** 09/23/2004 06:09:39

Organization : Mrs. Catherine Omstead

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am an LPTA and LMT. I worked in a geriatric facility using both MT and PT therapy. PT's do not have time to do extensive massages. People would not get the massage necessary because of that lack of time. MT and PT are complementary. MT should not be isolated to PT Depts. MT during a PT session is costly @ $100+/hr.

Submitter : Ms. Laura Roberge **Date & Time:** 09/23/2004 06:09:29

Organization : Ms. Laura Roberge

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please, do not pass this policy where 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. If this is passed, it will limit the choices of the physician and will not allow the physician to make choices based on what's best for the patient.

Submitter : Ms. Cyndi Kettmann **Date & Time:** 09/23/2004 06:09:14

Organization : Sutter Health

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Sutter Health Comments File Code CMS-1429-P, RE: GPCI

CMS-1429-P-3357-Attach-1.doc

September 22, 2004

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

File Code CMS-1429-P, Re: GPCI

To Whom It May Concern:

We appreciate the opportunity to comment on the referenced proposed rule dealing with physician payment localities. Because Sutter Health serves more than twenty Northern California counties and has care centers in more than 100 communities, we feel we are in a unique situation to provide insights into the practical impact of the Medicare Physician Fee Schedule.

Sutter Health has long advocated for fair and adequate reimbursement for physicians and has been particularly troubled by a flaw in the physician fee schedule that unfairly impacts physicians practicing in certain areas. The problem stems from the methodology used in 1997 to create new payment "localities." Under the physician fee schedule each locality has a unique geographic adjustment factor that reflects the relative resource costs difference among all localities. This factor is applied to the base rate to determine the adjusted rate to be paid to physicians in the respective locality.

The 1997 methodology established unique localities with costs that were at least 5 percent higher than the combined average cots of all lower-cost localities in the state. The rest of the localities, i.e. those with cost equal to or less than the 5 percent threshold, within the state were combined into a single "rest-of-state" locality because, it was assumed, their costs were relatively homogenous. These rest-of-state localities are called "Locality 99."

We believe the major flaw in this methodology is that Medicare did not start in 1997 by looking at the relative costs difference of each county, instead it used the localities established in 1967 for Medicare's reasonable charge based physician payment system. The current localities in all states were established under the 5 percent threshold noted above by comparing the then existing locality costs—not by comparing individual county costs. The result is, at least in California, that the state's Locality 99 includes at least ten counties with cost differences exceeding 5 percent.

We appreciate that CMS requested public comment in August 2003 on the status of physician payment localities. Furthermore, we appreciate that CMS recognizes our ongoing concerns in California that the existing physician payment localities in our state fail to adequately adjust for the considerable variations in practices expenses in this state. However, we are concerned that CMS has yet been able to find an adequate solution as it indicated in November of 2003, when CMS responded that the physician payment localities would "necessitate further review and study." A solution was again delayed most recently in August of 2004, as CMS stated in a proposed rule: "we have not yet been able to come up with a policy and criteria that would satisfactorily apply to all situations."

While we certainly appreciate that it will be difficult to provide a solution that will be satisfactory for all situations, this flaw in the methodology will only exacerbate an already dire situation. We wish to call to your attention that the problem, while severe in 2004, will become desperate in 2005 and 2006 under your proposed rule.

First and foremost, the economic trends in California contrast significantly to what has occurred in other smaller, more homogeneous states. California's 58 counties have demonstrated, since 1999, considerable polarization of geographic adjustment factors (GAFs) that is unique nationally. These unique trends call for an immediate remedy distinctly tailored to the problem in this state.

In addition, the proposed published GAFs for 2005 for California's current localities show two important trends: a rapid relative inflation of GAF values for many Bay Area counties, and a comparable increase in costs in two Bay Area counties currently assigned to California Locality 99, Santa Cruz and Sonoma counties. The central valley of California is seeing similar trends. Payment boundaries across county lines are important factors to be considered as new payment rules are proposed. We are concerned that two of our communities will experience the greatest payment boundaries in the nation: Sonoma County (payment boundary of 14%) and Santa Cruz County (payment boundary of 25.1%).

Clearly, without some immediate action, the payment disparities amongst California physicians will continue to escalate. We strongly urge that CMS act now to establish new payment localities within California where payment mismatches and boundary payment discrepancies demand such corrective action. **CMS should act now to establish new payment localities for any county within Locality 99 whose individual county GAF is greater than the proposed GAF for Locality 99. This would re-designate ten California counties into their own payment localities: Santa Cruz, Sonoma, Monterey, San Diego, Santa Barbara, Sacramento, El Dorado, Placer, San Luis Obispo, and San Joaquin.** A national policy may follow from this locality revision.

We understand the difficulties involved with the constraints of budget neutrality if CMS were to designate these ten counties into their own payment localities. However, we believe the impact

on the remaining Locality 99 counties could be distributed in such a way so as to preserve budget neutrality for California and ensure that the proposed (rural) Locality 99 counties would be held harmless (held at their 2004 payment values).

In addition we recognize and support the unique role that state medical societies play in crafting a reasonable and equitable solution to the physician payment schedule, particularly as it impacts multi-locality states. We have worked closely with our colleagues at the California Medical Association on this effort and understand that the state medical society continues to be committed to working with CMS to establish a long-range policy acceptable to California's physicians. While we support overall policy reform, we hope that an equitable interim solution could be developed prior to January 1, 2005. Consequently, we strongly urge corrective action and a revision of your proposed rule at this time that could address those physicians' needs, and Medicare beneficiaries access, in the referenced counties most dramatically impacted.

Thank you for providing us the opportunity to comment on this important issue.

Sincerely,

Cyndi Kettmann
Senior Vice President, Public Affairs
Sutter Health
2200 River Plaza Drive
Sacramento, CA 95833
916-286-6706 – office
916-286-8107 – fax
kettmaca@sutterhealth.org

CMS-1429-P-3358

Submitter : Ms. Kathleen Coleman **Date & Time:** 09/23/2004 06:09:04

Organization : VT. School of Professional Massage

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am opposing Medicare's proposed policy to eliminate any provider except PT's from providing incident to medical professionals services to physical therapists. Massage therapists are trained specifically to do massage and bodywork. If this is passed, many people will not be able to get the treatment they need. Massage therapists provide an important service in society. As many people as possible should be able to use this service. Massage therapists are professionals. They are trained, and very capable. They have helped many, many people.

Submitter : Mrs. Valarie Thompson **Date & Time:** 09/23/2004 06:09:28

Organization : The Point

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

See Attached File

CMS-1429-P-3359-Attach-1.doc

Valarie Thompson, ATC

5811 Zinfandel St

Greeley, CO 80634

September 23, 2004

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

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing 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,

Valarie Thompson, ATC
5811 Zinfandel St
Greeley, CO 80634

Submitter : Ms. Cecilia Menguito **Date & Time:** 09/23/2004 06:09:50

Organization : Dubuis Hospital of Beaumont/ Port Arthur

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 23, 2004

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

Dear Sir:

My name is Cecilia A. Menguito, P.T. I am a licensed Physical Therapist from the great state of Texas. I am sending this letter in response to the August 5 proposed rule on ?Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.?

I strongly support CMS? proposed requirement that physical therapist working in physician?s offices be graduates of accredited professional physical therapist programs. Physical therapists and physical therapist assistants under the supervision of physical therapists are the only qualified practitioners who have the education and training to provide physical therapy services. As such, unqualified personnel should not be furnishing physical therapy services. It will be a big disservice and harmful to the patients/clients who, in good faith, believe that they are receiving physical therapy.

Thank you very much for your time and consideration.

Sincerely,

Cecilia A. Menguito. PT
Texas License# 1041515
Dubuis Hospital of Beaumont/Port Arthur
2830 Calder Ave. 4th Floor
Beaumont, TX 77702

Submitter : Sherry Wilner **Date & Time:** 09/23/2004 06:09:54

Organization : AMTA and state of Hawaii

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do not limit of "incident to" payment or assignment to physical therapy only. There are many situations/patients who need massage therapy as well - in some cases instead of physical therapy..... Under a physician's care or recommendation, massage therapy should be a modality that is allowable.

CMS-1429-P-3362

Submitter : Ms. Brianne Booth **Date & Time:** 09/23/2004 06:09:14

Organization : Student Physical Therapy Assisting Club, Tri-C

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

I think it is a great idea to change billing practices in physicians offices concerning Physical Therapy. As a 2cnd year Physical Therapist Assist Student at Cuyahoga Community College, I have learned the knowledge it takes to perform therapy services. Despite other medical personnel having qualified training in their field, they do not have a degree to practice therapy services. To bill for physical therapy is wrong, when it is not performed by a properly trained therapist or therapist assistant. Not only do they not have the qualification to perform treatment, but they are giving patients an impression of what physical therapy is. Since the physician is not formerly trained in therapy services, patients are not getting the full picture of what therapy is. Patients might get a negative opinion of physical therapy, because the person claiming to do therapy is not qualified. Please help keep not only our patients safe from injury from untrained medical personnel, but help keep the reputation of all Physical Therapists, and Physical Therapist assistants intacked.
Thank you,
Brianne Booth

Submitter : Albert Kozar **Date & Time:** 09/23/2004 06:09:28

Organization : Albert Kozar

Category : Physician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dear Dr. Mark McClellan,

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

I am writing this letter to outline my concerns to you regarding the recent proposal by Medicare to limit the Certified Athletic Trainers ability to work under a supervised physician delivering health care to the American population. These changes that will limit their scope of practice will have detrimental effects on the public's ability to access and receive quality health care from an ATC who specializes in the treatment, rehabilitation, and care of the physically active population.

As a primary care physician who specializes in sports medicine, I have worked with a large number of ATC's in high school setting, college setting, professional sports setting, and in private practice. I have found ATC's to be just as qualified, and sometimes even better qualified, then physical therapists and physical therapy assistants to handle rehabilitation of various injuries and chronic pain states. From my personal experience having had ATC's as part of my private practice health care team, one of my best rehabilitation staff has been an ATC.

Besides my private practice, I routinely refer patients for rehabilitation of both sports and chronic pain issues to private physical therapy centers that use ATC's who provide excellent care. In a number of these instances I specifically refer the patient to the ATC.

The ability of a physical therapist or ATC primarily depends on their training and experiences. A well-trained ATC is just as good as a well-trained physical therapist.

In addition, I find it disturbing that Medicare wishes to limit the scope of practice of ATC's, from what the government has already outlined as very qualified. The Department of Labor via Specific Vocational Preparation (SVP) ratings, rates ATC's as 8+ which is higher than that of occupational therapist (7 to <8), and occupational therapy and physical therapy assistants (4). The Medicare proposal is not limiting occupational therapists and/or occupational and physical therapy assistants.

I hope that the full breadth and affect of such a policy change will be realized by those pushing this proposal. I strongly feel that this will have a large detrimental effect on the availability and application of good rehabilitation to the American population.

Thank you for considering these thoughts. For any questions I can be contacted.

Albert J Kozar, DO
Team Physician ? University of Hartford
Valley Sports Physicians & Orthopedic Medicine, Inc
54 West Avon Road, Avon, CT 06026
860-675-0375; (f) 675-0358
akozar@jockdoctors.com

Submitter : Mrs. Celia Pienkosz **Date & Time:** 09/23/2004 06:09:47

Organization : Munson Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Celia Pienkosz
5239 Liberty Drive
Traverse City, MI 49684

Sept. 22, 2004

Centers for Medicare & Medicaid Services
Dept. of Health & Human Services
Attn: CMS-1429-P

Re: Therapy - Incident To

Dear Sir/Madam:

I have been in the field of Athletic Training for 18 years, including my schooling. I have helped thousands of people in their quest to be healthy and live a healthier lifestyle. Is this not our goal for the future? Is this not our goal for our young and old generations that we service? To create a law that will prevent the Certified Athletic Trainer from doing what we do best is to say the least extremely upsetting. We have filled a void and filled it for so many years that you won't realize the loss until it occurs and then it will be too late. I would like to continue to do my job and do it to the very best of my abilities without having to worry about whether I will have this job next year. If you look further in your search for the truth you will find that the Certified Athletic Trainer is an extremely qualified individual with a vast array of experience and the skills necessary to do the job that you are questionning.

Don't you think that the health care community has more important issues to deal with than if qualified health care professionals should be treating patients that we have been treating amazingly well for decades. These changes that CMS wishes to make are truly distressing to the whole field of Athletic Training and will be to our patient population as well.
Please listen to our voices. Let us do our jobs and do it well.

Yours in Health,

Celia Pienkosz A.T.,C.

CMS-1429-P-3365

Submitter : Mrs. Tracey Mooney Joan Rogers **Date & Time:** 09/23/2004 06:09:01

Organization : Independent Dialysis Foundation

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

Issues 10-19

SECTION 623

Please read the attached document from this small chain of non-profit dialysis facilities

CMS-1429-P-3365-Attach-1.doc

September 23, 2004

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

To Whom It May Concern:

Independent Dialysis Foundation is a small chain of non-profit dialysis facilities located in Maryland. We have been in business since 1978 and our only mission is to care for those who suffer with End Stage Renal Disease. We wish to comment on the impact of the changes in reimbursement that will occur as detailed in the document CMS-1429-P.

Adequate Medicare reimbursement is critical to our dialysis facilities because it provides coverage for 90% of our patients. Our costs have been rising due to inflation, severe nursing shortages and new more costly technologies and medications. At the same time, our patient population is growing older and has more complex medical problems that we must treat. We are facing the most difficult fiscal crisis ever. We are the main provider to the University of Maryland and serve a highly indigent population. Because we are not for profit our struggles are much greater in our urban settings where the population is its poorest. Increased reimbursement is necessary for our survival.

The Medicare Modernization Act calls for changes to drug reimbursement that sets reimbursement from Medicare at Average Selling Price minus 3%. The Average Selling Price as obtained by the OIG appears to be the most rock bottom pricing that could be found in their analysis. The OIG and CMS both recognize that independent facilities have not been able to purchase ESRD drugs at ASP minus 3 percent; the OIG found that these facilities paid 3 to 19 percent more than the ASP reported to the OIG. ASP minus 3 percent would be a particular hardship on independent facilities. A policy that sets reimbursement at ASP minus 3 percent must be rejected because it does not represent acquisition cost for these facilities. Even if providers were consistently gaining access to such pricing, why would a business choose to participate in a program that tells us to buy the drugs and we will pay you 3% less than what you paid. CMS has recommended that the small provider, like us, band together in cooperative arrangements with other like providers to gain some of these economies that are enjoyed by the larger chains. As a professional in this industry that has long suffered with inadequate reimbursement we have always participated in such coops. My entity runs a very lean, no frills shop. We have always operated in a thrifty manner and have typically gained access to the best pricing available. We never had a choice, since we have been under funded for years. We don't have excess expenses that can be cut to make up for Medicare under reimbursing drugs. This ASP –3% is being passed on to all Medicare Providers, but Medicare much more heavily funds Renal Providers. Hospitals and Nursing Homes for example can make up their losses on Medicare patients with increased payer mixes from commercial insurance patients. Facilities that I operate seldom see many patients with commercial coverage. By virtue of their disease many patients that have commercial

coverage lose it during the early stages of their kidney failure when they don't continue to work.

While we recognize that CMS has taken some of this into consideration by adding-on to the composite rate to offset the differences in the drug payments, this add on is not enough and will be extremely fatal to providers that take care of patients that have the greater needs for the various costly drugs. Patients could then be forced to switch to less-effective therapies simply because they are considered less costly. The Proposed Rule could ultimately force rural and independent facilities to close. Our projections are devastating.

We understand that the ASP-3% pricing will be implemented in January 2005 and we urge CMS to implement more equitable pricing for independent facilities.

The implementation of a case mixed methodology to the composite rate that will be made effective 4/1/05 is also very frightening to us as a small independent chain. This proposal indicates that CMS's "expected impact of the patient characteristic adjustments on ESRD facility payments will, for the most part, be minimal." This is CMS's rationale for delaying such methodology. If the impact is minimal, what is the point in taking a single rate system and implementing what will now be tiered with a combination of ages and diagnoses to roughly 24 different rates? The complexity of this change alone will result in added burdens to providers to implement said changes. The proposal in no way indicates how this would be carried out. The case mix methodology is also flawed because it reduces payments for patients that are in certain age ranges to less than today's current reimbursement. There is no way for providers to sustain such impacts. This will be especially damaging to facilities that provide care to populations that are dominated by these age groups. Again this could cause many facilities to close particularly in Nursing Homes that have more of this age category in their population.

We urge CMS to abandon the Case Mix Methodology and work towards more equitable measures for facilities to be reimbursed. The reality is that even with perceived increases from these changes, we still aren't being paid enough to cover the true cost of care. We are running out of options to offset the inequities in the Medicare reimbursements system. We urge you not to make if worse.

We welcome any further opportunity to comment. Since our clinics are close to CMS we invite you to visit to discuss first hand these matters.

Sincerely,

Tracey Mooney, CPA
Chief Financial Officer

Joan Rogers, RN
Director of Operations

CMS-1429-P-3366

Submitter : Mrs. Dorothy D. Leon **Date & Time:** 09/23/2004 06:09:45

Organization : American Massage Therapy Association

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am opposed to ONLY physical Therapists being allowed to a physician referring to 'incident to' services. ALL qualified health care proiders should be allowed to provide services to patients with a physicians prescription or under their supervision.
This is WRONG. Who was at the Pentagon and At NYC Ground Zero to assist the rescue workers? It was Massage Therapists..NOT Physical Therapists. Just ask ANYONE...FBI, Military, Transportation Dept,
Task force on Terror, etc, etc. How was THAT for them? Don't prevent the patients from that benefit. We have documented proof from research that Massage reduces pain, stress and promotes well being. Don't do it!!!
Darlene Leon, RN, CMT

THERAPY STANDARDS AND REQUIREMENTS

Each state has their standards for number of hours that a person
goes to massage school. Mine was 500hrs and I have since added
many many courses. I'm going in Nov. for a 4 day workshop in Lymphatic drainage. Physical therapists don't have that expertise.

Submitter : **Date & Time:** 09/23/2004 06:09:19

Organization :

Category : Physician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Physical Therapist are only one of the licensed and capable persons to do incident to thereapy. I oppose limiting it to physical therapists only.

CMS-1429-P-3368

Submitter : Mr. paul carter **Date & Time:** 09/23/2004 06:09:47

Organization : Mr. paul carter

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

please see attachment

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

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CMS-1429-P-3369

Submitter : Nancy Casella **Date & Time:** 09/23/2004 06:09:21

Organization : American Massage Therapy Association

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I beg you to please 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 physician's prescription or under their supervision. Thank you.

Submitter : Miss. Megan Mock **Date & Time:** 09/23/2004 06:09:20

Organization : Miss. Megan Mock

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attachment

Department of Health and Human Services
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Submitter : Mr. Donald Wendt **Date & Time:** 09/23/2004 06:09:50

Organization : Decatur Memorial Hospital

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

To Whom It May Concern:
I would like for you to reconsider the proposal related to the 'therapy-incident to' services because of the negative ramifications it would have upon society's quality of healthcare. As a practicing Certified Athletic Trainer of seven years, I have gained respect from MD's, PT's, and PTA's as a qualified allied health professional that effectively cares for the health of patients. Certified Athletic Trainers are highly skilled allied health professionals that should be recognized as competent in performing these services as indicated. Medical patients should have the opportunity to be treated by the professional most suited to address the condition. I appreciate your reconsideration regarding this matter as it is in the best interest of the care of society.

Sincerely,
Donald Wendt, MS, ATC/L

Submitter : Ms. kris knox **Date & Time:** 09/23/2004 06:09:13

Organization : nata

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

9/20/04

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 !V 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:
?h 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.
?h 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.
?h 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.
?h 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.
?h

On a personal note: I work with several PT!|s, OT!|s, PTA!|s in a clinical setting. They have never told me that I am qualified or properly trained. I do several inservices on rehabilitation, mobs, isokinetic testing. The clinic I work in has adopted my patella-femoral protocol with overwhelming success. I am currently doing 3 research studies involving balance with the geriatric population. I really feel it would be a shame to my patients if I would not be able to use my education to it fullest.

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,

Kris Knox, MS, ATC/L
1205 George Rock Dr.

Farmer City, IL 61842

CMS-1429-P-3373

Submitter : Mr. Matthew Koschnitzky **Date & Time:** 09/23/2004 06:09:19

Organization : Trinity Intl' University Athletic Training

Category : Academic

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

To Whom It May Concern:

As a future certified athletic trainer, I am compelled to oppose the CMS-1429-P proposal. Following through with this proposal would not only be detrimental to patients who need to receive quality care, but also to the unique and diverse AMA allied health care profession of Athletic Training.

Athletic Training is a growing field and essential resource to the physically active. This profession specializes in prevention, assessment, treatment and rehabilitation of injuries to all those involved in daily physical activities. Utilizing the athletic trainer to serve in this particular population has been adapted by physicians, hospitals, and clinics, including physical therapy clinics. Other professionals are recognizing the need for specialists in the realm of the physically active. The certified athletic trainer is a highly educated and qualified professional whose special role in patient care should not be hindered, but rather given an opportunity to thrive.

Should the proposal at hand pass, many jobs of certified athletic trainers would be threatened and many athletes would not receive the immediate and specialized care they will be so desperately in need of and rightfully deserve. CMS-1429-P is unnecessary and a clear step in the wrong direction of the health care profession as a whole.

Sincerely,
Matthew Koschnitzky
Athletic Training Student
Trinity Intl? University
Chicago, IL

CMS-1429-P-3374

Submitter : Mr. Don Mohle' **Date & Time:** 09/23/2004 06:09:14

Organization : Mr. Don Mohle'

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I have been made aware that CMS has misclassified Santa Cruz County, California, as "rural" based on an outdated map drawn in 1967. This classification MUST be revised immediately to "urban" in order to provide Santa Cruz County with adequately reimbursed medical care.
Santa Cruz county abuts Santa Clara County ("Silicon Valley") and contains considerable high-tech and other business, and has currently one of the highest median home prices in the country ($630,000). Such home values do not describe a "rural" area, and indeed indicate that medical practitioners here face living expense comparable to New York City, San Francisco, and Washington, D.C.
Any perpetuation of this obsolete and inaccurate "rural" designation will serve only to limit the availability of medical care in Santa Cruz County.
I urge CMS to rectify this long-standing wrong by immediately revising Santa Cruz County's status to "urban".

CMS-1429-P-3374-Attach-1.pdf

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

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Submitter : Mr. Jason Dyer **Date & Time:** 09/23/2004 06:09:00

Organization : Mr. Jason Dyer

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

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

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CMS-1429-P-3376

Submitter : Mr. David Graeff **Date & Time:** 09/23/2004 06:09:00

Organization : Mr. David Graeff

Category : Academic

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dear Sir/Madam:

I am writing this letter in response to the proposal that is recommending a change to Medicare regulations that would no longer allow physicians to be reimbursed for therapy services administered by a certified athletic trainer in a physician's office. If this proposal is passed then this would have a negative impact on the health care profession.

While deciding this proposal, please take the following points into consideration:

- Certified Athletic Trainers are a valued member of the health care professional team. Our job consists of prevention and care of acute and chronic injuries. Rehabilitation plays a major role in caring for our athletes and helping them to have a speedy and sufficient recovery. Although our job description is not solely rehabilitation, it is a crucial aspect of caring for the athlete. Therefore, the NATA exam tests an individual in their proficiency of proper and current rehabilitation techniques before allowing them to be certified.

- Athletic trainers have an advantage over other health professions in that we have experience in many different job environments. Athletic trainers are found in high school and college institutions, corporate companies, physical therapy clinics, and professional sports teams. Therefore, we have the knowledge and experience to deal with all different types of injuries and people of all ages. This is what makes the athletic trainer a very holistic member of the medical team.

- The education required for an individual to become an ATC is very similar to a that of a physical or occupational therapist if not more intense. According to the federal government, the preparation that an athletic trainer undergoes is rated as equivalent if not more intense than that of a PT, PTA, OT, and OTA. Before becoming certified, the athletic trainer must complete courses such as: Prevention and Care of Athletic Injuries, Anatomy and Physiology, Structural Kinesiology, Evaluation and Assessment, Modalities, and Rehabilitation Techniques. Also, ATCs are required to complete a certain amount of CEUs in order to stay certified. This helps ATCs stay up to date with new techniques in the health care industry.

In closing, if it is the desire of CMS to provide quality health care for individuals, then it is advantageous to employ a certified athletic trainer in physical therapy clinics and physician's offices. Athletic trainers are equally educated and have experience with several different environments and the injuries typical to that setting. It would be in the best interest of CMS and the patient to refute this proposal.

Sincerely,

David Graeff
2001 Alford Park Drive
Kenosha, WI 53140
Box 471

CMS-1429-P-3377

Submitter : **Date & Time:** 09/23/2004 06:09:16

Organization :

Category : Academic

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

As a student in a 6 year Masters PT program I am much in favor of the 'Therapy incident to' revisions for several reasons. These revisions will help preserve the integrity of the PT profession. To become a PT it is mandatory that one have a masters degree as well as a license to practice. The level of schooling required is extensive in the physical function of the human body and understanding normal/ pathological conditions. Allowing non-PT medical staff to practice and bill as PT is a disservice to the patient first and foremost, and to the general medical community as well.

PT's are highly trained professionals who are able to effectively evaluate, and treat patients with a variety of diagnoses. When non-PT's with insufficient information and education begin administering treatments there is poor regulation of treatment efficacy and cost-efficiency. This will lead to poor timely treatment of a certain condition which will increase healthcare cost due to poor PT care. The increase cost from poor PT interventions provided by a non-PT will also decrease individual therapy benefits under the $1500 Medicare cap. Non-PT's do not have the training to determine the best, most cost effective treatment. This could be detrimental to the care of a patient with ongoing therapy goals and needs. The revisions will also help maintain a certain level of care across the board.

Thank you for consideration of my comments, and I hope they help you to make a sound decision.

Submitter : Miss. Megan Mock **Date & Time:** 09/23/2004 06:09:59

Organization : Miss. Megan Mock

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attachment.

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

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Submitter : Dr. **Date & Time:** 09/23/2004 06:09:00

Organization : Dr.

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I strongly urge you to pass the incident to law as this will protect the public from potential harm by untrained and uneducated personell. Additionally this will reduce the abuse by medical physicians from performing unskilled and over perscribed therapies.

Submitter : Mrs. Kara England **Date & Time:** 09/23/2004 06:09:36

Organization : AMTA

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 prescriptions or under their supervision

Submitter : Anne Gallagher **Date & Time:** 09/23/2004 06:09:32

Organization : The Vernont School of Professional Massage

Category : Academic

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Re: Proposed Medicare & Therapist Policy
Without having read the Medicare & Therapist Policy, but having knowledge of its exclusion of Massage Therapists as instrumental to doctors in treatment of patients, I offer these comments. I disagree strongly with the policy's non-inclusion of Massage Therapists as key players in the health profession. I fail to understand your logic for excluding Massage Therapists as credible contributors. Please reconsider the policy language before putting it into practice. There is much room for both the Physical Therapists and the Massage Therapists in the health profession.

Thank you.

CMS-1429-P-3382

Submitter : Ms. Yamil Sarabia **Date & Time:** 09/23/2004 07:09:12

Organization : Healthy Living Therapeutics, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We are urging you to NOT PASS this policy whereby a physician can only refer 'incidents to' services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription. I'm beginning to think that the Chiropract and physician community are taken aback at how many people are choosing massage therapy and they want to grab hold of the market to their financial advantage. They are forgetting thier oath and obligation to maintain the wellbeing of society. Massage therapy is older than 6,000 years and it is still around becuase it works! No health care provider can provide better care to a patient in regard to massage therapy other than a therapist who specializes in this field and has recieved exclusive education in it. Speaking analogously, no physician can provide better care to a patient with heart problems than a Cardiologist. Physical therapy is it's own specialty and massage therapy another. Thank you.

Yamil Sarabia, LMT, EMT-CC

CMS-1429-P-3383

Submitter : Mr. John Coster **Date & Time:** 09/23/2004 06:09:53

Organization : National Association of Chain Drug Stores

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

Please accept the attached documents for comments on CMS-1429-P on behalf of the National Association of Chain Drug Stores (NACDS).

CMS-1429-P-3383-Attach-2.doc

CMS-1429-P-3383-Attach-1.doc

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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:

The National Association of Chain Drug Stores (NACDS) is writing to respond to the proposed rule published August 5, 2004 that would make certain changes in payment to pharmacies under Medicare Part B for covered drugs and DME, and change some of the requirements regarding the processing of prescription for these drugs.

NACDS represents more than 200 chain pharmacy companies operating almost 32,000 community retail pharmacies. Our industry is the primary provider of outpatient pharmacy services in the United States, providing about 70 percent of all retail prescriptions. We are also providers of Medicare Part B drugs to Medicare beneficiaries.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

Section 302 – Clinical Conditions for Coverage of DME

This section of the proposed regulation would create new standards for coverage of DMEPOS, including drugs and supplies. Because many of our member companies operate in multiple states, we would prefer that conditions for clinical coverage for DMEPOS items, such as national prescription renewal requirements, be made nationally and simply administered through the DMERCs. This will reduce the level of variability among DMERCS, and allow for uniform procedures among multi-state providers, reducing their costs of participation. Suppliers must also rely on the prescription or order as evidence that the physician has complied with all the requirements relating to satisfying the conditions for ordering these products. Suppliers, such as pharmacies, cannot be expected to verify that the physician has in fact performed a face to face examination for the for the purpose of treating and evaluating the patient's medical condition, or whether the physician has created appropriate documents in his records.

NACDS encourages CMS to eliminate the required insulin dependency code on prescriptions for covered diabetic supplies, such as test strips. Obtaining this code creates a significant amount of additional documentation and administrative issues for pharmacies in providing these products. No other third party payer requires such a code on their prescriptions for these supplies. We believe that the pharmacist can calculate the appropriate amount of product to be dispensed based on the physician's testing directions.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

Section 303 – Payment Reform for Covered Outpatient Drugs and Biologicals

NACDS is providing extensive comments on this section, given that this is the part of the proposed regulation that will have the most significant impact on community retail pharmacies. The use of ASP to determine pharmaceutical reimbursement under Medicare Part B, rather than Average Wholesale Price (AWP), will have a significant impact on community retail pharmacies. This will be further magnified and multiplied if other public and private prescription drug programs such as the Medicare outpatient drug benefit, Medicaid, private PBMs, insurance companies, DOD's TriCare program, and the FEHBP program, use ASP rather than their current reimbursement system.

We strongly urge that CMS use its regulatory discretion, as well as the discretion provided to it under the Medicare Modernization Act (MMA), to set Part B reimbursement rates to assure that retail pharmacy providers can recoup all their costs in acquiring and managing a Part B pharmaceutical inventory, as well as provide for adequate return on investment in this expensive inventory.

Average Sales Price (ASP) Methodology

NACDS continues to be concerned about the use of the ASP methodology to reimburse pharmacies for Part B drugs, and the potential lack of certainty in the reimbursement amounts that will be paid to pharmacies for these drugs, many of which are too expensive. NACDS is concerned about the impact of the ASP reimbursement methodology on a retail pharmacy's ability to provide Part B pharmacy services to Medicare beneficiaries. ASP is an inappropriate reimbursement metric for many reasons. For example:

ASP Represents Manufacturer's Revenues, Not Purchasing Costs: Any changes to the Medicare Part B payment system must ensure that pharmacies receive reasonable and adequate compensation for the costs of obtaining and managing an inventory of pharmaceuticals provided under Medicare Part B. This amount should include payment for direct costs of purchasing the product as well as the costs of obtaining the product from the manufacturer through the wholesaler. Indirect costs of obtaining and distributing the product, such as storage, transportation, costs of inventory, and overhead must also be compensated. CMS must recognize that purchasing costly pharmaceutical inventory is an investment made by a pharmacy for which appropriate compensation and return for making this investment must be provided.

However, ASP represents net revenues to the manufacturer for the quarterly sales of a particular drug, and has no relation to the pharmacy's cost of purchasing and storing the pharmaceutical, which includes costs relating to complying with Federal and state regulations. In fact, ASP ignores the costs added by other components of the pharmaceutical distribution system. For example, ASP does not account for the fact that pharmacies have to purchase drugs through wholesalers, which add costs on to the ASP, and are passed through to pharmacies. Because CMS is not collecting data from wholesalers, it cannot calculate the mark-up that wholesalers add to the ultimate cost that they charge the providers, including pharmacies. As a result, a significant part of the six percent mark-up that pharmacies are allowed to add onto the ASP is eroded by the costs added by wholesalers.

ASP is not Determined in "Real-Time" and Will Be Outdated: Each quarter's ASP value will be calculated with data from the second previous quarter's data. For example, the value of the ASP for the first quarter of 2005 will be based on data from the third quarter of 2004. As a result, the value of ASP will also be up to six months outdated, ignoring the fact that manufacturer's price increases may have occurred on these drugs during that time. This means that purchasers, such as retail pharmacies, will have to absorb these manufacturers' price increases because ASP will always lag behind. This further erodes the value of the six percent add on over ASP. To mitigate this problem, CMS should allow for an inflation factor on top of the six percent amount allowed under the statute. This will at least assure that some of the value of the six percent add on will not be eroded through manufacturer price inflation.

ASP Ignores Important "Class of Trade" Realities: Given the wide differences in prices charged by manufacturers to various purchasers – resulting from "class of trade" pricing – an add on of six percent to the ASP for a drug will not likely allow a retail pharmacy provider to recoup its purchasing costs for the drug. In fact, given the combination of the lack of accounting for the wholesaler's mark-up, the outdated data used to calculate ASP, and the class of trade pricing inequalities, it is highly unlikely that retail pharmacies will be able to recoup their costs of purchasing Part B drugs.

ASP assumes that all purchasers in the pharmaceutical market buy drugs at similar prices. This is simply not the case, given all the classes of trade in the marketplace. Retail pharmacies are generally charged higher prices than other pharmaceutical purchasers, which include hospitals, managed care plans, and other closed-door pharmacies. Thus, the use of ASP would drive down the reimbursement to a point that might be well below a retail pharmacy's purchasing price. An ASP cannot be calculated across purchasers, it must be calculated across each class of trade.

Even the Federal Medicaid rebate law as enacted in OBRA 90 recognizes that there are different classes of pharmaceutical trade because it established a separate retail-based metric to serve as the basis for the rebates that manufacturers pay to states – the average manufacturers price, or AMP. AMP is defined as the average price paid to manufacturers by wholesalers for drugs distributed to the retail class of trade. The original drafters of OBRA recognized that basing the rebate on a simple average across all purchasers (i.e., like an ASP) would reduce the amount of rebates that would be paid to states, and not reflect the actual net costs paid by the state for drug products. That is because the retail class of trade pays higher prices than other pharmaceutical purchasers.

Depending upon the prices charged to the various purchasers, and the distribution of these purchasers in the marketplace, the addition of six percent to the ASP may not make pharmacy whole just for acquiring the drug. Additionally, the costs of storing, inventory, warehousing, and distribution of the drug would not be covered by this reimbursement. This would force participating pharmacies to provide these products at a loss, and create access problems for Medicare beneficiaries. At a minimum, ASP should be established for each class of purchaser, including retail pharmacies.

ASP Ignores Variability of Discounting and Could Eliminates Prudent Purchasing: The interim final rule contemplates reducing ASP by the value of certain purchasing incentives (called transactions in the interim final rule) that are frankly more appropriately retained by the purchaser. These should not be captured by the Medicare program through a reduction in ASP. 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 incentives for prudent buying if the Medicare program is signaling to providers that it will pay the costs of drugs, rather than allowing some purchasing incentives to remain in the system.

Discounts, rebates and other price concessions are not available for all purchasers to earn on an equal basis. ASP ignores the fact that not all purchasers have the same access to discounts, nor are all discounts earned by the purchasers themselves. For example:

- Some smaller purchasers may not have access to the same discounts as larger purchasers, creating a disadvantage to smaller purchasers from an ASP-based reimbursement method. Many of these smaller retail pharmacy suppliers are in rural and underserved areas where many Medicare beneficiaries live. This could jeopardize access of these patients to important immunosuppressive and cancer drugs;

- Retail pharmacies (both independent and chain) do not have access to discounts, rebates, or price concessions on brand name drugs that are available to other purchasers (such as hospitals, clinics, and managed care plans.) Thus, retail pharmacies could incur a significant economic loss when dispensing expensive Part B branded drugs;

- Prompt pay discounts given to wholesalers by manufacturers may not ultimately be passed along to the purchaser. However, including the value of these discounts when calculating ASP, as the regulation requires, would not reflect the fact that these discounts were not passed along by the wholesalers to the ultimate purchaser.

- Third party payors, such as pharmacy benefit managers (PBMs) receive some discounts through rebate agreements with manufacturers. These rebates or chargebacks are paid to the third party, not to the purchaser, and are not reflected in lower prices paid by purchasers. Thus, including these rebates and chargebacks when calculating ASP further lowers the rate beyond which even large and prudent purchaser are able to obtain these drugs. It is inappropriate to include these when calculating ASP.

For these reasons, we strongly urge that these types of transactions be excluded from the calculation of ASP, not deducted as the regulation suggests.

ASP Lacks Transparency and Predictability in Pricing: Unlike AWP 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 and whether and how it will change. Nor will they be able to find ASP in a pricing source to know how these ASP rates will impact the Medicare book of business and their overall business. Providers and businesses cannot be expected to make decisions about participation in health care programs without at least some knowledge of current and future reimbursement rates. This ability does not exist under an ASP system. In addition, CMS is given wide latitude to use various metrics for reimbursement purposes, such as ASP, the WAC, the Widely Available Market Price (WAMP), or can substitute another number as determined by the Secretary. CMS cannot expect to providers to participate in a program with this much unpredictability in reimbursement, especially when dealing with very expensive drugs.

CMS has provided no additional guidance in the proposed rule as to how a WAMP will be surveyed or calculated by the OIG, or for which drugs it might be used. The use of the term "widely available" could have several different meanings and several different interpretations. For example, will CMS consider a price to be widely available if 50 percent or more of purchasers can obtain it at or below the WAMP? What if the price is widely available to one class of trade, but not another? Given the lag time involved in survey results, will the WAMP be calculated for the same period or quarter as the ASP?

We believe that any time that CMS uses its authority to substitute another payment rate for the ASP rate - such as an AMP or WAMP based rate - it should only do so after publishing the full methodological results of how it (or the OIG for that matter), arrived at such a WAMP or AMP calculation, and only after a period of public comment. After that, there should be a sufficient time period before which the new rate goes into effect, and it should only last until the next quarter until it can be compared once again to ASP data. The statute may provide little maneuvering room for CMS in implementing these provisions. However, the agency has to mitigate against the possibility that widely fluctuating and unpredictable quarterly payment rates for Part B drugs - many of which are expensive - may lead to fewer providers willing to participate in Medicare Part B, creating access problems for beneficiaries.

ASP Increases Costs by Discouraging Generic Dispensing: An ASP-based reimbursement also discourages generic dispensing and could have the unintended effect of shifting beneficiaries away from generics to more expensive brands. That is because pharmacies have little financial incentive to dispense a generic when it will only be paid the ASP plus six percent. Given that generics are generally less expensive than brands, the pharmacist has an economic incentive to dispense a brand since a greater dollar margin will be earned on the brand rather than the generic.

In conclusion, we caution CMS about the use of an ASP-based reimbursement system in general, and especially as it relates to retail pharmacy. We urge CMS to create a separate payment rate for retail-based drugs that reflect the unique market for these Part B drugs sold to retail pharmacies.

Supplying Fee

We support the establishment of a supplying fee for Part B drugs. This fee was not established by CMS in 2004 as required by MMA. We are encouraged that the agency intends to establish a fee for 2005. This fee is required by the MMA for oral immunosuppressive drugs, oral cancer drugs, and oral anti-emetic drugs. The agency needs to publish the exact amount of this supplying fee as part of the final rule, since it was not published in the draft rule.

The agency should also indicate how it intends to update the supplying fee amount. The fee should be updated each year to account for increasing costs to pharmacies for supplying Part B drugs, such as pharmacist salary increases, rent, utilities, computer expenses, and other increasing overhead costs. The agency should publish the updated supplying fee amount for the next year as part of its physician fee schedule rule. We suggest that the fee be update by the average annual increase in the costs of pharmacies supplying these drugs to Medicare beneficiaries, but no less than the increase in the medical care inflation index for the most recent twelve months for which it can be calculated before the next calendar year.

Chain pharmacies will not be in a position to determine whether the proposed $10 supplying fee is an adequate supplying fee, given that they will not know until late 2004 what the actual Medicare reimbursement rates will be for Part B covered drugs. That is because the data from the third quarter of 2004 will be used to calculate the ASP for the first quarter of 2005. Given that manufacturers have 30 days after the end of the quarter to report the data, it is likely that reimbursement rates for 2005 will not be known until December. Pharmacies will then have to assess whether these drug product payment rates, combined with the proposed $10 supplying fee, are sufficient to warrant continued participation in the program.

Even if they do believe that they can financially participate in the program, the level of uncertainty surrounding future Medicare reimbursement rates – even in 2005 – may give some providers pause. Because some of these Part B products are very expensive, and thus have significant inventory carrying costs, a pharmacy will have to determine whether the return on investment is worth providing these drugs. Pharmacies are also concerned that these lower payment rates will make it difficult to provide the quality of pharmacy services that are needed to help beneficiaries use these Part B drug effectively.

In general, NACDS can submit that a $10 supplying fee would appear to be inadequate given recent cost of dispensing surveys that illustrate that the average cost to a retail pharmacy to dispense a prescription ranges anywhere from $7.50-$8.00. This cost of dispensing amount is for average non-Medicaid third party or cash-paying prescriptions, which are usually much less costly to fill than Medicare or Medicaid prescriptions. While many third parties pay less than this to dispense, generally there is enough financial cushion on the product side reimbursement to compensate somewhat for a low dispensing fee.

However, under an ASP-based system, any "product spread" on the Medicare drug side has been eliminated by these new ASP payment rates, and may in fact pay pharmacies less than their acquisition costs for these drugs. Thus, the pharmacy is basically looking at $10 to cover any product costs not covered by an ASP-based reimbursement, the costs of dispensing Medicare prescriptions, which are higher than the average third party prescription, as well as realize some return on investment. Pharmacies will determine whether the significant inventory carrying costs for some of these immunosuppressive drugs are worth the small, if non-existent, return on investment.

Given these facts, a supplying fee of $10 may not be sufficient to cover the costs of enrolling and maintaining supplier status in Medicare, as well as completing the paperwork necessary to process Medicare Part B prescriptions. In essence, Medicare would want to pay $2.00 to $2.50 more per prescription than the cost of filling an average third party prescription when the costs of participating in Medicare are significantly higher. Pharmacy labor costs alone have increased significantly over the past few years, especially pharmacists' salaries. We submit a comprehensive list of costs involved in dispensing the typical prescription.

CMS has asked for comments on whether pharmacies should be paid an additional fee beyond the supplying fee for providing the initial prescriptions of certain types of drugs, such as immunosuppressives. Pharmacies do have additional work to obtain the correct information required by CMS for the first prescription of immunosuppressives, such as diagnosis codes. This assumes that the DIF form will be eliminated in October 2004.

We believe that it would be appropriate to compensate pharmacies a higher supplying fee or an "add on" supplying fee for the additional work and time involved in this initial prescription fill. Some of our members indicate that an initial fee of $50 for an immunosuppressive prescription would be necessary to cover the initial costs of providing these prescriptions.

Some also indicate that any time a beneficiary switches to another provider, there is additional paperwork involved to appropriately obtain all the information necessary to process the prescription and file the Medicare claim. Exceptions should be made to the $10 supplying fee in these exceptional circumstances, even if this is not the original prescription.

Issues Relating to Billing Requirements

NACDS appreciates the attempts by CMS to streamline the paperwork burdens involved in providing prescription services to Medicare beneficiaries. As we have noted, Medicare has more burdensome requirements to process prescriptions than any other third party prescription program. We urge CMS to assure that the agency requires all four DMERCs to make the changes listed in this proposed regulation so that Medicare billing requirements are made uniform throughout the program. This is especially important for multi-state chain pharmacy corporations who may be located in different DMERC regions.

Medicare is one of the few prescription drug benefit programs that still use "batch billing" of medical and prescription claims, rather than online real-time adjudication. This type of system creates various operational and patient care problems for beneficiaries and pharmacy suppliers. For example, many claims are not adjudicated (i.e., paid) the first time they are processed, necessitating subsequent billings by the pharmacy supplier. For this reason, CMS needs to establish an efficient, online real-time system for adjudicating Part B prescription drug claims. This system would support, among other functions, online eligibility checking, determination of plan enrollment status of beneficiaries (i.e. whether they are in FFS Medicare or are a member of a Medicare Advantage plan), and adjudication of prescription claims. The lack of an online system often results in more frequent Medicare claim rejects, the need for resubmission of claims, and coordination of benefits issues that significantly increases costs and requires more manual involvement in claims submission.

The lack of an online system also creates potential patient care problems because the pharmacist is not able to access a more comprehensive medication history of the patient to perform important patient safety checks. That is because the DMERC databases and the pharmacy databases do not have interconnectivity. These patient safety checks include detecting important potentially serious drug interactions. This is important given that individuals taking Part B drugs are likely to be chronically ill individuals taking a number of different medications that can result in potential drug interactions.

We also believe that the Medicare enrollment and reenrollment process for providers must be significantly streamlined. Medicare requires pharmacy suppliers to submit extensive and often duplicative pharmacy-specific paperwork that is more voluminous than any other third party plan in which retail pharmacies participate. Thus, the lack of an online claims processing system, combined with the burdensome Medicare enrollment and reenrollment procedures, also add a significant level of participation costs for suppliers unlike any other third party program.

Having said this, we agree with some of the changes proposed in this regulation's preamble, and will suggest that CMS make further changes that would help modernize the Medicare Part B prescription drug processing and payment system.

- **Original Signed Order:** NACDS appreciates the fact that CMS has already clarified that a pharmacy does not need to obtain an actual signed written prescription before filling the prescription. In fact, as CMS indicates in its preamble, most DME items, including drugs, can be filled based on verbal orders, but a written order from the physician still must be obtained before billing. However, we believe that CMS policy regarding this matter should indicate that a prescription can be filled and billed based solely on a verbal order from a physician. The pharmacy should not have to obtain an actual written prescription before billing the prescription if the original order was a verbal order.

  In fact, during a CMS Open Door Forum on July 10, 2003, it was stated by a representative of CMS that Medicare does allow for oral prescriptions to be paid through DMERCs, and that there were only a few items that required written orders.

The representative went on to say further than he recommended that the supplier follow up with obtaining the written order, but the clear implication was that it was not required. We ask that this policy be clarified in the final regulation.

This policy should be extended to orders that are transmitted electronically from the physician's office to the pharmacy (such as an E-prescription). Promoting the use of E-Rx is consistent with Medicare policies in the new Part D drug benefit, which encourages the use of E-Rx. In general, there are very few cases in which a physician needs to provide the pharmacy with an actual written order after phoning in a prescription. The requirement that the pharmacy still obtain a written order for a prescription to be able to bill Medicare still creates significant administrative burdens for pharmacy because it often times requires persistent followup with the physician.

- **Assignment of Benefits (AOB):** NACDS agrees that the AOB form should be eliminated for Part B drugs, since pharmacies can only accept assignment for these drugs. This will help reduce the paperwork burden to dispense Medicare prescriptions not found in other third party prescription plans. Moreover, we suggest that this form be eliminated for diabetic supplies as well dispensed by pharmacy suppliers to Medicare beneficiaries.

- **DIF Forms:** NACDS agrees with the elimination of the DIF form for immunosuppressive drugs on October 1, 2004, and asks that CMS assure that this requirement is applied uniformly by all the DMERCs. While this step will reduce the time and cost involved in filling immunosuppressive prescriptions for Medicare beneficiaries, we also urge CMS to consider eliminating the requirement that a diagnosis code be required on the prescription. Obtaining this information from physicians can be as burdensome as obtaining a DIF form from physicians.

  Given that claims for both physician services and drugs are processed through the Part B program, this diagnosis code could be obtained from the physician's billing records and matched with the prescription submitted by the pharmacy supplier. This would further reduce the administrative costs in filling Medicare Part B immunosuppressive prescriptions. This policy should also apply to other Medicare Part B drugs that are only covered for a specific diagnosis.

- **Prescription Shipping Time Frames:** NACDS supports the revision made earlier this year by CMS that provides flexibility regarding the timeframe for refilling Medicare prescriptions. Most third party plans allow pharmacies to refill prescriptions within five days of the end of usage for the previous prescription quantity dispensed. In Medicare, however, too often, many suppliers were still having their refill prescriptions claims rejected, even if the beneficiary only had a few days worth of prescription supply remaining. However, the pharmacy didn't know the claim had been rejected at the point of service because of the lack of an online system. This means that, once the claim was returned to the pharmacy, the pharmacy had to rebill the claim, creating more paperwork, and delaying reimbursement on expensive Part B drugs.

- **Reconciliation Process:** For Medicare claims that are automatically crossed over, Medicare DMERCs will indicate to the pharmacy on the remittance advice that the claim has been paid by Medicare, or the claim has been rejected and crossed over to another payer. In either case, however, the remittance advice fails to indicate the payer to which the claim has been sent. For the purposes of assuring appropriate payment from third party source, Medicare DMERCs need to tell pharmacies on the remittance advice the identity of the third party payer that received the claim.

- **Unique Physician Identification Number (UPIN):** Medicare Part B requires that suppliers submit claims with the physician's UPIN number. Most third party plans require the physician's DEA number. Generally, the physician's DEA number is readily available on the prescription or quickly given during a verbal order. The UPIN number results in additional administrative burden by community pharmacy for Medicare Part B claims. NACDS appreciates consideration by CMS to adopt the usage of the physician's DEA number instead of the UPIN number.

- **Claims Payment:** Because of the substantial investment that pharmacies make in pharmaceutical product inventory, it is important for pharmacies to receive payment for these products as quickly as possible. This is especially important for expensive products such as immunosuppressive drugs and certain cancer medications. CMS current sets a floor limit of 14 days for electronic clean claims. That is, electronic claims must be held 14 days from date of receipt by the DMERIC before payment can be made. If clean claims are not paid within 30 days, interest accrues and is paid with the claim. A special field on the supplier's remittance indicates the amount of interest included on each claim. NACDS encourages that claims be paid by the 14th day, than allowing these claims to accrue nominal interest. Given the delay in billing due to gathering the additional documentation, the floor limit should be removed or applied based on the date of service not the DMERC received date.

Section 305 – Payment for Inhalation Drugs (Nebulizer Drugs)

NACDS supports the continuation of payment of an appropriate supplying fee for the dispensing of nebulizer drugs. We believe that this is especially important, given that a six percent mark-up on these products, almost all of which have a lower-cost generic base, will not provide enough margin to pharmacies and other suppliers to dispense these drugs and assure beneficiaries know how to appropriately administer them. CMS itself expresses a concern about the impact on beneficiary access to these drugs under these significantly reduced payment rates.

NACDS does not necessarily agree that a significant shift toward the use of the metered-dose inhaler (MDI) versions of these drugs will occur when the Part D drug benefit comes online in 2006. Many beneficiaries and many physicians will continue to prefer using the nebulizer form of these drugs for various reasons, including clinical reasons. These drugs will continue to be available to other patients with diseases such as COPD and asthma, so there is no reason why Medicare beneficiaries should have any less access.

Previously, reimbursement for these drugs consisted of the payment rate for the drug (which included some "spread" between the payment rate and the provider's acquisition costs), as well as a $5 dispensing fee. The totality of these payments made it possible for a supplier to dispense the drugs, teach beneficiaries how to use them, and still make a profit. The new ASP-based rate must be supplemented by a supplying fee for these drugs, and part of this supplying fee schedule should include a reasonable payment for any type of compounding that is needed, as well as services that might need to be provided.

We agree that certain chronic use medications should be provided in larger quantities (i.e. 90 day supply), since this will help reduce shipping costs for these medications. We might urge, however, that such products not be sent automatically to beneficiaries until they have nearly exhausted their existing supply. This will help reduce stockpiling and waste of these products.

We appreciate the opportunity to comment on these proposed regulations, and ask that you contact us for further information about these issues.

Sincerely,

John M. Coster, Ph.D., R.Ph.
Vice President, Policy and Programs

Attachment: Pharmacy Dispensing Costs

NACDS
NATIONAL ASSOCIATION OF CHAIN DRUG STORES

IssueBrief

Elements of a Pharmacy Dispensing Fee

This brief describes the importance of paying an adequate pharmacy dispensing fee and the components that comprise the cost to dispense. This brief outlines many components that go into the provision of pharmacy services, and which should be considered when developing accurate pharmacy supplying fees.[1]

Elements of Pharmacy Service Costs	
I. Staffing	
	Salaries (pharmacists, technicians, managers, cashiers, etc.) Licensure and/or continuing education for pharmacists, technicians
II. Store operations and overhead	
	Rent or mortgage Cleaning, repairs and security Utilities (heat, light, telephones) Computer systems, software and maintenance Marketing and advertising Accounting, legal and professional fees Insurance, taxes and licenses Interest paid on pharmacy-related debt Depreciation Complying with federal and state regulations (e.g., HIPAA) Corporate overhead (central management, etc.)
III. Preparing and dispensing prescriptions	
	Prescription dispensing materials (packages, labels, pill counters, etc.) Compounding the Rx (if necessary) Special packaging (unit dose, blister packs, bingo cards) Special supplies (syringes, inhalers)
IV. Assuring appropriate use of medication	
	Drug use review Consumer/patient counseling Consulting with prescribers Disease management Education and training
V. Reasonable profit	

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Alexandria, Virginia
22313-1480

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www.nacds.org

[1] The survey instrument from a South Carolina Medicaid dispensing fee study and a listing of included elements of a pharmacy dispensing fee from Myers and Stauffer's California dispensing fee study are included with this memo as background material.

Staffing: Staffing is listed as the first item in Figure 1 because it is probably the most important factor in determining an accurate pharmacy supplying fee. Labor costs include total salaries, payroll taxes and benefits. Prior studies that estimated dispensing costs typically allocated these costs based on employees' time spent in the prescription department. Owner compensation, particularly in the case of pharmacist owners, may require special modifications to account for differences unrelated to the normal compensation for a typical employee or employee pharmacist. Corporate overhead must be considered in any cost of dispensing calculation.

Pharmacy staffing costs are particularly important in California. California has one of the highest average salaries in the nation for pharmacists, an estimated $91,170 as of May 2003. The national average pharmacists' salary for the same period was $78,620. California also has a very low technician-to-pharmacist ratio, 1:1 for the first pharmacist and 2:1 for additional pharmacists. Many states allow ratios of 3:1 or higher. Given that the average technician salary in California was just over $32,000 in May 2003, this low technician ratio leads to higher costs for California's pharmacies. In fact, Myers and Stauffer's June 2002 study of Medi-Cal Pharmacy Reimbursement highlights higher pharmacist salaries as the primary reason why California has a higher cost of dispensing than other states that they have observed.

Overhead & Other Dispensing Costs: Overhead and other dispensing costs are important factors that can be difficult to quantify, particularly by outside observers. In its June 2002 study, Myers and Stauffer considered the following costs to be entirely prescription-related:[2]

- Prescription department fees
- Prescription delivery expense
- Prescription computer expense
- Prescription containers and labels
- Continuing professional education for a pharmacist

Overhead costs that Myers and Stauffer did not allocate as prescription expenses include income taxes (because they are based on profit), bad debts, advertising and contributions. South Carolina appears to allocate all taxes based on the prescription department's sales ratio, and also includes prescription department advertising under the cost of dispensing.

Most other overhead costs were partially allocated as prescription costs by both Myers and Stauffer and South Carolina. Some overhead costs were allocated as a percentage of floor space, such as real estate taxes, rent, janitorial service, and utilities.

Repairs and depreciation were allocated based on floor space by Myers and Stauffer, but sales ratio by South Carolina. Other overhead costs were allocated based on sales ratio by both studies, including: personal property and other taxes, insurance, interest, accounting and legal fees, telephone and supplies, dues and publications.

[2] NACDS prepared an analysis of the Myers and Stauffer study that indicated key shortcomings of and exclusions from their dispensing fee estimates. This document is available from NACDS.

Submitter : **Date & Time:** 09/23/2004 06:09:13

Organization :

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please continue to allow all qualified health care providers to service patients with prescriptions or under the physicians supervision.

Submitter : Mrs. Valencia Hill **Date & Time:** 09/23/2004 06:09:29

Organization : Mrs. Valencia Hill

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

Submitter : Mr. Tim Christy **Date & Time:** 09/23/2004 06:09:45

Organization : Downers Grove South H.S.

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

1. I am opposed to proposed changes to "incident to" billing regulations.
2. I support recognition of Certified Athletic Trainers as providers of rehabilitation services.

Submitter : Ms. Candice Ostendorf **Date & Time:** 09/23/2004 06:09:10

Organization : Ms. Candice Ostendorf

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 23, 2004

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

Re: Therapy ? Incident To

Dear Sir/Madam:

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 certified athletic trainers, 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,

Candice Ostendorf
Senior Athletic Training Student
University of South Carolina

Submitter : Ms. Leslie Ann **Date & Time:** 09/23/2004 06:09:24

Organization : Ms. Leslie Ann

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I do not support this revision making PT's the only health care professionals allowed to provide medically related care to physician's. I have been practicing massage therapy for just over ten years and heard from client after client about the benefits of massage in their lives / with their recovery. Many of these same people have completed rounds of physical therapy, with their bodies still requiring additional care in the form of massage and other modalities, which provide a level of care unmet by surgery & physical therapy. The benefits of massage (and other unsaid modalities, ie. chiropractic, cranial sacral therapy, and others) should not be shut out at a time when an increasing number of patients are turning to it, indeed requiring it for more optimal rehabilitation and quality of life. If Medicare withdraws coverage---and therefore acceptance of a whole population of healthcare providers, it will be a huge step backward for our entire medical community both for providers and those persons we have dedicated our lives to provide our services to: our patients and clients.

CMS-1429-P-3389

Submitter : **Date & Time:** 09/23/2004 06:09:04

Organization :

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I have been a licensed physical therapist for 11 years and have worked in both private outpatient physical therapy clinics and a rehabilitation hospital. I am also a physical therapist educator and hold both a masters and doctoral degree in physical therapy. I strongly believe that physical therapist?s are the most qualified individuals to provide physical therapy service to Medicare clients/patients. I strongly support the proposed rule that would require physical therapy services provided in a physicians office ?incident to? a physician?s professional services be furnished by personnel who meet certain standards. Specifically, licenses physical therapists and physical therapist assistants functioning under the supervision of a physical therapist. 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 a foreign trained physical therapists.
Medicare should only reimburse physical therapy services when provided by licensed physical therapists and physical therapist assistants.
The physical therapy profession continues to require higher and higher educational standards. Currently all physical therapy educational programs are at the masters or doctoral level. Allowing individuals to provide physical therapy services that are not physical therapists or physical therapist assistant?s will significantly decrease the level of care for the Medicare beneficiaries. These individuals will be receiving a substandard level of care and could potentially be harmed if poor decisions are made.
Medicare beneficiaries are at times the most challenging patients, due to their complicated medical histories in conjunctions with typical musculoskeletal injuries. A physical therapist has the educational background and clinical reasoning skills to determine the plan of care and modify this plan with the medical team as the patient progresses. If an unqualified individual with no educational background in physical therapy is allowed to take over part of this care just because they are in a medical practice the patient will be receiving a substandard level of care. The unqualified individual will not have the expertise to manage the patients throughout the treatment plan and make daily assessments of the patients needs. The Medicare beneficiary will not be receiving the best level of care and it will not be quality care. Poor care will only result in the patient requiring care by a qualified professional, the PT, down the road, thus increasing costs.
Thank you for your attention to this very important issue.

CMS-1429-P-3390

Submitter : Ms. Janet Schafer **Date & Time:** 09/23/2004 06:09:34

Organization : NY State Society of Medical Massage Therapists

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

IMPACT

IF THIS GOES THROUGH YOU WILL ELIMINATE THE FUTURE OF MEDICAL MASSAGE THERAPY AND THERAPISTS IN THIS COUNTRY, AS THE PRIVATE INSURANCE COMPANIES WILL FOLLOW YOUR EXAMPLE.

THERAPY STANDARDS AND REQUIREMENTS

As a provider of medical massage therapy to senior citizens and other people in pain and need of massage therapy, discontinuing your practice of reimbursing for licesned massage therapy will directly affect the lives of those who recieve and benefit from my work. At $60.00 per hour, licesned massage therapists provide immediate and lasting pain and symptom relief for far less cost to the government than other healthcare providers...A precedent will be set if this goes through, which the private insurance companies will surely follow (as they have followed medicare policies in the past), effectively eliminating compensation for our work, and ELIMINATING OUR FUTURE IN THE MEDICAL INDUSTRY WE HAVE TRIED SO HARD TO MAKE STRIDES IN. Please, we provide a helpful service for fairly little money which provides long-lasting and immediate results. Often we

Submitter : Mr. Carlos A Diaz **Date & Time:** 09/23/2004 07:09:03

Organization : Self Enrichment Center

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I totally disagreed with Medicare eliminating any provider servicing and treating our community rather than PT's, because it is a shame that we as a licensed Massage therapist we are qualified and aknowledgeable to treat any patient with some medical conditions.Thank you very much.Carlos Diaz.

Submitter : Mrs. Jeanette Flaig **Date & Time:** 09/23/2004 06:09:03

Organization : Mrs. Jeanette Flaig

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please so NOT pass this policy which allows physicians to refer "incident to" services only to physical therapists. Research has shown that other qualified healthcare professionals are beneficial in assisting patients in recooperating from injurys, illness and disease. Furthermore, all qualified healthcare providers should be allowed to provide services to patients with a physicians prescription or under supervision.

Thank you.
Jeanette Flaig CMT, BS, MS.

CMS-1429-P-3393

Submitter : **Date & Time:** 09/23/2004 06:09:31

Organization : AMTA

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I OPPOSE Medicare's proposed policy to eliminate any provider except physical therapists from providing "incident to" medical professional's services to patients. Massage is an ancient skill and practice, allowing the body to heal itself. When used in conjunction with medical professional services, massage is proven to sustain chiropractic manipulations, soothe tension for needed rest, enhance athletic performance, shorten rehabilition time from injuries, as well as reduce over all pain and irritability. More and more today, the public is focused on wellness, and searching for natural cures and methods toward a healthful lifestyle. Massage is the least invasive and most natural of therapeutic modalities. To disallow massage therapy in conjunction with professional health care would be a disservice to the public, young and old.

Submitter : Mrs. Joanne Heinz **Date & Time:** 09/23/2004 06:09:49

Organization : American Polarity Therapy Association

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I want the freedom to choose how to care for myself in as many different ways as are good for me.

CMS-1429-P-3395

Submitter : Mr. james scott **Date & Time:** 09/23/2004 06:09:51

Organization : aurorauniversityfootball

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

In all areas of industry, health care, education and even government we have found that inorder to have maximum effectiveness with limited resourses we have to form patnerships. In smaller rural areas the coverage of athletic teams has become acute, especially has physicals per capita decreases. Using PTs as athletic trainers on a shared basis is a way of life. We either continue to follow this practice and assure adequate care or we provide inadequate care which in turn will continue to exasperate the health care crisis that we have and are now experiencing. No question we are being penny wise and dollar foolish. Sound familar when we allow the tail to wag the dog.

J. Scott
Head Football Coach
Aurora University

CMS-1429-P-3396

Submitter : Mr. Mark Domyahn **Date & Time:** 09/23/2004 07:09:37

Organization : Medtronic Neurological

Category : Device Industry

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

See Attached Word File for Comments

CMS-1429-P-3396-Attach-1.doc

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604

September 23, 2004

Centers for Medicare and Medicaid Services
Department of Health & 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 – File Code CMS-1429-P

Dear Madam/Sir:

We appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule for changes to the Medicare physician fee schedule for calendar year 2005. The comments below are in reference to refill procedures for implantable drug infusion pumps. We provided similar comments in a two separate letters dated October 2 and October 10, 2003. These comments were provided during the comment periods for the proposed revisions to payment policies under the physician fee schedule for 2004, and the proposed rule for Medicare payment reform for Part B drugs, respectively.

Therapy

Intrathecal drug delivery is utilized for many purposes including the treatment of chronic pain (both malignant and non-malignant), delivery of chemotherapy directly to the hepatic artery for the treatment of liver cancer, and the treatment of severe spasticity caused by cerebral palsy, multiple sclerosis, spinal cord injury or stroke. Our data indicates that approximately 30-40% of patients with implanted pumps are Medicare beneficiaries.

Intrathecal drug delivery involves the implantation of a drug pump and catheter into a patient. The catheter is placed in the intrathecal space in the spinal column, and connected to the drug pump that is implanted in the abdomen of the patient. Drug from the pump's reservoir is directed to the intrathecal space to provide relief of pain or spasticity. By injecting the drug directly into this space, the dosage required to achieve symptom relief is significantly less than that provided by other routes of administration. As a result, patients typically do not experience the same side effects that occur with higher doses of oral or injectable drugs required to achieve similar symptom relief.

Prior to being treated with an implantable drug infusion pump, patients have typically been treated with all other forms of medical management for their disease symptoms. These patients commonly have multiple clinical issues and problems. Not only do they consume a much larger percentage of the physician's time compared to other patients, but also the management of these patients involves a significantly higher amount of clinical decision-making. Additionally, once a patient has received a

drug infusion pump, the managing physician becomes involved in all aspects of the patient's care to ensure that the drug infusion pump is considered when other care decisions are made.

After implantation, the patient will visit his/her physician periodically, typically 60-90 days, to revaluate the drug dosage and the rate of drug infusion. The process of refilling the pump is the topic of these comments.

Coding for Drug Refill

Prior to 2003, there was one CPT code applicable to the refill of an implanted pump. That code was:

CPT 96530: *Refilling and maintenance of implantable pump or reservoir*

Currently, there are two CPT codes applicable to the refill of an implanted pump for drug delivery to the spine or brain. They are:

CPT 95990: *Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventicular),* and

CPT 95991: *Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventicular) administered by a physician*

CPT 95990 was implemented on the 2003 Physician Fee Schedule, and CPT 95991 was implemented on the 2004 Physician Fee Schedule. The primary reasons for the creation of CPT codes 95990 & 95991 were that the procedure for refilling an implantable pump used for drug delivery to the spinal canal or brain is a more complex procedure than refilling a reservoir (as reflected in the addition of physician work RVUs), and to reflect the differences in the sites of drug delivery. This request went to the CPT Coding Committee, which approved the two new codes.

CPT 95990 does not include a physician work component and is used when a clinician other than the physician performs the refill procedure. CPT 95991 was sent to the RUC and was surveyed to determine the physician work component in 2003. The RUC did determine a value and made that recommendation to CMS. Effective January 1, 2004, the work value associated with this CPT code is 0.77

When CPT 95990 was introduced in 2003, the descriptor for CPT 96530 was changed to read:

CPT 96530: *Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (e.g., intravenous, intra-arterial)*

Please note that one of the approved indications for implanted drug infusion systems is Hepatic Arterial Infusion (HAI therapy), which is chemotherapy administration directly to the hepatic artery for the treatment of liver cancer. Because the site of delivery for this therapy is neither the spinal canal nor the brain, a refill procedure is still coded with CPT 96530.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

The MMA dramatically increased physician reimbursement for certain CPT codes to account for changes in the reimbursement for outpatient drugs and biologicals. The methods used to increase reimbursement for these specific codes were to increase the practice expense RVUs based on external survey data, and to include a 32% transition adjustment. One of the specific CPT codes identified for this increase was CPT 96530. However, CPT codes 95990 & 95991 were not specified, and thus were not increased.

CPT codes 95990 & 95991 were originally derived from CPT code 96530, which is now used exclusively by oncology for chemotherapy and insulin administration. The primary differences between 95990 & 95991 and 96530 are the site of delivery of the drug, and that the refill procedure for the first two codes requires additional physician time as reflected in the physician work RVUs (see table below). Other than those differences, we contend the practice expenses associated with these procedures are practically the same, especially since the same refill kit is used for these procedures.

The MMA adjustments created a significant payment difference for these procedures. CPT 95990 originally had a higher payment due to the additional complexity to refill an infusion pump for pain relative to refilling an infusion pump for chemotherapy. In 2004, the payment of CPT 96530 compared to 95990 & 95991 was (98%) and (37%), prior to the application of the transition adjustment. This trend continues in the proposed 2005 physician rule as CPT 96530 is paid 98% higher than CPT 95990, and 31% higher than CPT 95991.

	Physician Work RVUs			Practice Expense RVUs			Total Payment		
CPT	**2003** [1]	**2004** [2]	**2005**	**2003** [1]	**2004** [2]	**2005**	**2003** [3]	**2004** [3]	**2005** [3]
95990	0	0	0	1.49	1.50	1.50	$56.65	$58.25	$59.12
95991	NA	0.77	0.77	NA	1.43	1.53	NA	$84.38	$89.44
96530	0	0.17	2.86	1.05	2.86	2.86	$40.46	$115.37	$117.11
96530	(with transition adjustment)							$152.29	

	2003	**2004**	**2005**
Prior to Transition Adjustment:			
Percentage Difference between 95990 & 96530	**28.6%**	**-98.1%**	**-98.1%**
Percentage Difference between 95991 & 96530	**NA**	**-36.7%**	**-30.9%**
After Transition Adjustment:			
Percentage Difference between 95990 & 96530		**-161.4%**	
Percentage Difference between 95991 & 96530		**-80.5%**	

[1] Per Federal Register dated December 31, 2003

[2] Per Federal Register dated January 7, 2004

[3] Calculated using no geographic adjustment factors

Recommendation

We contend that the practice expense RVUs associated with CPT codes 95990 & 95991 should be adjusted in a similar fashion to those of CPT 96530. Given that the two newer codes describe similar services as – and were originally derived from – CPT 96530, we believe it is inappropriate to not apply the same MMA adjustments to CPT 95990 & 95991 as those applied to CPT 96530. We believe the existing payment differential is inequitable and that a similar adjustment to CPT 95990 & 95991 is warranted. Further, the MMA does provide CMS the authority to make revisions to other drug administration services beginning in 2005.

Except for the case of HAI therapy, it is the disease symptoms that are being treated for these patients, not the actual disease itself. It is the patient's chronic pain or severe, intractable spasticity that is being relieved by use of a drug infusion pump. The results are commonly a significant improvement in the quality of life for the patient and often the caregiver. When payments are not appropriate for both the drug and the drug administration, this treatment option will become significantly less and less available to patients.

As the payments for drugs have become more restrictive, an increasing number of physicians are either discontinuing or limiting this treatment option. While we agree that the appropriate payment should be

made by CMS for the drugs used, we also believe that these drug infusion pump refill codes should accurately reflect the costs of administering these drugs to these patients.

We appreciate the opportunity to submit these comments. If you have additional questions, or require additional information, please do not hesitate to contact me at (763) 505-0201.

Sincerely,

Mark Domyahn
Senior Manager, Health Policy and Payment
Medtronic Neurological

Submitter : Terese Sartino-Dreger **Date & Time:** 09/23/2004 07:09:04

Organization : Terese Sartino-Dreger/Alternative Day Spa

Category : Other Technician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am asking you NOT to pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care provides should be allowed to provide services to patients with a physicians presciption or under their supervision.
Thank you,
Terese Sartino-Dreger/Alternative Day Spa

CMS-1429-P-3398

Submitter : Ms. Faeterri Silver **Date & Time:** 09/23/2004 07:09:41

Organization : International Association of Healthcare Practition

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I have run the Vermont School of Professional Massage since 1989 and have been licensed by the Ohio State Medical Board for the limited practice of massage since 1980. I have worked with Medical Doctors, Chiropractors, Osteopaths, and Physical Therapists practicing Massage Therapy. My students are trained in a 765 hour program in Professional Massage. They learn in depth anatomy and physiology, pathology, and massage therapy. Our training is extensive. We as health care professionals need to be included as providers of Massage Therapy and other Touch Therapies. I request that you consider my statement as you look at eliminating any provider except physical therapists from providing "incident to" medical professional's services to patients, that you do not exclude trained massage therapy professionals. I thank you very much for listening to my comment.

CMS-1429-P-3399

Submitter : Miss. diann swanson **Date & Time:** 09/23/2004 07:09:35

Organization : fhn

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Absolutely not... this would not benefit anyone, but hurt patients